Making The Functional and Fashionable Feasible

The Australian Herbal Medicines Industry Feasibility Study

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A joint venture between The University of Queensland and Southern Cross University

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Foreword

Recently there has been growing interest in the opportunities for further development in Australia’s medicinal herb industry, focusing on import replacement and supplying the large global market. Australia’s advantage is seen to be its capacity to supply niche markets with premium quality product.

The aim of this project was to conduct a feasibility study on the potential of growth and development of medicinal herb production and processing in Australia.

The study examines the components of the Australian supply chain to identify impediments to future growth. It highlights the need for raw material suppliers to meet the requirements of processors for consistent supplies that meet their stringent quality requirements. It also finds that a major impediment in the supply chain is the lack of an entity (or entities) focused on the development of new scientific intellectual property on herbal medicine.

A key achievement of the project and its associated industry workshops is an agreement to set up a company to function as an IP bank, whereby projects would be funded for development to a commercial ready stage and then licensed to commercial industry members.

This project was funded from RIRDC Core Funds which are provided by the Australian Government. Funding was also provided by industry and the universities involved (Queensland University of Technology, the University of Queensland and Southern Cross University).

This report, an addition to RIRDC’s diverse range of over 1200 research publications, forms part of our Essential Oils and Plant Extracts R&D program, which aims for an Australian essential oils and plant extracts industry that has established international leadership in production, value adding and marketing.
Most of our publications are available for viewing, downloading or purchasing online through our website:

- purchases at www.rirdc.gov.au/eshop

Peter O’Brien
Managing Director
Rural Industries Research and Development Corporation
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Executive Summary

This feasibility study was initiated to evaluate the requirements for the growth of the Australian herbal medicine industry to one of greater economic, scientific and social significance. The study commenced against a background of growing public utilisation of complementary medicines in Australia, of which herbal medicines are a major component, and the projected value of the global herbal medicine industry reaching $USD 5 trillion annually by the year 2050. The primary aim of the feasibility study was to determine what was required to enable Australia to claim an increased share of both the domestic and global herbal medicine markets.

The initial approach was to focus on developing a clear picture of the Australian supply chain. Specifically to clarify its components, determine if gaps existed in the chain which hindered progress and identify areas of potential development.

The literature pertinent to the feasibility of developing a herbal medicines industry suggests that wide variations in economic returns exist at the production level, which is a potential area to develop competitive advantage. There was also a diversity of suitable locations within Australia where an industry hub could be based which would need to be differentiated based on economic and social criteria. In addition, a number of herbs were identified as having potential for development and commercial application. These represent different opportunities for pursuing the development of a viable herbal industry. It was determined however, that the focus needs to be at the market end as the driver for any significant development. If farmers are to benefit from the growth in herbal medicines they must provide processors with consistent supplies of raw materials that meet the processors’ quality requirements.

As the study progressed it became clear through a series of industry workshops that the major missing link in the Australian supply chain was an entity (or entities) that was focused on the development of new scientific intellectual property on herbal medicine. Those entities which currently exist in foreign countries were seen to provide significant value addition that provided the driver for an international herbal industry. It was identified that the Australian industry required a corporate entity that would play a lead role in scientific application and the advancement of commercial opportunities that will impart competitive advantage. This finding
resulted in a convergence with a concomitant initiative by The University of Queensland (UQ) to commercialise intellectual property (IP) generated by the university which in turn has led to the establishment of Healing Power (CM) Ltd., a company set up to function as an IP merchant bank. Projects would be funded for development to a commercially ready stage and then licensed to industry.

Healing Power (CM) Ltd. through its strategic alliance with the Australian Centre for Complementary Medicine Education and Research, plus its other associations with universities, institutes and industry partners, will act as a vehicle through which the complementary medicine industry can advance.

This outcome has progressed the feasibility study from an assessment of the herbal medicines industry and the identification of potential opportunities or strategies, to one of implementation of an identified strategy and establishment of a corporate entity. Flow-on effects from the commercialisation process will proceed along the supply chain contributing to the development of an Australian herbal medicines industry in a sustainable manner.
1.1 Purpose of the Feasibility Study

The purpose of this study was to evaluate the requirements for the growth of the Australian herbal medicine industry to one of greater significance, economically, scientifically and socially. One of its aims is to place the herbal medicine sector on the “agenda” of Government, the health care sector and potential stakeholders. The study was also undertaken to gain increased recognition for this sector and the potential benefits that it could deliver.

1.1.1 Background

In mid 2002 the Queensland sugar industry was facing a significant testing period of low commodity prices, continuing drought, and viability uncertainty for many (predominantly small) cane farmers. The consideration of diversification by cane growers into growing medicinal herbs was proposed by a group of researchers from the Australian Centre for Complementary Medicine Education and Research (ACCMER) a joint venture of The University of Queensland (UQ) and Southern Cross University (SCU), and Queensland University of Technology (QUT).

A number of benefits were identified that would result from the implementation of this or a similar development proposal. These benefits included:

i. Growers in the sugar industry who are currently marginal or not viable have the opportunity to participate in a sector for which there is a growing demand for its products (raw and processed).

ii. The ability to utilise (perhaps with some modification to planters) farm equipment without requiring major capital investment.

iii. The transition from supplying sugar cane to a mill to supplying herbs to a mill subsidiary although not seamless is not a significant culture change.
iv. Although some cane growing land would be lost to cane growing, the formation of cooperative farms could still lead to efficiency gains for the sugar industry.

v. The establishment of the herb production sector, as an industry with a significant critical mass would allow existing growers to develop and provide them with a more defined structure and options for their consideration.

vi. The option of establishing a mill subsidiary entity would provide a means of value-adding to mill resources and mill profitability. In general, mill revenue is divided a third to farmers, a third to the Government and a third retained, except where the resource is mill owned, for example molasses, power generation, income from land holdings and so on. Depending on the establishment arrangements, the subsidiary company could be in a position of competitive advantage.

vii. The local environment would benefit as herb growing areas would not follow the current cane growing fertiliser practices or add (in fact lessen) to the cane grub problem being experienced in many areas.

viii. The interspersion of herb areas amongst cane areas would also help in dispersing pests associated with the herbs being grown, thus providing an opportunity to decrease certain chemical use and increasing environmental quality. It is acknowledged that suitable areas for herb growing would be restricted due to pesticide contamination within sugar areas.

ix. Mill involvement could also extend the processing period requiring further use of infrastructure and providing on-going employment.

x. Diversification would allow growers; mills and rural communities to more effectively cope with periods of economic down turn. The Queensland sugar industry generally regarded as a $2 billion industry is only expected to return between $1.3 – 1.6 billion per year over the near future.

xi. The complementary medicine industry would become less reliant on herb imports. This would have the effect of contributing to the balance of payments while having greater control over raw material inputs.

Although a degree of interest was expressed by a number of individuals in the sugar industry, the concept lacked support pending the outcomes of this study. However, discussions with herbal medicine industry members identified considerable support and willingness to be involved in the feasibility study.

The Australian herbal medicine industry at this time was also facing challenges of its own associated with sustainability and viability.

Due to the increased interest in and acceptance of herbal medicines (HM) in the major developed countries, increased demand for quality raw materials and value-added supplies has
resulted. This increased demand has led to a number of broad ranged quality issues in sourcing raw materials, which include inconsistent batch quality, contamination, misidentification, and many others.

These challenges were recognised as presenting an opportunity for the Australian industry to be reviewed and establish the requirements for developing an Australian herbal medicine industry that is more focused on the global market.

Australian indigenous HM sources have the potential to provide novel products that could contribute to financial stability and employment in traditional communities. In addition, these products could also provide the HM sector with global market differentiation.

1.1.2 Terms of Reference

This study aimed to assess the potential for the development of an Australian herbal medicine industry where industry structure, production, processing and marketing are integrated and managed by best practice standards.

This involved:

- a systematic literature search;
- determination of the scope and potential of a new primary industry;
- holding workshops with industry members and relevant Government bodies and instrumentalities;
- a call for stakeholders and stakeholder meetings;
- the establishment of a stakeholders reference group;
- determination of target herbs;
- determination of options for the industry structure; and
- a triple bottom line analysis, economic, environmental and social.

One of the main purposes of the feasibility study was to determine if a vertically integrated Australian industry was viable and to make recommendations on how the development of the Australian industry in herbal medicines should proceed and how to maximise the benefits to Australia from involvement in this global commodity.

1.1.3 Feasibility Study Group

The management team consisted of a tripartite collaboration between Queensland University of Technology and the Australian Centre for Complementary Medicine Education and Research (a joint venture between UQ and SCU).

The working group consisted of a broad representation across the HM sector which included:

- primary producers
- manufacturers and marketers
- Complementary Healthcare Council (CHC)
- State and Federal Government representatives
• regulatory affairs consultants
• corporate advisors
• entrepreneurs
• health and environmental research scientists

Funding for the study has been provided by the Rural Industries Research and Development Corporation (RIRDC), industry members and each of the universities.
The Complementary Medicine (CM) sector which comprises both medicines and therapies, is experiencing steady growth nationally (Pirotta, et al., 2000) and globally, with usage rates of CM by the general population being in the order of 40% (USA and UK) and 60% (Australia) (Bodeker, 2002). In European Union countries such as Germany, CM is a primary mode of healthcare.

2.2 Potential Impact of Complementary Medicines and Herbal Medicines

In Australia healthcare costs are increasing: For example the cost of the Pharmaceutical Benefits Scheme (PBS) for the year ending June 2004 was $5 billion which represents a 9.3% increase over the previous year (Department of Health & Ageing, 2004). Over the medium term the aged sector (> 60 years) is projected to almost double in terms of proportion of the population. Based on current trends the PBS will increase to approximately $10 billion by 2020 (ABS, 2000), a figure that has been described by the Federal Treasurer as unsustainable.

Complementary medicines have significant potential to impact favourably on healthcare costs by increasing the diversity of user-pays healthcare options, and by decreasing the burden of illness within the community. This can occur as a result of direct benefits from complementary medicines which have proven efficacy and through indirect benefits, where using complementary medicine decreases the utilisation of conventional approaches which have a high side-effect profile.

A case example is the treatment of osteoarthritis with glucosamine. This complementary medicine has recently been accredited as an anti-arthritic medicine in Sweden and raised to equivalent drug status. Glucosamine’s safety and efficacy is supported by compelling scientific data (laboratory and clinical trial data) and is very rarely associated with significant adverse events. Herbal extracts including those from ginger have likewise been recently demonstrated to be safe and effective treatments for osteoarthritis.
In comparison, the use of pharmaceutical non-steroidal anti-inflammatory drugs (NSAIDs) is associated with highly significant adverse events including gastrointestinal bleeding and potentially fatal peptic ulcers and renal effects that result in an additional 40% to the primary drug cost. This comprises of costs associated with hospitalisation and the requirement for patients to take additional medications to counter the effects of the primary pharmaceutical drugs. In the year ending June 2004, anti-inflammatory and anti-rheumatic products were subsidised by the Federal Government to the value of $212 million. However, the true cost of these drugs is likely to be an additional $100 million when the cost of treating associated adverse events is included.

Currently the top ten drug groups (anatomical therapeutic chemical) listed on the PBS have a total cost of $AU 4.02 billion of which the Australian Government subsidy is $AU 3.3 billion (Department of Health and Ageing, 2004). Thus CM and the HM sector in particular has the potential to make a major impact on healthcare costs by helping to mitigate the burden of pharmaceutical benefit costs.

2.3 The Need for Scientific Validation of Herbal Medicines

There are numerous publications within the scientific literature dealing with complementary medicines including their use, acceptance by the public and health professionals, quality issues, risks associated with combined pharmaceutical use, world trends and so on. Many of these publications recognise the need for 1) greater research effort to be made, funding programs established to allow for an increased evidence-base to be developed; and 2) governance/regulations or policy development to adequately handle the issues resulting from increased public use of HMs.

Herbal medicine has a long history of usage and frequently relies on traditional use for evidence of its safety and efficacy. Over the past 30 years there has been an ever increasing amount of scientific data on the laboratory and clinical aspects of herbal medicine which has added to this traditional use to build a more substantial and scientifically validated evidence-base. Many gaps still exist in our scientific understanding of herbal medicines and the potential of traditional knowledge about herbs is not fully realised. It is imperative that significantly more research be undertaken to allow the herbal medicines industry to progress to an equivalent of ‘pharmaceutical status’ by generating evidence-based data through scientifically grounded laboratory investigations and clinical trials. In doing so, it will obtain Government policy recognition at the public health level.

Herbal medicines evaluated for safety and efficacy to equivalent pharmaceutical standards have the potential to significantly impact in a positive way on the public health budget through impact on the PBS and assist in the maintenance of general public ‘wellness’.
2.4 Current and Potential Size of the CM and HM Markets – Domestic and Global

The CM domestic market has been valued at $AUD 2.3 billion per annum (MacLennan, Wilson and Taylor 2002). This is broken down into $AUD 1.67 billion in medicines and $AUD 616 million in therapies. The USA CM industry is currently valued at $USD 34 billion per annum (MacLennan, Wilson and Taylor 2002). Herbal import replacement into Australia is currently valued at up to $AUD 400 million per annum while USA sales of herbal products were around $USD 23.2 billion dollars in 2002.

Europe and the United States are the two major herbal medicine markets in the world, with a market share of 41 percent and 20 percent respectively, with the global herbal market valued at $USD 60 billion in 2001 (Williams, 2002; ITCOT, 2002). Steady growth of the herbal industry is anticipated and the WHO has forecast that the global market for herbal products will be worth $USD 5 trillion by the year 2050 (RocSearch 2002). In 2050 a 5% share of this market would be worth $USD 250 billion per annum.

Ancillary industries such as cosmetics (including perfumes), culinary applications (nutraceuticals, essences, functional foods and supplements) and veterinary healthcare products are also expected to experience similar growth and offer potential synergies for co-development.

2.5 Current State of the Herbal Medicine Industry

Increased interest in and acceptance of HMs by developed countries has led to an increased demand for quality raw materials and value-added supplies.

Raw materials are facing a number of quality issues which have been identified to include:

- Inconsistent batch quality
- Lack of appropriate reference standards
- Price pressure that may compromise quality
- Lack of adequate quality assurance (QA) programs
- Potential for substitution and mis-identification
- Some, but not all, suspected low quality raw material from countries including China and India
- Inconsistencies across testing facilities and manufacturers
- Lack of specifications by sponsors
- Lack of validation at input
- Re-badging of bulk material
- Insufficient policing of good manufacturing practice analytical laboratories (GMPALs) [This is probably of less concern post Pan Pharmaceutical’s events]
- Deficiencies with respect to quantification of extracts at input
- Insufficient testing (heavy metals, pesticides and microbiology) (Johanson, 2002)
These raw material issues are also present to varying degrees in Australia and are a reflection of the fragmented state of the industry as a whole in this country. The herbal medicine industry has largely seen its development occur in Australia during the 1990s. This development has not occurred in a structured way but in an opportunistic/scattered manner with plant quality varying considerably. For example -

- A number of grower groups currently exist but there is no single group that represents the industry.
- The grower segment is small with limited outlets and negotiation options.
- Typically the crops planted are less than 20 hectares.

There is a ground swell of interest in developing herbal production and processing in a managed and rational way. There is a major expression of desire across the industry for industry progression based upon sound management application, unification within the industry and a strategic plan for future development. There is a strong desire for the industry to be developed in an integrated and vertical manner. The Complementary Healthcare Council (CHC) has indicated strong support for this approach and their desire for active involvement in strategic planning.

Expressions of interest have been received across the industry ranging from primary producers, processors and retailers, and also including kindred industries, for example a Queensland sugar mill has indicated interest.

### 2.6 Potential Benefits of the Herbal Industry to Rural Australia

Concomitant with the demand for herbal medicines are concerns being expressed by Government and Industry sectors regarding small farm viability and rural / regional sustainability. One example is the small scale sugarcane grower. The nature of the herbal industry is such that it lends itself to a general rural application due to its diverse climatic requirements with associated potential to add to the diversification opportunities available to Australian farmers.

By implementing a structured approach, where areas suitable for growing particular herb species are identified, the industry might start with the objective of import replacement (currently valued at up to $AU 400 million) before focusing on exports (the global herbal market valued at $US 60 billion in 2001, Williams, 2002; ITCOT, 2002). Like other Australian primary industry exports, promotion using Australia’s ‘clean and green’ image would assist with market entry.

Because herbal medicine is a sunrise industry it has the potential to provide ongoing opportunities for future generations on the land. Establishment of the HMs industry will also provide opportunities for support industries including the organic fertilizer industry and contribute to environmental sustainability and biodiversity.

An approach using high value crops such as medicinal herbs has the potential to address the considerable economic issues being faced by the rural and agribusiness sectors. With the application of existing technology, good farming practices and the fostering of market
development through the implementation of a sound development program the herbal and ancillary sectors could become a primary industry of national significance.

2.7 Potential Advantages for Queensland

Queensland has the potential to assume a lead role in this multi-billion dollar industry (for example 5% of the current global market would return approximately $AU 5 billion per annum in 2004). This potential lead role in the herbal and ancillary industries has its foundation in the biodiversity as well as the geographic and climatic diversity of regional Queensland, supportive existing infrastructure and the proactive role of the Queensland Government in facilitating major commercial developments. Should the Queensland Government choose to support the herbal medicines industry in the way that it has supported biotechnology, the aviation and film industries and medical and healthcare research facilities, the industry would make a major contribution to both state and national economies.

Therefore, this study seeks to establish the viability of the herbal medicines industry and identify the means by which to progress identified opportunities into commercial reality.

References


Williams, F., WHO global health plan will give boost to alternative medicine. Financial Times; May 17, 2002. London.
3. Scope and Potential of the Herbal Medicine Industry

3.1 Scope of Herbal Medicines and the Herbal Medicine Industry

Herbal and traditional medicines have been applied across the disease and health care spectrum for many centuries. Many of the popular drugs in use today originate from botanical sources. Drugs that are used to treat a wide range of conditions (Table 1).

### Table 1 Common Drugs of Plant Origin

<table>
<thead>
<tr>
<th>Drug</th>
<th>Application</th>
<th>Botanical Origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atropine</td>
<td>Anticholinergic</td>
<td>Atropa belladonna</td>
</tr>
<tr>
<td>Camphor</td>
<td>Rubefacient</td>
<td>Cinamomum camphora</td>
</tr>
<tr>
<td>Cocaine</td>
<td>Local anaesthetic</td>
<td>Erythroxylum coca</td>
</tr>
<tr>
<td>Codeine</td>
<td>Analgesic/anti-tussive</td>
<td>Papver somniferum</td>
</tr>
<tr>
<td>Digtoxin</td>
<td>Cardiotonic</td>
<td>Digitalis purpurea</td>
</tr>
<tr>
<td>Ephedrine</td>
<td>Sympathomimetic</td>
<td>Ephedra sinica</td>
</tr>
<tr>
<td>Hyoscamine</td>
<td>Anticholinergic</td>
<td>Hyoscamus niger</td>
</tr>
<tr>
<td>Levodopa</td>
<td>Anti-Parkinsonian</td>
<td>Mucuna deerlingiana</td>
</tr>
<tr>
<td>Morphine</td>
<td>Analgesic</td>
<td>Papaver somniferum</td>
</tr>
<tr>
<td>Noscapine</td>
<td>Anti-tussive</td>
<td>Papaver somniferum</td>
</tr>
<tr>
<td>Quinine</td>
<td>Anti-malarial</td>
<td>Cinchona ledgeriana</td>
</tr>
<tr>
<td>Reserpine</td>
<td>Antihypertensive</td>
<td>Rauwolfia serpentine</td>
</tr>
<tr>
<td>Scopolamine</td>
<td>Sedative</td>
<td>Datura metel</td>
</tr>
</tbody>
</table>


It is expected that new drugs of plant origin will continue to be developed given the resources being allocated by pharmaceutical companies to botanical prospecting for medicinal agents and the increased popularity/attention that herbal and natural medicines are receiving.
The development of products of natural origin to the level where they provide an alternative to existing drug treatments is within the scope and goals of the complementary medicine sector. An example is the ‘drug’ status accredited to glucosamine by Sweden’s medicines regulatory body.

The achievement of natural medicinal product listing with the Pharmaceutical Benefits Scheme (PBS) would be an ultimate goal of development. The benefits from such an outcome are diverse and include:

- lower cost to the PBS system
- lower incidence of adverse events and so improved patient well being, plus fewer hospitalisations for drug induced medical problems
- lower demand being placed on the health system (through lower adverse events)
- decreased resistance to pharmaceutical drugs e.g. antibiotics if eventually used through decreased exposure at condition on-set, and
- greater credibility attributed to alternative medicines.

With Australia’s virtually untapped biodiversity there are significant opportunities to capture competitive advantage in the global market sector.

### 3.2 Potential Areas for Development

Together with the ageing population is a concomitant increase in the prevalence of many diseases and an increasing demand for improved quality of life. Diseases such as cancer, cardiovascular disease and diabetes are prevalent and impact considerably on an individuals’ quality of life. Hence, there is considerable interest being shown in products that can prevent or alleviate the prevalence of such diseases.

Currently, a considerable amount of attention is being directed to antioxidants and the role they play in cancer prevention. For example, lycopene, an acyclic carotenoid has exhibited anti-carcinogenic properties (Wondu Holdings, 2000). Other antioxidants such as extracts from sunflowers have been shown to be as effective as the synthetic antioxidants butylated hydroxytoluene (BHT) and butylated hydroxyanisole (BHA) (Yoshiaki and Koji, 1994)

Some of the areas that are believed to be applicable to the Australian medicinal herb industry are listed in Table 2.
### Table 2  Areas for Future Development

<table>
<thead>
<tr>
<th>Category</th>
<th>Herb/Agent</th>
<th>Potential Market Value (Millions of $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory (Coughs, colds)</td>
<td>Echinacea spp</td>
<td>$USD 3,000</td>
</tr>
<tr>
<td></td>
<td><em>Panax pseudo-ginseng</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Marrubium vulgare</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The plant derived drugs of digitoxin and digoxin (<em>Digitalis</em> spp), ouabain (<em>Strophanthus fratus</em>), quinidine (<em>Cinchona</em> spp) and reserpine (<em>Rauwolfia serpentine</em>) feature significantly.</td>
<td></td>
</tr>
<tr>
<td>Antioxidants</td>
<td>Vitamin C</td>
<td>$AUD 314.2 (1998)</td>
</tr>
<tr>
<td></td>
<td>Antioxidant/carotenoid formulas</td>
<td>$AUD 96.8 (1998)</td>
</tr>
<tr>
<td></td>
<td>Vitamin A, D, K</td>
<td>$AUD 11.5 (1998)</td>
</tr>
<tr>
<td></td>
<td>Vitamin E</td>
<td>$AUD 323.9 (1998)</td>
</tr>
<tr>
<td></td>
<td>Lycopene (tomatoes), lutein (leafy green vegetables) and zeaxanthin (yellow fruit, vegetables) are also attracting current interest. Antioxidants are a key class of compounds being targeted in cancer prevention. They are also indicated in the prevention of artherosclerosis.</td>
<td></td>
</tr>
<tr>
<td>Immune system</td>
<td>Uncaria tomentose (cat’s claw), Astragalus membranaceous, Antioxidants (various sources including seaweed)</td>
<td>Natural vitamin C market in 1998 valued at $AUD 314.2; vitamin E $AUD 323.9</td>
</tr>
</tbody>
</table>

Source: Adapted from Wondu Holdings, 2000, Kane, 1999 and Roche Vitamins, 2003

Those conditions that affect quality of life and are of most concern in the USA are:

- amputation
- arthritis
- blindness
- cancer
- cardiovascular disease
- diabetes
- hearing problems,
- orthopaedic problems and
- paralysis

(Cutler and Richardson, 1999)

Obesity is associated with cardiovascular disease and diabetes. An increasing percentage of the USA and Australian populations (Western countries in general) are over weight or obese with increasing demand for weight control products.
Cognition/memory enhancement will also continue to be an area of concern and provide opportunities for product development, given the cohort of ageing ‘baby boomers’.

Given the broad range of conditions for which herbal medicines have traditionally been used, it is likely that some or all of the major disease targets could become the focus for a concerted development effort.

References


4. Government Support

4.1 Federal Government

The Rural Industries Research and Development Corporation has a number of programs that support primary industry initiatives such as:
- New and Emerging Industries
- Established Rural Industries
- Sustainable Systems; and
- Capacity Building and Competitiveness

Within these programs the sub-programs of most relevance to the herbal medicine industry are:
- New Plant Products
- Essential Oils and Plant Extracts and
- Global Competitiveness

A brief summary on RIRDC is included in Appendix 3 – Workshop No. 2 Minutes.

Other assistance at the Federal level could be provided through:

Pooled Development Funds scheme

The Pooled Development Funds program is designed to increase the supply of equity capital for growing Australian small and medium-sized enterprises. Increasing the supply of equity capital for small and medium-sized enterprises is achieved through the use of pooled development funds. Pooled Development Funds are private companies, established under the Pooled Development Fund Act, that raise capital from investors and use it to take equity in Australian small and medium-sized enterprises. In return Pooled Development Funds and their shareholders are taxed at a lower rate on income generated through Pooled Development Fund activities.

Regional Assistance Program

The fundamental purpose of the Regional Assistance Programme is to generate employment in regional, remote and metropolitan Australia by encouraging local community action to boost business growth and create sustainable jobs. It provides seed funding for innovative, quality projects of value to the community. Funding is available to fund projects nationally.


Venture Capital

Venture capitalists provide equity financing and managerial advice to investee companies to assist in their rapid growth. The investee company receives capital, managerial expertise and enhanced business reputation as a result of the venture capital investment. In return for the provision of capital, a fund manager acquires a part-ownership of the company and usually a seat on the Board of Directors. The fund manager’s ultimate goal is to make a profit in the long term, patient investment, through capital gain. Venture Capital is a high risk industry, and therefore fund managers will only invest in potentially successful companies, that will grow quickly and provide high returns.


Biotechnology Innovation Fund

The Biotechnology Innovation Fund is a Commonwealth Government program supported by the National Biotechnology Strategy and the innovation statement Backing Australia’s Ability, which aims to increase the rate of commercialisation of Australian biotechnology ventures by reducing the cost of demonstrating ‘proof of concept’ for new biotechnology initiatives. The program aims to address the critical gap between the research and commercial stages of development, where it can be difficult for companies to source funds to prove the viability of a new concept. By part funding technical testing and product analysis at this pre-seed stage, the program aims to increase the flow of Australian biotechnology projects proceeding to commercialisation. Where applications meet the program’s eligibility criteria, Biotechnology Innovation Fund will fund up to 50% of the costs of establishing proof of concept, to a maximum individual grant of $250,000.


Innovation Access Program

The Innovation Access Program (IAccP) - Industry is a competitive program designed to foster innovation by increasing the take up of leading edge technologies and best practice processes by Australian firms. Applications are accepted for industry led proposals from private sector companies and industry organisations, or consortia which can include additional organisations such as Cooperative Research Centres, training institutions and Commonwealth scientific organisations.
Pharmaceutical Industry Investment Programme

The Australian pharmaceutical industry is a knowledge based, technology intensive industry. The Industry is uniquely placed to capitalise on Australia’s strong medical research skills. Pharmaceutical Industry Investment Program aims to stimulate investment in pharmaceutical activity and to develop Australia as a regional centre of excellence in both research and development and manufacturing, by offering partial compensation for the impact on activity from the Government exercising its monopoly (sole purchaser) purchasing power under the Pharmaceutical Benefits Scheme.

Research and Development (R&D) Start (grants and loans)

The Research and Development Start program, available to Australian companies, is a merit-based program designed to assist Australian industry to undertake research and development and commercialisation through a range of grants and loans. The objectives of R&D START grants and loans are to:

- increase the number of Research and Development projects with high commercial potential that are undertaken by companies
- foster greater commercialisation of R&D projects with potential benefits to Australia
- foster collaborative R&D and related activities through companies working together, or working with research institutions

4.2 State Government

State Governments also offer assistance through various programmes. For example the Queensland Government offers a number of development programmes through the Department of State Development. For example:

Queensland Investment Incentives Scheme

The Queensland Government is committed to creating an operating environment for business that will attract major new investments to the economy and that will support the Government’s Smart State Strategy.

This commitment applies across all areas of regional Queensland and especially to the building of globally competitive business through reinvestment in new product and process technologies and through continual innovation.

In Queensland most investment occurs without the need for any Government intervention because of the significant operating and competitive advantages that exist in that state.
Given the strong business case for locating in Queensland, financial incentives are only provided in a small number of cases, when and if required by the State, to influence the location of major projects and strategic investments to Queensland.

It is important to note that financial incentives are not offered by the State as a general reward for investment or to meet a funding shortfall by a company. The decision to offer assistance is at the sole discretion of the State and is only made in exceptional circumstances to secure an important investment project that will support current Government priorities and that, in the absence of incentives, would locate elsewhere.

The principal mechanism for offering financial support to eligible projects is the Queensland Investment Incentives Scheme.

To be eligible for consideration under this Scheme, a company or project must:

- promote the competitive base of the State economy
- provide a significant net economic benefit to the State
- demonstrate commercial viability in the absence of incentives
- demonstrate a need by the Government to provide support to overcome a short-term impediment to a project’s development in Queensland
- demonstrate no significant detriment to and/or substitution for, existing businesses in Queensland.

Support, if offered, may be in the form of State tax rebates or establishment grants depending upon the type of short-term impediment affecting the development in Queensland. All offers are conditional and subject to the fulfilment of due diligence requirements and contractual obligations.


Each of the other states offers similar programmes of assistance through their respective departments. For additional information refer to the respective State Government websites.

Reference

All information sourced from respective program web sites
5. Stakeholder Perspectives

5.1 Introduction
A process of engagement was initiated to determine stakeholder perspectives. This involved:

i. The conduct of four industry member workshops. These workshops established a working group (see 1.1.3).

ii. Stakeholder involvement was also sought following the dissemination of discussion papers in order to further develop themes identified in workshop discussions.

5.2 Workshop No. 1 – Australian Herbal Medicines & Ancillary Industries Pilot Data Exercise
A workshop of invited industry leaders representing each of the supply chain links was convened by ACCMER on 27 February 2003 at, Mater Health Services Brisbane. Minutes of the workshop are included in Appendix 1. The major exercise undertaken at this Workshop was to outline the industry supply chain. This revealed that Australia has all the components of the supply chain within the herbal medicines industry except the ‘Research and Development’ component which was identified at the top end of the chain. It was noted that in other major Western countries this R&D component initiates the development of new herbal medicines which then move down the chain finally reaching the consumer. In addition this component is responsible for the significant value addition that occurs within the chain in other countries. There was significant consensus amongst the participants that this was a vital missing link in Australia and its formation would be essential to kick start the development of a large-scale and viable herbal medicines industry in this country.

A summary of the major issues and ideas identified at the workshop are shown below.

Summary

1. New industries require a sales outcome
2. There are other options in addition to primary industry that need to be addressed
3. Marketing / PR issues are first priority
4. Adopt a chain orientation, for security and long-term competitiveness
5. Examine IP and IP management
6. Partnerships creation is essential
7. What drives the chain? Is there a chain champion?
8. Education, starting at consumer level
9. Explore indigenous herb possibilities
10. Explore how to disseminate IP to “industry”
11. Fund development / capital
12. Mini CRC - manufacturing, processing, R&D focus. Develop IP around evidence based medicine. Maybe an equivalent service company would be more appropriate / effective?
13. A role exists for smart brokers
14. Portfolio’s versus industry products - would a cooperative be the best management model

Structure options considered were presented back to Industry prior to Workshop No. 2 as a discussion paper (Discussion Paper No. 1).
DISCUSSION PAPER No. 1
A STRATEGY DISCUSSION

By
Dr Bruce R Rich (QUT)
Dr Phillip A Cheras (ACCMER (UQ / SCU))
Prof Stephen P Myers (ACCMER (UQ / SCU))

INTRODUCTION
Development potential for the Australian Herbal Medicines and Ancillary Industries exists and is generally acknowledged by industry associates. However, recognition of how this may be achieved requires clarification.

An initial review of the herbal industry in Australia revealed an industry that was fragmented, basically small scale, minimally oriented towards exports and deficient in strategies to achieve future development. The review also identified companies that were successful – in both production and processing, in addition to being progressive and niche market aligned.

During the review and at the first industry workshop held on the 27 February 2003, sentiment was expressed that supported the concept of developing an industry strategy and a structure to achieve strategy objectives. In order for such a strategy to be developed and a structure identified that is acceptable to industry members, a consultation process is being followed.

This paper is part of that consultation process. Its purpose is to draw on the options of the review, the points made and issues raised at the workshop. These have been refined and presented for discussion.

CURRENT STATE AND ISSUES
Australian Medicinal Herbal Industry Environment
A number of points can be made regarding the Australian Medicinal Herbal Industry Environment. Firstly, the medicinal herbal industry is concentrated in the Northern Rivers district of New South Wales. Tasmania, Victoria and Queensland are active in production and processing but all on a small scale. Secondly, little collaboration seems to exist between industry members, although efforts are being made in NSW to develop the herbal industry at the regional level with NSW Government support. On the Queensland Gold Coast an association of processors has been founded with Queensland Government support.

Thirdly, within the industry there is no ‘leader or champion’ firm. This may indicate an industry in its infancy and/or an opportunity to develop a mechanism that will lead the industry into a more substantial future.

Australia’s scientific capability is recognised as being world class in the medical and health related disciplines. Similarly, Australia is recognised as a technologically advanced country and an efficient primary producer. In several primary and resource sectors (wheat, wool, aquaculture, coal, aluminium) Australia is seen as having significant international standing.
Finally, the Complementary Healthcare Council is the industry representative body, which has good access to Government and the means to influence policy. Thus an avenue exists to establish the case for development assistance and recognition of the benefits that complementary medicines (CM) can bring to the health sector. For example, there is no separate funding or granting body for complementary medicines. Research into herbal medicines is generally poorly funded by mainstream granting organisations in Australia, despite the herbal medicine sector being valued at ca. $1.6 billion.

Critical Issues for Strategy Development

A number of issues were identified at the industry workshop that need to be addressed, which will influence strategy formulation. Although these issues cover a broad spectrum, they can be grouped into specific categories which contribute jointly in the formulation process.

These categories include Risk Management, Supply Chain Relationships, and the need for a Commercial/Corporate entity to fund CM commercialisation.

Risk Management

- Association with global partner
- Forward contracts
- Need final sales outcome
- Need to cooperate to compete in a global environment.
- In a changing environment, it is essential to cooperate in order to compete effectively.
- Need an organised, concerted push at all levels - the following three points will be pushed:
  i) Natural therapies benefit all - they are cheaper, and allow us to live longer and in better health whilst costing less to the economy
  ii) We need to understand CM properly - CM should be a first choice for physicians where appropriate, once we know CM are safe and effective. Physicians might be proven negligent if they prescribed a pharmaceutical that is more dangerous, for a condition that could be treated with a less harmful herbal medicine (HM).
  iii) Affordable access to CM is the right of all Australians - as such, it deserves a fair share of tax support
- Need to stabilise industry

Supply Chain Relationship

- The ability to integrate into the supply chain to be a competitive unit comes down to the ability to innovate.
  In the long term, partnerships result in:
  i) Increased profit
  ii) Chain loyalty
  iii) A hard strategy to copy
  iv) Ability to keep out competitors
- Brokers are more like “relationship adders” – they know who to contact for what, and cultivate these relationships (Partnerships need to be part of strategy)
- Supply chain management (SCM) strategies – 6 key principles
  i) Focus on customers and consumers
  ii) Creating and sharing value
  iii) Getting the product right
  iv) Ensure effective logistics and distribution
  v) Having information and communications strategies within the chain
  vi) Building effective relationships
It is possible to hand-build a supply chain using a rational process, and abiding to the six principles. The challenge is the innovation within the firm or within the supply chain when you are vertically integrated. The driver is competitive firms in competitive supply chains.

Coordinate with farmers to promote cohesion that is missing. A broker might be appropriate for this task.

Commercial/Corporate Entity

- Chain leadership is a question (role for corporate entity)
- Intellectual property (IP) and clinical trial production currently occurs overseas. It is where a high percentage of capital goes. What about doing this in Australia, rather than just the USA? Capture the source!
- Need both IP and primary component.
- Identify core group of people keen to support CM
- Evidence based medicine, through research, is used to support CM
- Industry is driven by regulated supply, through tightly controlled specifications
- Possibly a mini-CRC type activity
- Mix industry, Government, and research bodies together
- Possibly private and Government funding
- Pool research
- Each member of the project takes a stance on whether they will buy into the process or not
- IP is generated, along with standardisation, and evidence of efficacy
- Australian driven assault on global CM industry, supported by data to back up our claims
- This may be a five or ten year plan
- Need a willingness to share with competitors
- Need a service company to coordinate this?
- A short R&D period is required
- Potential products with IP possibilities do exist in Australia
- Companies need an investment portfolio

Source: Herbal Industry Workshop No. 1 Minutes

ORGANISATIONAL STRUCTURE OPTIONS

Views expressed at the workshop of 27 February 2003, indicated a preference for an Australian medicinal herbal industry that was internationally competitive in its own right. This might be achieved through innovation originating from initiatives supported by the industry that would confer ‘competitiveness’, preferably competitive advantage.

Given the current scientific and resource capability that could be drawn on by the industry, this is thought possible. However, without resource accessibility, it is likely to remain unattainable. This discussion is therefore focussed on various options for consideration, which accommodate the list of issues stated above and will confer ‘competitiveness’.

In order to assist identification of an appropriate structure the industry could adopt and develop, alternatives are presented. Organisational structure alternatives can be broadly stated as a choice between a Functional, Divisional, Hybrid, Matrix or Network approaches.
The functional, divisional or hybrid approaches are also broadly referred to as Mechanistic models. The mechanistic model is based on a hierarchical approach. While the matrix and network approaches are broadly grouped under an Organic model.

**Option 1 – Mechanistic Model**

A functional structure application to the medicinal herb proposal is shown below.

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This structure is reliant on a top – down approach as it is the R & D and subsequent IP generated that provides its differentiation. The issues of cost for access or share availability need to be considered. Is the company a limited company or open to all industry members? Option 1 addresses the issues raised above in the following way.

**Risk management**

- **Global partner** – Although not specifically stated there is opportunity and a desire for an international firm to become a shareholder. As such opportunities could be explored to a mutual benefit.
- **Sales/contract orientation** – The establishment of scientific and clinical data would lead commercial development and sales outcomes. Single brand marketing would allow a market niche to be established based on quality and efficacy. The products marketed would compete in their own right.
- **Stabilisation of Industry** – Industry shareholder members would have privileged access to IP and would be able to increase their operation’s value through being a limited supply chain link member. Non-shareholder industry members can participate in Industry stabilisation by adoption of best practice code, certification of herbs, obtain endorsement and build independently on the underlying quality theme of the Corporation.

**Supply Chain Relationship**

The shareholders, consisting of representatives from all links within the supply chain rely on building relationships and cooperation. Each of the six (6) key principles of SCM strategy is able to be addressed, with the ‘shareholder membership’ bond contributing to each of the principles being maintained.
The shareholder approach is consistent with partnership development and the resulting long term benefits of
- Increased profit
- Chain loyalty
- A hard strategy to copy
- Able to keep out competitors

Through shareholder membership the ability to hand build competitive supply chains also becomes an option.

Commercial/Corporate Entity

The Corporate Executive Group would provide leadership through access to and/or generating IP and shareholder input. As a commercial entity it would be eligible for a broad range of research and development grants.

In association with CHC the Corporation using evidenced based data could then provide representations to Government to elevate the status of selected herbal medicine products for inclusion on the pharmaceutical benefits scheme (PBS) and target marketing activities used in raising awareness levels within the professional medical industry.

The mechanistic approach like most choice options has advantages and disadvantages.

Advantages
- A stable environment is created which would assist components of a fragmented industry to unify and consolidate.
- Stability fosters development of expertise, a necessary component if global recognition is to be achieved.
- Paths of action or supply chain links are clearly defined
- Internal coordination is minimal which may lead to efficiency gains
- Roles and responsibilities are clearly defined.

Disadvantages
- Can diminish innovation at the individual level
- Conflicts over product priorities can occur
- May foster politics in resource allocation

Option 2 – Organic Model

The Organic approach is less rigid, maybe less hierarchical and can be more accommodating of change. Three alternative approaches within the organic model are Simple, Matrix and Network. The Simple approach is often used in an owner/manager situation. A matrix application is used where duplication of systems maybe relevant. A network approach can offer advantages in linking geographically and/or activity diverse operations together. Of these three approaches the matrix and network approaches would seem to be the most appropriate to apply in terms of a national focus.

a) Matrix model

The matrix structure is useful where duplicate divisional and functional sub-units exist simultaneously. Given that one of the goals of the medicinal herbal industry strategy is development at the national level, this approach may have appeal.
b) Network model

Networks are useful when inter-organisational relationships are being considered. There are a variety of types of networks – vertical, horizontal, agreement-joint venture and regional industrial systems to name a few.

This approach relies on industry members becoming members of the Corporation. It has broad application. The Network Executive Group would operate as a coordinating body.

Supply chains would be created in response to an identified opportunity. Under such an arrangement brokerage from IP to market would be undertaken. IP would most likely be franchised to the Network Group with ownership remaining with the innovator.

A flagship model showing collaborative relationships among major players in a business system is illustrated below.
The degree of privilege conferred by membership is much less than the mechanistic model. However, outlay is much less and the integration into an individual company's strategic development is also of less significance, compared to the mechanistic model. However, the impact at the industry level can be quite significant, through the involvement of a larger number of industry members and subsequent channels of communication.

The issues of risk management, supply chain relationships and corporate structure are still able to be addressed but in a more fluid manner. Like option 1 this option also has advantages and disadvantages in its implementation, viz.

Advantages
i) Approach provides a good degree of flexibility
ii) Multidisciplinary cooperation is stimulated
iii) Approach is thought to involve, motivate and challenge participants
iv) Response speed is generally enhanced

Disadvantages
i) There is a risk of creating a feeling of anarchy
ii) There is a risk of creating power struggles
iii) Network is prone to instability and disintegration
DISCUSSION

The options presented above are intended to highlight the different approaches that can be taken. The organisational design and organisational strategy impact on one another and significantly influence subsequent directions being followed. This is an important point for consideration as industry development strategy has not yet been determined. However a desired strategy outcome is acknowledged to be a unified entity that could be either an industry leader or an industry coalition that will generate advancement and secure an international market presence.

As the options presented are quite broad a number of points need to be taken into account when deciding the most appropriate approach to select. These points include but are not limited to the following:

- Given that the Australian CM industry is currently a fragmented, generally independent body of participants in the medicinal herb sector, it is important that the industry establishes an image of consolidation and structure from the organisational design. The time frame for this to be achieved is probably 5 to 10 years.

- If the industry is to realise its potential it will need Government support and involvement. How this can best be achieved and what influence this has on organisational design is a further point for consideration. If selected herbal therapeutic products are to attain equal status to allopathic drugs in the treatment of conditions or diseases, and make a contribution to the PBS, a more comprehensive research funding program is required. How this is best achieved is open to debate.

- Consideration of what the industry’s desired future composition should be and how the various supply chain members interrelate is needed. Will the industry be based around a select few? Is an incubator program required? Are ‘hobby’ or very small scale participants an asset or a distraction?

- Clearly if the industry is to develop and compete internationally in its own right, it needs to develop IP quickly. For this to occur funding would need to be available. Funding options will need to be considered and be consistent with organisational design preferences. For example if the approach is to create an incorporated company, venture capital may be appropriate. If an industry-Government alliance is sort, lobbying efforts may be required to have herbal medicine included in research funding programs. A combination of approaches is likely to be required.

- Development of the industry at the national level will require the establishment of a number of linkages and representations. What they should be and who should undertake them will also need to be consistent with the structural design and strategy objectives.

- The creation of a corporate entity will require operational, developmental and seed funding. How this is sourced, from whom and over what time frame are issues that will greatly impact on the ability of the corporate entity to perform its role. A number of options exist: share issue, venture capital, Government support and underwriting, or commercial finance sector.

SUMMARY

The herbal medicine industry has the potential to become a competitive industry in the global market in its own right. For this to occur a structured and well funded program is required to progress identified intellectual property to a commercial outcome. Along with this progression, industry development is also required to unify the industry and clearly define future strategy and structure of the industry.

A review of the industry identified a number of issues that were of concern and that needed to be addressed if industry potential was to be realised. In seeking resolution of these issues while tackling the future strategy and industry structure considerations a number of options have been presented.

Industry member preferences for these options or a hybrid of them will be a major discussion topic at the second workshop. A desired outcome of the second workshop is to have consensus on the structure of a commercialisation entity and an appropriate development strategy.
5.3 Workshop No. 2 - Australian Herbal Medicines & Ancillary Industries Determination of Options for Industry Structure

Herbal medicines industry workshop number two was convened by ACCMER on the 19 June 2003 at Mater Health Services, Brisbane. This workshop’s main focus was to identify the preferred industry structure option and develop a future strategy that would carry the industry forward. The goals and partner relationships associated with the proposed new corporate entity are shown in Appendix 2. The preferred industry structure and strategy would then be refined and put to the wider stakeholder body for consideration and resolution.

Workshop No. 2 minutes are included in Appendix 3. A summary of Workshop No.2 outcomes is shown below.

The theme of workshop number two was the establishment of a corporate entity. From the first workshop three broad categories of issues were identified: risk management, supply chain and corporate entity. The first two can be overcome in part by addressing the third category, corporate entity. Before a structure could be determined, the goals and objectives of the corporate entity needed to be identified. This was addressed by dividing workshop participants into two groups to identify the three most important aims of the corporation and the good, bad and gap characteristics of the industry (Table 1).

Table 1  Aims of Corporate Entity and Current Industry Characteristics

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Good:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aims:</strong></td>
<td>• Consumer demand</td>
</tr>
<tr>
<td>1. To provide a platform for industry, research provider, Government agency interaction</td>
<td>• Safety of CM products – low risk</td>
</tr>
<tr>
<td>2. To drive an innovative, viable industry</td>
<td>• Clean and green</td>
</tr>
<tr>
<td>3. To produce commercially viable intellectual property</td>
<td>• Lower barriers to entry</td>
</tr>
<tr>
<td></td>
<td>• Established historical use – traditional</td>
</tr>
<tr>
<td></td>
<td>• Emerging science</td>
</tr>
<tr>
<td></td>
<td>• “passionate” industry – commitment and dedication</td>
</tr>
<tr>
<td></td>
<td>• Economic opportunity – huge.</td>
</tr>
<tr>
<td></td>
<td>• Domestic and overseas market opportunity</td>
</tr>
<tr>
<td></td>
<td>• High standards in Australia, internationally recognised</td>
</tr>
<tr>
<td></td>
<td>• Technologically advanced practices in Australia</td>
</tr>
</tbody>
</table>
### Bad:
- Fragmentation
- Low incentive for research
- Small economic base
- No lead company
- Lack of market awareness – education of public
- Poor perception of decision makers of industry, integrity (versus pharmaceutical/medical/perceptions)
- Poor quality starting materials from some sources
- Identifying appropriate industry standards.
- GST on products.

### Gap:
- Lack of independent knowledge assessment.
- Insufficient efficacy data
- No Government funded research body
- Lack of Government support and recognition
- Lack of industry involvement in Government practices
- No Government R&D corporation
- Insufficient validation of product quality
- Limited scientific resources
- Lack of global presence due to few global products.

### Group 2

#### Aims:
1. Commercialisation of Australian products
   - Raw material (locked in?)
   - Australian native plants
   - Grow ingredients to use in products in Australia
   - Aggressively Commercialise Australian product
2. Networking
   - Develop body to support use of Australian native plants
   - Foster R&D
   - Coordinating/facilitating
   - Raising money (for various stages of commercialisation)
   - Saleable to community (income, staff, facilities)
3. Plan
   - Solicit venture capitalists
   - Identify motivation for bringing group together
   - Project basis (need funding, clinical trials, business plans, partners, R&D, develop IP).
   - Government? Commercialisation of Industry
   - Not cohesive (fragmented players)
   - Simple model – medical, herbs company e.g. tea tree oil, lavender (Tas.) began with Australian plants, poppies
   - The Key players/companies – motivation – not enough "Oomph"
   - Small farms not viable
   - What is the structure and viability of structure – need funding just for structure
   - Match up researchers and entrepreneurs

#### Good:
- Abundant interest
- Substantial amount of IP exists
- To become part of industry (desire)
- Indigenous community development through farming native Australian products e.g. Broome Kakadu plum
- Clean and Green image of Australia
- Plentiful resources in Australia (land, native products)
- The dream process “Australian aloe vera” pig face research facility/specialists/uni (use them on contract) link with university.

#### Bad:
- Lack of sufficient lobbyists
- Lack of adequate Government funding
- Embryonic industry – scattered and unorganised
- Lack of support for the CM industry in Australia in comparison to other countries e.g. NZ
- Lack of a global player
- Herbal companies going into satellite countries
- Lack of encouragement for Australian CM industry
The two groups suggested similar aims – integration, developing a network, and sustainability including commercialisation.

A HM corporate entity would be a lead player that would assist classification, endorsement, and recognition by and of the herbal medicine industry. It would assist in a seamless transition from raw material to retail product with a brokerage role identified as an outcome from the first workshop. A single brand or endorsement logo that conveys a corporate association could be developed, that is recognised for its quality in an integrated market. A single brand managed through share holders or a company – produced to a certain standard and code giving customer reliability. The code applying beyond raw materials to ensure that products developed are meeting a set standard. At the moment marginal products are confusing the market.

A national perspective is essential when considering the corporate structure of a new corporate entity for CMs.

What is the preferred corporate structure?

A number of essential corporate characteristics were identified, namely:

- It needed to be able to attract funding (before Pan, investment was difficult to source and after Pan investors are less interested)
- The structure needs to be loose and simple
- It needs to be established in the commercial mould to attract investors – having a close relationship with universities but standing outside the universities. It needs to find a balance between attracting investors and being a peak research body. This would also require research to be done by the best person (or organisation) to do the job at the best price – to be commercial.
- The structure needs to allow unification of the various industry sectors.

In order to facilitate discussion at workshop No. 3 a second discussion paper was circulated on corporate structure options for the medicinal herb company. (Discussion Paper No. 2).
DISCUSSION PAPER No. 2
CORPORATE ENTITY STRUCTURE SCENARIOS

By
B Rich and P Cheras

INTRODUCTION
An undertaking at workshop 2 was to develop two or three scenarios that reflect the characteristics of simple structure, loose or flexible association, which is able to be built on, is research focused and operates as a commercial entity. These scenarios were then to be circulated for comment.

Could you please review the following scenarios and forward comments to Dr. Phillip Cheras <p.cheras@uq.edu.au>

Scenario 1
Scenario 1 is based on comments to keep structure simple and loose. The company would commercialise the IP either solely or through the IP owner, with supply chain members operating to an acceptable code. The products produced as in all model options would be supported with solid scientific data with the aim of offering an alternative to a pharmaceutical drug. The lower incidence of adverse events and hopefully a cost incentive could be used in PBS considerations.

This model is one representing an independent commercial entity trading under its own banner. Board members would be selected on shareholding and by appointment if appropriate. The percentages indicated below are indicative only.

1. Natural Products P/L (NP) company is formed with ACCMER holding 30-50% shareholding with the remaining 70-50% held by investors. ACCMER involvement would meet the strong desire expressed by the group for ACCMER to play a significant role. Separate company establishment avoids any conflict or confusion with ACCMER's established agenda.

2. An IP project is brought to NP for a data profile to be established and commercialised. NP holds 15% stake and IP owner 25% stake with remaining 60% offered to investors or industry supply chain members based on cost of development.

3. Individual supply chains are assembled to suit the project.

4. All products commercialised would be “badged” in someway with NP if not going under the NP label.

This approach allows integration to occur through IP holders able to access the appropriate R&D service. Allows supply chain members to take part based on a business decision. It is supportive of innovation as it provides a path for commercialisation to occur albeit through a trade-off of IP share. It is self-sustainable for NP through the 15% stake.

Scenario 1 Simple Structure Coordination
Scenario 2

Scenario 2 is based on a requested structure that includes all segments yet remains loose. (Association is a firmer relationship than network). Here the thinking is that the association could have nodes or chapters in each state and act as a conduit into the corporate entity as required. This model introduces another level but has the potential advantage of demonstrating unification of the industry and it would be seen as a national presence. Companies or individuals would have improved access and support in the process of taking an IP to commercialisation.

1. Establish an association and subsidiary company. The purpose is to formally show support for the company and an access pool facilitating supply chains.

2. Association membership fee pays for administration.

3. Association would act as a forum for industry innovation, information and issues identification/raising to feed to CHC.

4. Association subsidiary would operate in a similar way as in scenario 1

5. There is broad potential for general industry involvement and the opportunity to consolidate the industry and demonstrate a unified industry approach to the industry’s development.
Scenario 3

Scenario 3 reflects the desire to have ACCMER as a lead agent

1. If ACCMER were to establish a subsidiary company it would avoid any agenda conflicts with ACCMER operations.
2. IP owned by ACCMER could be the hook for investors such as Pool Development Funds.
3. It supports innovation by allowing IP holders to have it developed to a commercial outcome through trade-offs.
4. The company would be an industry leader through the R&D focus but also through the close involvement with ACCMER education programs.
5. The ability to contract R&D would exist as the company would be a commercial entity set up outside of university governance.

Whatever the preferred model Governments will need to be convinced that the industry is unified, focused and committed, before any financial support would be considered. The German model regarding prescription herbal medicines could be worth looking at for developing strategy.
5.4 Workshop No. 3 – Industry Structure and Funding Options

A model was presented for the funding and commercialisation of biotechnology innovations. It performs a similar role and function as the corporate structure desired by the herbal medicine sector. The model guaranteed funding each year for development of new ideas, developing IP to take research into commercialisation.

Slide 1  Intellectual Property Pipeline Model for Commercialising Biotechnology (Company XYZ)

Slide 2  XYZ Investment Process (on Project Basis)

Deal Flow/Research Pipeline
- Medical/herbal technology opportunities brought through strategic relationship with SCU and UQ

Investment Analysis
- Potential opportunities are screened on following basis:
  - market
  - unique features
  - risk balance in portfolio
  - stage of development
  - competitive advantage
  - consistency with chronic disease treatments, herbs or diagnostics
- IP position-proof of concept
- Formal investment proposal to executive directors

Investment Exit
- Active market testing of trade sale, partnering, licensing, dilution or IPO for product manufacturing and marketing

Deal Negotiation/Approval
- Negotiate farm-in with minimum 40% with IPO rights
- ‘Clean IP’
- Clear milestones for farm-in investment
- Technical due diligence
- Research contracts
- XYZ must be manager
- Board approval requested
- Execute agreements for technology SPV

Investment Management and Partnering
- Active participation at Board level with:
  - strategic planning
  - financial reporting
  - research expenditure
  - key decision making
  - goal setting
- Supply position on natural medicines while local alternatives are found
- TGA/clinical testing in ACCMER for herbs
Prior to the final workshop a discussion paper was developed for circulation (Discussion Paper No. 3)
DISCUSSION PAPER No. 3
HERBAL RESEARCH CENTRE

By
David Catsoulis and Jaydeep Biswas (PhD)

OPPORTUNITY

The herbal medicine industry in Australia is undergoing dramatic change:

- The herbal medicine market for common ailments and chronic diseases is growing exponentially in Australia (multi-billion $) and internationally ($5 trillion in 2050) (Figure 1).
- The Pan Pharmaceutical demise has highlighted the need for strong regulation in the industry as well as proof of efficacy to protect the interests of producers and consumers.
- Ideas and species from Australia’s extensive biodiversity are not penetrating the market because of the lack of seed capital for testing research concepts. The major players in the industry are marketers and distributors who consider investment in commercialisation only once the concept is proven.
- Industry, Government and researchers appreciate that a sustainable and growing industry taking into account Australia’s biodiversity will require early stage capital for ‘proving up’ research concepts as well as capabilities to test the efficacy of herbs for market credibility and to conform to an expected stricter TGA regime.
- The lack of early stage funding to test credibility of claims allows the opportunity for a new entrant to bring Australian products to local and international markets backed by funding and research/medical expertise as well as support by the major marketers, distributors and Government.

The essence of this proposal is to leverage off the unique herbal medicine development and efficacy testing facilities at ACCMER which have TGA-credibility and the clinical expertise of one of Australia’s top medical universities and hospital systems (UQ) in combination with major industry partners and investors to create a one stop shop to take species from Australia’s biodiversity all the way through analysis, clinical trials, product development and then finally to market via joint venture.

STRATEGY

1. Form XYZ Pty Ltd as the commercialisation and management vehicle for industry, Government and investors for funding early-stage research by assessment of IP from CHMR (Centre for Herbal Medicine Research; to be merged with ACCMER at its core) and elsewhere as well as being the key vehicle for industry to interact with the regulator on implications of new policy initiatives.

CHMR will be a global centre of excellence in herbal research. CHMR would be joint venture between SCU and UQ to take advantage of the existing herbal medicine and clinical facilities and TGA/FDA track record at both universities.

CHMR would have nodes at other leading universities such as Griffith and have the Qld. State Govt as a partner.
2. CHMR would be funded by Government and industry research grants, supplemented by commercial investor funds raised by XYZ Pty Ltd.

3. CHMR would be a one stop shop from developing drug targets, testing, extracting and screening of herbal medicine candidates, testing from cell lines to patients as required, securing TGA approval for the preferred candidates and developing the final herbal drug going to market. CHMR would also retain a foundation of knowledge on implications of herbal medicine on human health and hence be a primary component of the industry discussions with regulators on future regulatory policy.

This approach has proven benefits for the researcher, practitioner, patient, Government and industry alike. It will attract world class researchers from different geographies under ‘one roof’ to investigate, prioritise and develop one strategic herbal medicine program for either medical, biological, molecular, biochemical, cellular, or drug delivery. It will also develop research staff, procure and distribute know-how nationally and or internationally amongst researchers to keep them abreast of developments and attract Government and institutional grants for the stated purpose of the CHMR.

4. XYZ Pty Ltd would:

   a) administer the Centre on a budget approved by trustees of CHMR (including negotiation of arrangements to set-up Centre of Excellence, examine all possible fund raising activities, ensure statutory requirements are met, manage funds and accounts, propose strategies and priorities, provide market/competitor/IP assessment capabilities, develop business and public relations plan, assist Centre of Excellence in Government grant applications) etc. Build working relationship with existing researchers and fill the specific requirements of the various drug targets identified by hospitals etc… to be based in Queensland if sufficient local incentives are identified through the Queensland State Government.

   b) secure commercial investor funds (wanting exposure to herbal medicine sector) to assess/register/commercialise IP developed in Centre of Excellence, procure further investment funds on an IP specific basis, develop markets and products, procure raw material contracts, secure partners on an IP-specific basis, facilitate manufacturing and distribution, and ensure commercial returns to investors and CHMR acceptable to trustees (latter by royalty stream). XYZ Co. is to be managed as a profit centre in its own right under a Board to provide incentives for initial commercial investors and management.

   An agreed portion of the XYZ Pty Ltd profit would be redistributed back to CHMR and its nodes (probably around 33%). XYZ Pty Ltd would be listed within 3 years.

   Develop and manage financial products such as PDFs to provide diverse tax-effective opportunities for attracting investment fund providers and seed capitalists (see Crescent Capital Trustees/Pioneer Investment Funds model).

   c) bring Eastern herbal medicines for testing/analysis at CHMR and if efficacy is proven, develop Western export markets for the products as well as find substitutes in Australia’s biodiversity.

   d) seed new business lines for the future such as nutraceuticals for the pet and livestock markets.

5. The initial focus of CHMR is the assessment and development of the research pipeline (200+ herbal extracts). An example of this is the work being undertaken by SCU specifically targeting Chronic Paediatric Diseases (e.g. Renal Disease & Type II Diabetes).

   It is estimated by the WHO that one in four adult humans will contract Type II Diabetes by 2020 and that this cause of renal failure will be a major disease of the ensuing 25 year era.
PROFIT SHARING FROM HERBAL RESEARCH COMMERCIALISATION

XYZ Pty Ltd can assist in lowering the barrier to communication and synergy with respect to IP developed by different researchers and nodes through a third of all profits from the commercialisation being returned to the CHMR for funding further basic research (to be known as a IP protected Research Tent). This can be achieved by the micro-registration within the CHMR Tent of registering individual research IP.

For any specific piece of IP developed, XYZ Pty Ltd would assess, commercialise and vend the IP to the highest bidder at the market ready/TGA licensed stage of development; XYZ Pty Ltd would negotiate contracts or licensing agreements with an array of established distributors. The net profits (after taxes, cost of capital, etc) will be received by XYZ Pty Ltd and shared equally between XYZ, CHMR (incl. its nodes) and the researchers who developed that specific piece of IP. If this sale of IP was not possible or prudent, XYZ Pty Ltd would set up an IP-specific SPV (special purpose vehicle) and secure commercial funds/partners as equity contributors to the SPV along with the designated researchers as shareholders (for that piece of IP) to take the product to market via contract manufacturing.

While CHMR would be owned by the universities/Government with royalty agreements with researchers, the shareholding of XYZ Pty Ltd would be split between drivers of XYZ, seed capitalists, industry partners and the key foundation researchers/universities of CHMR. The seed capitalists and industry partners would initially raise A$10M by share issue to sustain XYZ Pty Ltd, invest in IP/market/competitor assessment capabilities, invest in the initial activities and research programs in CHMR (additional to existing budgets at SCU, UQ and ACCMER which would be merged with and be the core of CHMR) and ensure CHMR has the capabilities to attract Government grant funding.

CONCLUSION

The ultimate aim of the CHMR is to bring together the best minds in the field of herbal medicine research, discovery and complementary medical practice so as to devise a programme for targeting and procuring a world class knowledge base and state of the art testing authority utilising the latest innovation available in the field of endeavour. It is surmised that by this method we (as an industry) will have the best chance of controlling and defeating the disease regimes which the non-herbal industry have struggled with since the beginning of modern medicine. For example, if CHMR based research and development can save one renal patient from the requirement for dialysis this would save the Health System $120,000 p.a. and dramatically increase quality of life for the patient. Such outcomes have enormous cost savings implications that Governments can not afford to ignore.

The focussed commercial nature of XYZ Pty Ltd will allow CHMR to concentrate on its strengths, that is research and development.

At present this interchange of information and technology is impeded by the walls which have been established to protect intellectual property around the world. Whilst initially, researchers in herbal treatment and research would not be seen to be directly benefiting by the sharing of such information, it is conceived that a protected legal registration of ideas and concepts could be established cost effectively within the CHMR as a whole. It is proposed that by having a policy of “one win all win” mandated across the CHMR then, such artificial walls will fall and information flow and communication dispersal will prosper on a constructive rational and open basis between researchers, institutions, practitioners and the community at large to the benefit of all.
Figure 1 Overview for Research and Commercialisation of IP
5.5 Workshop No. 4 – Herbal IP Company Corporate Structure

Following the circulation of discussion paper no. 3 a fourth workshop was held to reach consensus on a final IP corporate structure based on the XYZ Ltd. model (Figure 2).

**Figure 2** Herbal Subsidiary Relationships Proposal

The proposed working process for developing IP and generating commercial outcomes was discussed based on the flow diagram depicted in Figure 3.
Following further group discussion, acceptance of the XYZ Ltd model by the workshop participants was unanimous. A time frame of activities was agreed to (Appendix 5) with the registration of a complementary medicine intellectual property development and management company set to occur by end of February 2004.

The final relationships for the IP pipeline for the IP company (referred to here as Herbal Co.) is shown in Figure 4. The organisational structure of the company follows that of a mechanistic model (Figure 5).
Capitalisation of the company will follow a staged process. Revenues generated from products that have been commercialised will be used to fund future IP development and dividends to shareholders.
6. Herbs Targeted for Commercialisation

6.1 Introduction

It was originally envisaged that of the 300 plus commonly used herbs, 50 would be identified and initially targeted in the establishment phase of the medicinal herbs industry. The thinking being that herbs of emerging national and global interest would be progressively introduced following evidence based data at the appropriate time.

This approach is essentially a production focused approach. In contrast to this approach is the IP commercialisation approach which has evolved during this study. Under this scenario, herb production would be based on a top down basis with proven R & D driven requirement for the herbs to be produced. This would provide an increasingly more profitable and sustainable herb growing sector.

6.2 Production Focused Approach

Many of the key issues that the medicinal herb industry faces are similar to those faced by any new primary sector wanting to establish itself in Australia. For example, a feasibility study looking at the establishment of olive oil processing plants in regional Australia identified the following issues which are also applicable to this study:

- site selection and analysis
- macro/micro climate, soil types, water availability and water disposal, nutrient loads, proximity to resources, cost
- selection of varieties
- availability of suitable nursery stock, international history and reputation, local history, yield potential in this locality, harvest interval and timing
- production skills and management capability
• planning and operating to achieve maximum production, adequate labour with commensurate skills utilising the best agronomic support advice available
• management of supply of raw materials or their components
• quality management systems
• quality assurance production systems in place including HACCP and a continuous improvement process
• crop support programs and
• availability of staff, expert advice, training, contracted equipment, service and resources.

(Myers Strategy Group Pty Ltd, 2001)

The current most commonly used medicinal herbs in Australia and the USA are listed in descending order (Table 2):

Table 2 Current Australian Ten most Popular Herbs Compared with the Ten Most Popular Herbs in the USA

<table>
<thead>
<tr>
<th>Common Name</th>
<th>Botanical Name</th>
<th>Australia</th>
<th>United States of America</th>
</tr>
</thead>
<tbody>
<tr>
<td>Echinacea</td>
<td>Echinacea purpurea, E. angustifolia, E. pallida</td>
<td></td>
<td>Echinacea purpurea, E. angustifolia, E. pallida</td>
</tr>
<tr>
<td>Phytoestrogen</td>
<td>Trifolium pratense</td>
<td></td>
<td>Hypericum perforatum</td>
</tr>
<tr>
<td>Evening Primrose Oil</td>
<td>Oenothera biennis</td>
<td></td>
<td>Ginkgo biloba</td>
</tr>
<tr>
<td>Garlic/Horseradish</td>
<td>Allium sativum/Cochlearia armoracia</td>
<td></td>
<td>Allium sativum</td>
</tr>
<tr>
<td>Valerian</td>
<td>Valeriana officinalis</td>
<td></td>
<td>Hypericum perforatum</td>
</tr>
<tr>
<td>Ginkgo</td>
<td>Ginkgo biloba</td>
<td></td>
<td>Panax ginseng</td>
</tr>
<tr>
<td>Hypericum</td>
<td>Hypericum perforatum</td>
<td></td>
<td>Aloe barbadensis</td>
</tr>
<tr>
<td>Guarana</td>
<td>Paullinia Cupana</td>
<td></td>
<td>Eleutherococcus senticosus</td>
</tr>
<tr>
<td>Celery</td>
<td>Apium graviolens</td>
<td></td>
<td>Valeriana officinalis</td>
</tr>
<tr>
<td>Garlic</td>
<td>Allium sativum</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(adapted from Wohlmuth et al., 2002

(Sadovsky, 2000)

Other medicinal herbs which are emerging as significant market leaders are shown in Table 3.
Table 3  Current most Popular Herbs

<table>
<thead>
<tr>
<th>Common Name</th>
<th>Scientific Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lemon balm</td>
<td><em>Melissa officinalis</em></td>
</tr>
<tr>
<td>Artichoke leaves</td>
<td><em>Cynara scolymus</em></td>
</tr>
<tr>
<td>Horse chestnut (seed extract)</td>
<td><em>Aesculus hippocastanum</em></td>
</tr>
<tr>
<td>Hawthorn leaf &amp; flower</td>
<td><em>Crataegus spp.</em></td>
</tr>
<tr>
<td>Sangre de Drago</td>
<td><em>Croton lecheri</em></td>
</tr>
<tr>
<td>Sea Buchthorn</td>
<td><em>Hippophae rhamnoides</em></td>
</tr>
</tbody>
</table>

Adapted from Blumenthal, 2000; Tyler, 1999

6.3  IP Commercialisation Approach

The IP development and management company will in its formative stage follow a strategy that will concentrate on re-engineering herbs that are popular in traditional Chinese medicine and Ayuverdic medicine. The strategy includes developing existing IP projects to more quickly obtain a commercial outcome and then develop IP for indigenous Australian botanicals that would have a longer lead time.

6.3.1 Examples of Areas for Initial Consideration

The following areas provide examples of opportunities for the development of an IP package around a specific herb or herb combinations. Each proposal for commercialisation will require a plan outlining the scientific approach required coupled with an analysis of the commercial feasibility. It is envisaged that these proposals be reviewed by an investment committee prior to funding.

**Chronic Renal Disease**

An active agent has been identified that is effective in the treatment of renal disease. Overseas this agent has been routinely prescribed by practitioners for renal diseases such as chronic nephritis, chronic renal dysfunction/failure, chronic pyelonephritis, and nephrotic syndrome. A review of 14 animal and 6 clinical studies indicates that this agent is beneficial in various renal diseases and intoxication states.

Other traditional plants demonstrated to be beneficial in chronic renal conditions have also been identified. Additional components will be sourced from these plants to be used in a superior renal formulation that will also provide significant anti-inflammatory and antioxidant properties.

The major expenses in the research required will be for clinical trials with smaller amounts for laboratory studies, medicine supply and intellectual property protection.

The resultant medicinal product should prove very attractive to consumers and a partnering herbal manufacturer.
Osteoarthritis
Osteoarthritis (OA) is the leading cause of musculoskeletal disease with an incidence higher than that of hypertension, cardiovascular disease and diabetes combined. ACCMER has considerable research strength in understanding and analysing the underlying disease mechanisms in OA.

Ayurvedic medicine offers Indian Ginseng (*Withania somnifera*), ginger (*Zingiber officinale*) and turmeric (*Curcuma longa*) for OA. Western herbal medicine also uses ginger, celery seed (*Apium graveolens*) and Devil’s Claw (*Harpagophytum procumbens*), There is also good evidence for the utility of glucosamine, chondroitin sulphate and avocado/soy extracts for the treatment of OA. Appropriate formulations will be developed.

Our aim with these CMs is to develop formulations that both alleviate symptoms and halt progression of the disease. In contrast, the common anti-inflammatory drugs are only symptomatic and actually accelerate the destructive process.

Oestrogenic Support Post-Menopause
While oestrogen replacement therapy has had a recent surge in popularity and, more recently still, a dramatic down-turn, medicinal herbs with traditional use from around the world have had great success in alleviating postmenopausal difficulties for thousands of years. Indeed plants possess a broad spectrum of oestrogenic components.

One key to developing an appropriate herbal product for this market is to activate the oestrogen receptor without stimulating oestrogen dependent cancers especially breast cancers. Using laboratory assays for oestrogen receptor binding and activation and by monitoring the stimulation of growth in cultured breast cancer cells, a combination of herbs will be optimised that meets these criteria. Plants from both Western and Eastern traditions will be tested.

References


Tyler, V. 1999  Read It Here First:  The Next Herbal Superstars. (medicinal herbs) *Prevention, May 51;5;105.*

7. Triple Bottom Line Analysis

7.1 Introduction
Due to the evolving direction of the industry development strategy within this study, a specific bottom line analysis is not practical. Once a commercial entity is established the selection of appropriate herbs for commercial production will be made based on intellectual property (IP) considerations, current treatment of a targeted condition, market opportunity, economic viability and medium to long term potential.

For these reasons the triple bottom line approach will be focused at a broad level. Indicative values for costs or revenues will be used as a demonstration point only.

7.2 Economic
According to the British Columbia Herb Growers Association (Nutraceuticals International, 2000) herbs in the top ten category of use should be avoided due to market price volatility. They also recommend that growers should only enter the medicinal herbal market if they are able to grow at least four but preferably six to eight different herbs.

The requirement for diversification is to offset the variability of demand and price for any specific herb. Variability may be seasonal or may be due to a variety of influencing factors such as market trends, economic performance, exchange rates or media reports.

The economic viability of medicinal herb production varies considerably according to the herb(s) concerned, locality and market status. Three Australian studies demonstrate this point (Table 4).
Table 4  Herb or Botanical Production

<table>
<thead>
<tr>
<th>Item</th>
<th>1 hectare</th>
<th>(\text{Variable according to location})</th>
<th>20,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enterprise scale Land</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Machinery Permits</td>
<td>Tractor/plough/hoe</td>
<td>(65,000^a)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Organic certification</td>
<td>(2,700^a)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sub-total</td>
<td>(87,700)</td>
<td></td>
</tr>
<tr>
<td>Location Crop</td>
<td>The Murray Mallee Culinary and medicinal herbs^a</td>
<td>Victoria Medicinal herbs^b</td>
<td>Tasmania Medicinal herbs^c</td>
</tr>
<tr>
<td>Input cost</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Establishment costs</td>
<td>Trickle irrigation</td>
<td>(5,000)</td>
<td>Initial investment</td>
</tr>
<tr>
<td></td>
<td>Glass house</td>
<td>(2,000)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Shade house</td>
<td>(1,000)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Grading table</td>
<td>(2,000)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hammer mill</td>
<td>(2,000)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drying room + plant</td>
<td>(50,000)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sub-total</td>
<td>(62,000)</td>
<td></td>
</tr>
<tr>
<td>Operational costs</td>
<td>Labour</td>
<td>(18,000^b)</td>
<td>Typical recurrent input costs</td>
</tr>
<tr>
<td></td>
<td>Plants</td>
<td>(5,000)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mulch</td>
<td>(3,400)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Water</td>
<td>(1,500)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fertiliser</td>
<td>(500)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sub-total</td>
<td>(28,400)</td>
<td></td>
</tr>
<tr>
<td>Revenue</td>
<td>Sage or Yarrow Estimated 1700kg dried herb/ha @12/kg (in third year)</td>
<td>(20,400)</td>
<td>Broad-leaf Echinacea Estimated 2000kg/ha roots@$32.50/kg 6250kg/ha Aerial parts@$8.00/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total</td>
<td>(20,400)</td>
</tr>
</tbody>
</table>

b.  Based on Hassall & associates Pty Ltd
c.  Department of Primary Industries Water and Environment Tasmania
d.  An updated (2004) financial analysis based on a medicinal herbal enterprise located in north eastern NSW indicates a modest net present value of enterprise @ 7% over 20 years of $15,119.

The purpose of the above table is to demonstrate the variable reported returns that can be projected from a production focused approach. The preferred strategy (that has been identified in this study) to be followed is to develop intellectual property (IP) in a value adding way and
then introduce the outcomes into the whole production chain system. A list of potential herbs and natural products for IP development was produced and circulated to workshop participants following appropriate confidentiality arrangements. From this list a selection will be made for project development by Herbal Co.

The strategy being employed is to invest in a number of projects and develop the IP to a commercially ready stage (Figure 6). Industry shareholders in the company (or others) will be able to secure the rights to manufacture and marketing on a competitive basis or through equity trading. The equity in the commercial products owned by the company contributes to sustainability and allows for growth.

**Figure 6** IP Value Adding Process

![IP Value Adding Process Diagram]

### 7.3 Environmental

**Primary energy**

Energy use for cultivation and other activities is assumed to follow a similar profile to other crop production applications. A typical breakdown of energy use and activity is depicted in Table 5.

Depending on the species of herb being grown, the production system being employed (conventional, minimal till, integrated or organic) the energy value will vary markedly. For example a comparison between a conventional wheat production system with that of an integrated wheat production system in the UK showed the conventional system required approximately 15,000 MJ/ha while the integrated system required approximately 12,000 MJ/ha (DEFRA, 2002)
As most herb production establishments in Australia follow an integrated system or organic criteria (the preferred industry status) energy use is thought to be at the lower consumer end when compared to conventional broad acre crops.

As the energy use is expected to be lower than conventional crop production so to is greenhouse gas emissions. Depending on the botanical species in question (herb, shrub, tree) the production may approach being greenhouse gas emission neutral.

### Water usage

Water usage will depend on the type of herb/botanical being produced. Plants with medicinal properties are sourced from all types of climatic zones. Herbs that require significant rainfall would need to be located in an appropriate region or supplemented by irrigation. As the majority of commercially produced herbs are preferred to be organic certified, any water run off is thought to be less environmentally intrusive than those production systems using fertilisers and pesticides.

Certain herbs are able to be grown using hydroponics which would provide water management and control at an absolute level. This application would depend on the type of herb, scale of production, facilities available and any restrictions placed on herb cultivation.

### Land disturbance

Land disturbance is a major influencing factor on the environment and local ecological systems. The method of cultivation can vary markedly from deep tillage to direct drilling. Many of the medicinal herbs are able to be produced without extensive tillage.

Other methods of production such as hot house production and hydroponic application also offer alternatives to land disturbance. The preference by manufacturers for organically grown medicinal herbs acts in a positive way in minimising the use of herbicides and pesticides and subsequent land contamination impact.
7.4 Social

It is not possible to identify all social change impacts and processes that may occur given the application of developing a medicinal herbal industry. This is particularly true of this study as areas involved in development of the industry vary markedly, given the national focus.

However, it is possible to categorise social change processes into a number of groupings (Vanclay, 2002) which are likely to apply across a range of situations. These groupings, identified by Vanclay will be used to guide this section’s approach.

I) Demographic processes

Many Australian rural and regional communities are struggling under continuing drought and external factors such as higher exchange rates. The number of farming families in Australia decreased by 22% between 1986 and 2001 (ABS Australian Social Trends Family and Community-Living arrangements: Farming families).

This exiting from the farming industry is having impacts in a variety of ways, namely:

Family Structure

The proportion of one-parent families is lower for farming families (3%) than that of all families (15%). Thus a relatively stable unit is being disrupted and relocated in a less stable environment. However it is noted that there may be a tendency for lone parents (predominantly women) to leave the farm. The 2001 census data showed a tendency for farming families with children to have more children (2.1) than all families with children (1.8). Given regional and remote areas where fertility is higher than total Australian fertility, it also showed that a greater proportion, 54% of farming families with children had children living at home compared to 47% for all families. So it would appear that a farming family environment is a positive environment for families with children and one to be encouraged.

Farmer Age

In 2001 there were 15% of farmers in farming families who were aged 65 years or more compared to 12% who were aged less than 35 years. The lack of subsequent generations going into farming has had the effect of shifting the median age of farmers in farming families from 47 years in 1986 to 51 in 2001.

Hours Worked

Farmers in farming families worked a median of 51 hours per week (on- and off-farm) compared to 41 hours for all self-employed people (in all jobs).

(ABS Australian Social Trends Family and Community-Living Arrangements: Farming Families).

II) Economic processes

Conversion and diversification of economic activities

A planned introduction of medicinal herb production in a region may offer new diversification options to small landholder farmers. With 71% farm businesses earning less than the average turnover per farm business (ABS Year Book Australia 2003), the industry is becoming less
attractive to the small farm farmer. One approach to overcome this situation is for small land holders to concentrate on intensive farming such as vegetables and cut flowers. This is common in inner regional areas. A second approach could be to produce crops of greater value with value-adding potential.

However if farmers are to benefit from the growth in herbal medicines they must be able to provide processors with consistent supplies of raw materials that meet the processors’ stringent quality requirements for the active ingredients.

Poverty
Impoverishment is affecting a greater number of families in regional and rural areas through a variety of reasons: drought, commodity prices, scale of operation and rising costs to name but a few. For example concerns are being expressed by Government and sugar industry members regarding small farm viability and mill viability (Fraser, A, 2002).

Globalisation
Economic globalisation is having an impact where economies are changing from being locally oriented to being globally orientated. The medicinal herbal industry with respect to Australia carving out a market presence needs to focus on the global market. A point clearly made in Workshop No.1 of this study.

Concentration of activity
The greater the concentration of economic activity at the regional level the greater the vulnerability of the local community to the fortunes of that commodity. In this regard the establishment of a medicinal herb capability (production and processing) would have positive benefits.

III) Geographical processes
Geographical processes consist of processes that affect land use patterns (and their effects) of a society which include:

Conversion and diversification of land use
The trend for broad acre and dairy farming has been to increase land holdings and scale of operation in order to be viable. By diversification into medicinal herbs, an intensive production application is followed, which utilises less area. This would provide a long term strategy for ongoing family occupancy for farming communities near large population centres. Centres where increasing land pressures gradually impact and transform regions.

Urban sprawl is having an effect on land use
With urban development also comes urban infrastructure pressure and development. This increases the number of roads in an area, population and traffic density, noise and air pollution. For example with the demise of the sugar mill at Nambour, some cane farmers are sub-dividing their land and investing the capital to generate passive income. This has brought about a major social impact for the area and for individuals. The social and business aspects of the area will change to meet differing needs. Diversification of crops would help maintain community life.
IV) Institutional and legal processes

Institutional and legal processes affect the efficiency and effectiveness of organisations (Government agencies, nonGovernmental organisations and commercial establishments) that supply goods and services on which people depend. These include:

Institutional globalisation and centralisation

Like the pharmaceutical industry, the herbal medicine sector is controlled by the Therapeutic Goods Administration (TGA), a federal Government statutory body. This central body not only regulates nationally but interacts at the international level, for example through international agreements such as the Australia – European Community Mutual Recognition Agreement (EC-MRA); Australia – European Free Trade Association Mutual Recognition Agreement (EFTA-MRA); Cooperative agreement between the USA FDA and TGA – Pharmaceutical GMP; Australia-Singapore MRA on Medicinal Products Good Manufacturing Practice (GMP) Inspection. (TGA).

Given the extent to which globalisation of markets, information exchange and interactions are occurring the potential exists for harmonisation of regulations for herbal medicine. This is made more plausible by all developed countries facing aging populations with increased pressure on health care and public benefit programs. The development and use of herbal medicines to drug equivalence, such as glucosamine as a treatment for arthritis in Sweden, as the first treatment protocol could be one way of lessening the financial burden on public programs.

One of the challenges facing the Australian medicinal herbal industry is to obtain recognition by federal research funding bodies. Currently there are very few research funds being allocated by the principal medical research funders to establish the requisite intellectual property that would attract investors and establish genuine alternatives to pharmaceutical drugs.

Public and private investment

Over recent years there has been concern expressed by both federal and state Governments regarding the commercialisation of public funded research. The establishment of the Australian Institute of Commercialisation is a result of this concern.

In line with this applied research focus, medicinal herb research would establish data that would be used to attract private investment and commercialisation of products. The financial benefits would flow concomitantly to the public coffers, through reduced burden on the pharmaceutical benefit scheme (PBS) and to the private sector in the form of profits.

Although the success rate of developing a medicinal herb through to a mainstream treatment is small, the potential returns far out way the research program costs. For example the costs to profile a particular herb and establish clinical data may require an investment of up to $1 million but the condition being targeted may have a market sector value in excess of $1 billion. The development costs of complementary medicine compare extremely favourably with those of major pharmaceutical agents that can cost up to $800M for development.
Arthritis, diabetes, and cardiovascular disease are all of epidemic proportions and potentially represent huge markets for appropriately validated complementary medicines.

V) Emancipatory and empowerment processes
Emancipatory and empowerment processes relate to those that allow decision making at the local level on issues that affect peoples’ lives.

Democratisation
By establishing and participating in a new industry at the national level, stakeholders have the opportunity to contribute to its structure, strategy and function. Although tied to a global market rather than a domestic one, novelty of products developed may allow differentiation and greater degree of influence. For example, engagement with the Australian Indigenous Community and the development of indigenous Australian plants. These plants have been under utilised in global medicinal applications and they have major potential to provide the focus for research programs that could provide significant outcomes for indigenous communities.

Marginalisation and exclusion
Australia at present is marginalised with respect to the global herbal medicine market. The only products with a recognised Australian presence are eucalyptus and tee tree oils. Australian herbal medicine manufacturers are very small when compared to the dominant international and multinational companies. These companies source much of their raw material through contractual arrangements as opposed to methods of many Australian companies.

Australia has an international reputation for being an efficient and clean primary producer with access to high quality scientific and technological support and application. However, this capability has not attracted the major herbal medicine companies to source their raw material, including extracts, from Australia. There is a major potential for development in this area.

Strategies to overcome this marginalisation need to be developed and implemented. A logical approach would be to initiate a relationship with one of the major international companies. This relationship could be based on existing popular herbs where involvement is satisfying an identified need or introducing new, perhaps Australian indigenous plant products.

Capacity building
One of the potential outcomes of developing the Australian herbal medicine industry in a structured way is capacity building in local regional communities. This could be achieved through increasing the skill base amongst local people involving the:

i) production of new crops
ii) application of technology in processing and value-adding
iii) expansion of networks
iv) increase in knowledge in and of the healthcare industry
v) provision of potential opportunities for leadership
Community capacity building would also be enhanced through increasing sustainability through improved farm succession prospects and the retention of the younger members of the community in the region.

**VI) Sociocultural processes**
Sociocultural processes affect the way people live and interact together in a society.

**Social globalisation**
The combined effects of information exchange (the internet), global travel and the level of influence of multinational companies have resulted in “a global community”. Many of the problems faced by a country are shared with many others. For example, western countries are all showing an increase in population longevity. Coupled with low birth rates, this is resulting in an ageing population. Aged care, health preservation and related public expenditure are all issues of mutual concern.

With Australia and New Zealand set to complete the harmonisation of the drug and complementary medicine sector a cross-border approach contributes to the broader views being adopted by Governments.

This is being further enhanced by Australia entering into a Free Trade Agreement with the United States of America and the subsequent influences this will have on pharmaceuticals, the PBS and healthcare in general.

**References**


http://home.vicnet.net.au/~warmplan/herbs.html
A review of the literature and discussions with industry stakeholders demonstrated that the herbal medicine industry was very under-developed in Australia and was being led by overseas countries. However, the potential for Australia to develop an industry of major significance was recognised and this was a prime motivator for initiating this study.

The potential of the industry is significant, with expectations that new drugs of plant origin will continue to be developed given the resources being allocated by pharmaceutical companies to botanical prospecting for medicinal agents and the increased popularity/attention herbal and natural medicines are receiving.

The development of products of natural origin to the level where they provide an alternative to existing drug treatments is within the scope and goals of the herbal medicine sector. The screening of Australian indigenous plants for active agents is an area that offers the Australian herbal medicine sector global market differentiation.

The feasibility study commenced with a broad supply chain approach in viewing the Australian complementary medicine industry, and in particular the herbal medicine industry. From the first industry workshop leadership and the development of intellectual property (IP) emerged as the areas of most concern.

The first workshop recognised that Australia has all components of the supply chain within the herbal medicines industry except the ‘Research and Development’ component which was identified at the top end of the chain. It was noted that this R&D component initiated the development of new herbal medicines which then moved down the chain finally reaching the consumer. It was identified that this component was responsible for the significant value addition that occurred within the chain. There was significant consensus amongst the participants that this was the missing link in Australia and what was required to kick start the development of a large-scale and viable herbal medicines industry.

Through successive workshops a corporate structure was identified that could carry the complementary medicine industry forward. This has resulted in the establishment of Healing Power (CM) Ltd.
Healing Power (CM) Ltd. through an arrangement with ACCMER will develop IP to a ‘commercially ready’ stage and then sell or license the IP rights to an industry stakeholder for commercialisation. Royalties generated, in part, will be used to fund further IP development. This will allow the Australian complementary industry to introduce innovative and indigenous products into the global market place.

Generating products based on scientific laboratory and clinical trial data will contribute to restoring credibility of complementary medicines following the collapse of Pan Pharmaceuticals and the stricter control being applied to them by the Therapeutic Goods Administration. In addition, it is anticipated that this approach will result in a new breed of registered herbal medicines that will be of equal or superior status to pharmaceutical agents.

The above outcome has shifted emphasis from the original primary sector/market approach to that of a targeted disease/health issue approach. This shift will provide a greater degree of certainty for supply chain members for a specific product. Although the number of individuals involved in the supply of raw materials may be small, the opportunity to overcome many of the issues associated with raw materials and to develop and implement standards exists.
Appendix 1

Herbal Industry Workshop No. 1 Minutes
Thursday 27 February 2003
Australian Herbal Medicines Feasibility Study
Workshop No. 1

Minutes

Minuted by Paul Curwell (B App Sc (Med & App Biotech), Dip Security (Risk Mgmt))
Kevin Cronin Room, Mater Health Services, Brisbane.

Program
1. Introduction and Objectives
2. Mapping the Herbal Medicine Chain – who are the players, what are the issues?
   Discussion
3. Session 1 – Exploration of Commercial Issues
4. Session 2 – Analysis of Collective Behaviour within a Chain
5. Session 3 – Strategies to Achieve Objectives
   Annex 1 – Group One Flow Chart
   Annex 1b – Group One Flow Chart Notes
   Annex 2 – Group Two Flow Chart
Introduction / Objectives

Time 10.11am

Opened by Dr Phillip A Cheras Ph.D.

Ray Collins and Tony Dunne from UQ School of Natural and Rural Systems will be facilitating the workshop.

Background

Dr. Phillip Cheras

The Herbal Medicine (HM) industry has experienced steady, global, growth over the last few years. HMs are experiencing increasing usage in Europe, North America, and Australia. World Health Organisation (WHO) predicts that the herbal medicine market will be worth $USD 5 trillion by the year 2050.

Issues regarding the quality of raw materials, and especially with the quality of raw materials sourced from overseas, need to be addressed by industry before a high degree of success can be realised. This issue will be assisted by the involvement of Australian Universities in Research and Development.

Australia’s HM industry generates imports worth approximately $AUD 400 million annually, with a considerable proportion of this being attributed to raw material costs. The Pharmaceutical Benefits Scheme (PBS) costs taxpayers over $AUD 4.1 billion annually, with Complementary Medicines (CM) poised to make a significant contribution to lowering this total annual subsidy of pharmaceuticals by the Government.

With the size of Australia’s population over 60 years of age increasing rapidly, the PBS bill is estimated at approximately $AUD 10 billion by the year 2020. CM has the opportunity to not only reduce PBS costs, but to make an additional contribution in terms of preventative medicine and “wellness”.

Costs of approximately $AUD 205.3 million for NSAIDs were reported in the year ending March 2002. In addition, costs of up to 40% are associated with this figure in response to the Adverse Effects (AE) resulting from adverse drug-patient interactions. During the year 2001, Australian Herbal Industry revenue was approximately $AUD 1-2 billion – only a small percentage of the $USD 100 billion global market.

The aim of this meeting is to propose a National feasibility study into the Australian Herbal Industry. UQ, in conjunction with QUT and SCU, are contributing multidisciplinary expertise to the process. In addition, support has been received from Federal and State Government agencies. Assistance from key industry players is seen as integral to program success.
The aim of the study is to launch the Australian Herbal Industry to the forefront of global practice, which is deemed worthwhile, provided industry backing is received. Today’s objectives are to gain an insight into relevant industry failures, to map the HM chain, to analyse data, identify essential issues requiring attention and most importantly to develop strategies to carry the industry forward.

Session 1: The Nature of New Industries – why do some succeed, why do some fail?

Time 10.15am

A/Prof Ray Collins (Natural & Rural Systems Mgmnt, Sch - Gatton).
Mr Tony Dunne (Natural & Rural Systems Mgmnt, Sch - Gatton).

In the area of ‘industry development’, there are many examples of companies that just failed. Rather than continue to refer to “industries”, the term “crops” will be used since it is more relevant. “New crops” refers to plants only.

Modes of Crop Development:

Most of the interest is in the Commercial Sector - R+D is hidden from view for the most part, and there are many barriers to industry success.

Using the USDA Linear Model for industry success, there are seven components to creating a successful industry:

1. Exploitation / literature review
2. Germplasm evaluation
3. Chemical / utilisation studies and analysis
4. Agronomic evaluation
5. Breeding program
6. Processing, production, and scale up
7. Commercialisation

Comment

• This model seems to bypass the concept of market research

Response

Acknowledged the model is flawed. It is driven by genetic and environmental interaction, and assumes that adaptation equals commercialisation. The model shows little or no understanding of commercialisation at all.

Questions

• Market research: is there a market?
• Does the product work? Has it been evaluated for efficacy?
• Regulatory barriers
• Internationalisation: global perspective, trade, import replacement, export etc.
• Investors and fund capital

Success and Failure studies

Successful Attributes:
• New ventures need champions to carry out major roles
• Adaptable species for the relevant environment
• Technology
• Financial management
• Strategies
• Government issues, support, regulation etc.
• Essentially, a combination of these factors is required for success.

Failure Attributes:
• Lack of information
• Fragmented, divided, industry
• Lack of market orientation
• Lack of market collectivity
• Lack of communication / interaction

Two lessons for 2003:
1. Need parallel and integrated R+D streams addressing products, technology, markets, and people. Integration is the key – some information will be of relevance to multiple areas.

2. Future industries are going to be based on competitive firms as members of competitive chains, e.g., Suppliers, producers >>>> market.

Discussion

Comment 1
• Thousands of herbs are possible candidates
• Not many herbs have a domestic market
• Need to focus on a new area, e.g., Global, or culinary herbs
• Is there a valid group of herbs (target group) to look at for this project?
• We cannot just develop a herb industry without a market

Comment 2
• Program has to have a domestic focus, in case we can’t get a global market

Response
• Need to balance research effort to ensure viability
• Need to reassure people in the chain that they will get a financial return for their efforts
• Problems are increased by the issue of growing raw materials – specifics, consistency, and reliability are all major issues to the customer

Question

• To whom is the product of value?

Comment

• 60% of herbs require additional import due to environmental conditions, access, climate etc.

Response

• A screening process examines these issues, placing the best candidate herbs at the top, and the poorer candidates at the bottom of the list

Comment 1

• Needs to be economically viable for the grower
• Most growers fail

Comment 2

• Needs a global player's interest to survive
• Need to get our act together before globalising, addressing issues such as contamination

Response

• Look at the issue from the opposite perspective – if I was a major player, why would I want to deal with someone in the Herbal Industry's current position?

Comment 1

• Supply issues, such as requirements for fresh herbs within 24 hours of picking need to be achievable to ensure the best extraction possible

Comment 2

• Do not think we can make an industry with the current crops
• Issues such as IP, competitive barriers, and import substitution make it hard to compete
• Maybe we should look at what the customer wants, and target the herbs from there?

Comment 3

• Potential is created by industry trends
• The global export market creates a strain on the supply of raw materials
• Large players can introduce contracts for growers
• Contracts with global player's channels us to what they want, which determines what we grow
• We need to convince global players that Australia has the ability to provide the service they demand

Response
• May be worthwhile examining the process from the perspective of firm up, rather than always starting with industry down
• The bottom line is profitable firms create a profitable industry
• This raises many questions, such as the issue of forward contracts.
• Basic philosophy of good industries making good firms is never seen, although plausible. Instead, good firms making good industries are abundant with examples
• Task is to look at the CM industry’s position, examining weaknesses, strengths, etc, from the firm’s position, focusing on the customer
• This is the task for the first group work session

Session 1: Mapping the Herbal Medicine Chain – who are the players? What are the issues?
Time 11:00 am

Conducted by Tony Dunne and Ray Collins

Group 1 presentation: (see Annex 1 and Annex 1b)
• Listed relevance of each entity in the chain first
• Then looked at the identity of each element
• Started with seed bank, then;
  - Farms
  - Processor
  - Possibly broker
  - Manufacturer
  - Wholesaler
  - Retail
  - Consumer

R&D elements were identified, and found to be present in each of the following stages:
Seed bank – strain, genetics etc
Farm – quality
Processing
Manufacturing – quality
Health professional – efficacy
Consumers – safety, effectiveness
Evaluation R&D: promotes confidence in the industry at all levels, as we know whether something works or not.
Group 2 presentation: (see Annex 2)

- Started with raw herb in chain diagram
- Farmer or importer
- Raw materials
- Suppliers
- Clinical trials
- Marketers
- Wholesaler
- Exporter or shop
- Consumer

Comments focused on the R+D aspect, and where it came into the chain.

Comments on both chains –

- Linear model
- Multi-layered system – networking may allow the stronger elements to bypass the weaker ones
- Can we reduce the two group's examples to a good working model?
- Development has to be market led
- To develop techniques to come up with a product we need Knowledge and Credibility, especially with consumers
- We need to ask “what does the consumer want?”
- Currently, clinical trials and production are all done overseas

Group 1: No Value Adding (VA) at the end

- Our weaknesses are all at the front, or Australian end
- We lack basic data on industry figures
- Many industry figures are speculative
- The project is focused on the weak area
- The difficulty is that we will be competing with established global competitors
- Our aim will be identical to our global partners if we correct our weaknesses

Ray Collins

- A “One size fits all approach” is not feasible
- Why? Because of quality and cost
- A trade off between both factors will determine your position in the industry

Tony Dunne

- There are three elements to the supply chain:
  1. Commercial
  2. R&D
  3. Regulatory environment, other Government etc.
     - Consumers are both strengths and weaknesses
     - Discretionary spending
• Retaining consumers
• Poor education of consumers regarding CM in Australia
• High acceptance of CM by consumers

End Session One

Session 2: Analysis of collective organisation within a Chain

Time 12.45pm

Reference: “An analysis of collective organisation within a chain” – School of Natural and Rural Systems Management CD-ROM.

To refresh, there are 3 dimensions to the supply chain:
1. Commercial
2. R&D
3. Regulatory / Government affairs

In 2003, the supply chain environment is characterised by what is occurring in it. What characterises the environment? We want to work at the level of the firm.

Answers:
• People (consumers, public) – recognising their perceptions of HM
• Consumer purchasing – changing wants and needs, purchasing trends
• Technology – is changing
• New extraction procedures
• Internet / IT revolution
• Analysis – QA / QC in the laboratory
• Clinical trials and models for indicating their efficacy

Fact: adapt or die in a changing environment.

Supply Chain Management CD-ROM:

Ray Collins

• Argument: in a changing environment, we need to cooperate to compete in a global environment

Comment 1

• Cooperation between
  - Research Scientists
  - Manufacturers – data on consumer wants and needs, what is realistically possible at each level (i.e. The farm, extract process, etc)
Comment 2

- Cooperation in
  - The Regulatory environment, such as lobbying Government
  - Consumer attitudes – culture a feeling of need (dependency?) or consumer want for the product

Response

- In the changing environment, it is simply cooperate to compete
- Shift company focus from firm versus firm to chain versus chain
- Be innovative
- The ability to integrate into the supply chain to be a competitive unit comes down to the ability to innovate
- Where is the vision?
- Where is the leadership?
- Vision and leadership drive the ability to innovate
- If you are going to cooperate, who do you choose as a partner? Ask yourself – why should someone want to cooperate with me?

“Readiness to Partner Profile” – CD ROM-based topic

1. How does your company rank?
2. Build your own profile
3. Customer loyalty – does it exist?
4. Can you, and do you, communicate with your partner?

If you are not compatible with a desired partner, but you still want to work together, how will you do this?

Tony Dunne

Transactional relationships
- Consider the structures and relationships that exist, and map them
- Successful partnerships are built on trust and commitment
- Transactional relationships are not reactive
- Companies that do not trust their partners enough cannot communicate effectively
- In a transactional relationship, the focus is on price

Ray Collins

- Why invest in consumer research once you have acknowledged its importance?
- Does it return its value back into the whole chain – particularly if you want to create an industry?

Tony Dunne

Preferred suppliers / customers
- Cooperation
• Information flow is improved
• Loyalty and reliability is expected
• Is of value to the customer
• Ability to marginally differentiate yourself from your supplier, making you more valuable to your partners

Focus shifts from competition to cooperation, resulting in:
• Increased efficiency
• Example – Woolworth’s has contracted its supply base (narrowed to better suppliers only), improved logistics and freight, and stocks a better inventory
• This has resulted in Woolworth’s becoming more competitive in terms of quality and costs
• What about its return to customers?
• Supermarkets do not even use the data they generate to check on an items sales progress
• Cooperation and trust change the focus from price and cost to revenue.
• Most industries are stuck in transactions

Examples of thriving partnerships –
Horticulture industry “Harvest” company, Queensland.
• Short supply chains
• Good relationships with growers, producers, and retailer
• Shareholders – growers own 50% of the company
• Market produce only to one retailer
• Produces seedless watermelons
• Price of seedless watermelons is higher than normal melons
• Higher profits are generated by keeping the chain secure with a close relationship between all participants
• No one sells outside the chain, making it harder for others to compete or gain entry to the market share
• Co-shareholder relationships create an interest in the area, with added bonus of loyalty
• Quality Assurance (QA) standards:
  - If crop does not meet QA standard, the entire crop is destroyed
  - No sub-quality watermelons are permitted to enter the market

Comment 1
• Has the HM industry allowed itself to become fragmented? High quality products sit beside lower quality ones on the retailers’ shelves

Comment 2
• 2 points on partnerships
  - Less money for participants than could be gained through competition
  - Create more work for all involved
Response

- In the short-term, yes, partnerships cost you more and create more work
- In the long term, partnerships result in:
  - Increased profit
  - Chain loyalty
  - A hard strategy to copy
  - Able to keep out competitors
  - Relationships will not work for everyone

The two methods, in summary are –

1. The commodity track – undifferentiated product, competing on price
2. Relationship / networking track – competing on quality, differentiated product

Discussion

Comment

- We are more of a competitive culture, which means option for number one above, but in the long term, it is not as competitive as option two

Response

- How will you (the industry) link with global suppliers if you do not opt for number two?
- These ways are more integrated – they cut out the hassle of multiple players, such as farmers
- Successful suppliers are becoming more prevalent, and they use integrated supply chains (in fresh foods)
- Mulgowi Farming company is Woolworth's supplier of the year
  - It grows corn
  - Buys other vegetables from selected producers
  - Markets to Woolworth's
  - Company ensures quality demanded by Woolworth's and consumers
  - Brokers are more like “relationship adders” – they know who to contact for what, and cultivate these relationships

Comment 1

- Believe value adding is the extraction process – to make globally competitive ingredients you need a “Pharma” approach to lead and provide strategies

Comment 2

- If you do not cultivate suppliers now, before you have done market research etc., will they be there when you want them?

Comment 3

- Chain leadership is a question
Response

- Chain leadership cannot be at the farmer level
- Brokers, such as the Mulgowi family, could take the lead
- Duboisia / Boerrhinger-Mannheim (BM) growers:
  - Retailers won’t be chain champions – they sell space
  - BM new what they needed, and innovated down the chain

Comment 1

- Are our aspirations within the vision?

Comment 2

- Perhaps raw material should be left to overseas producers

Comment 3

- Is there a need for Australian chains to integrate in Australia, or with material currently sourced from overseas?
- Australian farming has the highest efficiency, quality, and lowest human input in the world

Comment 4

- Why then can't this be done at a producer and higher levels?
- We should aim to become either the middle or top men in the chain

Response

- No matter how smart we are, you need a back end to the supply chain
- If this is overseas, how will you cope with issues such as disasters, floods, pollution etc?
- The six principles of supply chain management apply to both situations

Comment 1

- What about sourcing competitive, high quality produce from Australia?

Comment 2

- Most IP and clinical trial production currently occurs overseas
- It is where a high percentage of capital goes
- What about doing this in Australia, rather than just the USA?
- Capture the source!

Comment 3

- This still supports the industry down approach. I don't believe we should be hostage to overseas suppliers
Comment 4

- The opportunity is present to grow in Australia and profit from it
- Development of new varieties often requires good clean ground with no other similar plants growing nearby
- Australia represents likely virgin territory, and may be suitable for primary producers in this role?

Response

- These are all production-based issues

Comment 5

- Trying to show Australia has the ability to conduct top end trials
- This means everything needs to be produced domestically to ensure QA/QC
- Then export
- This is a long term investment – e.g. 10 years

Response

- IP – don’t just release to public (old way), irrespective of whether publicly funded or not
- New way with IP – chain based strategy
- Don’t release publicly
- Put the IP into the competitive chain for full value
- 10 years – need product, market, and develop in parallel with supply chain
- Otherwise, when you are ready for the market, the supply chain will not have been constructed properly
- Now – need to put players together in low risk situations before 10 years time

Comment 1

- Previous CRC application four years ago looked at something similar
- Used people from different supply chains and backgrounds
- It didn’t work

Comment 2

- Question to Growers – how do you see your situation as a supplier?

Growers

- Primary producers in Australia are used as a top up, lack long-term contracts
- Only working closely with one company
- Getting growers isn’t easy
- Need infrastructure
- One previous group of growers went into financial administration
- Forming relationships with broker – broker was told not to go ahead by his organisation, due to concerns: no partnership with the company

Comment 1
• Big hassle is the farm
• Would prefer to form a partnership with growers, and be assured of quality

Comment 2
• Price is frustrating
• Agreements for herbs at certain type and time regularly changed
• Leads to financial losses due to market shifts, decreased quality etc.
• No bond with company, due to companies spot buying
• Farmers do not trust the company

Comment 3
• Formed strong partnerships over last 12-15 years
• Preferred suppliers and sources for products
• Many still going strong

Response
• Evidence in room both for, and against, the idea of partnerships
• Times are changing in favour of the necessity for partnerships

Supply Chain Management Strategies – 6 key principles
1. focus on customers and consumers
2. creating and sharing value
3. getting the product right
4. ensure effective logistics and distribution
5. having information and communications strategies within the chain
6. building effective relationships

You only have SCM when you have 6/6 – lose one, lose SCM.

Introduction to the six principles
1. Customers and consumer relationships exist for both suppliers and retailers. Know what the customer wants from your product.
2. Share of SCM profits must be proportionate to the amount of their input into the chain. Find someone to take the place of a greedy member in the chain. You will usually find someone to do this.
3. Make sure each supply chain member knows what each customer wants.

Comment
Regulatory environments
• Need high quality
• Results in higher costs
• Some companies / people are going overseas to absorb this
• Regulatory approval is required for domestic, but not for International approval (e.g. FDA approval not required)
• Cost is an issue – answer is to increase revenue by selling more!
• Need to elbow way into the market – sell competitive products that the other companies don’t create

Response
• Western countries are more concerned about product safety
• GMP is important
• What benefits are there in altering the way you share returns down the chain?

Tony Dunne

QA premium is not returned to the chain in current agricultural products

4. Logistics and distribution affect quality in both directions, affecting costs and competitiveness.
5. Reliable data is required, as is effective communications. Withholding information along the chain invites others to do the same to you.
6. Relationships are the most critical element in effective supply chains. People are critical in SCM.

Discussion

Comment 1
• Issues about providing too much information too early have arisen previously – promoting confusion

Comment 2
• Issues centred around difficulties of building a good product line in a supermarket setting – the supermarket just wants sales data, whilst you want to establish your product line!
• Critical logistical issues are associated with upstream supply chain partners

Issues of trust – will the supplier make regular orders, and vice versa.

Summary

Message
• It is possible to hand-build a supply chain using a rational process, and abiding to the six principles
• The challenge is the innovation within the firm, or within the supply chain where you are vertically integrated
• The driver is competitive firms in competitive supply chains

End Session Two
Session 3: Strategies to achieve our Objectives

Time 3.10pm

“Guidance to potentially develop this vision”
- Identify important factors
- Possible next step: hold a large focus group, based on issues discovered today

Comment
- Title of study?
- Primary industry
- Needs final sales outcome
- Number of options exist – but the final one needs to be viable

History
Bruce and Phil opened initial discussions regarding a cross-discipline approach to developing the herbal medicine industry. Potential opportunity for rural communities was being explored. A proposal was presented at a meeting with Bruce, Phil and Stephen to explore the possibility of an application with the sugar industry sector. This evolved to a national approach with an international focus.

Comment 1
Marketing:
- No herb supply problems in Australia – not a big issue
- Doesn’t believe production is necessary focus
- SCM issue is good concept to apply across HM industry
- Start at either manufacturer or IP level
- Invite all to participate
- Excellent outcome for today
- Prefer to shift focus from just growing herbs
- Start by looking at IP aspects
- Driven by marketing that consumers will buy
- IP and market driven

Comment 2
- Agrees
- Wants to see SCM encouraged, especially from growers’ perspective

Comment 3
- Wants to get into more partnerships as preferential to going it alone

Comment 4
- What is going to push the industry?
- Just IP or just primary?
- Feel both are needed in tandem
Comment 5

- Main concerns relate to the education of consumers, retailers, and suppliers
- Need to stabilise the industry
- Important to impress the need for QA
- Keen to explore indigenous herbs

Comment 6

- Believe R&D, leading to IP, is where it all starts
- Starting point could be Bioprospecting or the use of existing IP
- Then look at sowing and growing in Australia
- Can't just ignore IP in the industry

Comment 7

- Concerned about creating an elitist group of companies solely because of their IP rights
- Who will pay to help create the industry?

Comment 8

- Government funding is a possibility

Comment 9

- My fantasy – ACCMER creates groups of people keen to support HM
- Evidence based medicine, through research, is used to support HM
- Industry is driven by regulated supply, through tightly controlled specifications
- Possibly a mini-CRC type activity
- Mix industry, Government, and research bodies together
- Possibly private and Government funding
- Pooled research
- Each member of the project takes a stance on whether they will buy into the process or not
- IP is generated, along with standardisation, and evidence of efficacy
- Australian driven assault on global CM industry, supported by data to back up our claims
- This may be a five or ten year plan
- Willingness to share with competitors?

Comment 10

- Example – toolmakers pooled to fill mass orders worldwide
- Possible to strategically capture the IP worldwide
- Don’t want IP stolen

Comment 11

- VCs, business angels, incubators, etc will support it if the business plan makes sense
- Example of salty plum bush – we did not create native Vitamin C tablets, because we
thought it was too much effort for $1 per tablet. Now the Americans have done it, and worse, done it in Australia (NT) – the only place it grows.

Comment 12
- Primary producers – concerned Australia will turn her back on Australian premium quality products and be left to source from markets such as China which are now excluded from the Californian market due to heavy metal contamination.

Comment 13
- Some herbs can be grown in Australia, others cannot.

Comment 14
- Standards in China will rise.

Comment 15
- Concerned about cutting out the Australian primary producer.

Comment 16
- Need to be able to give primary producers an order that will be in place for 5 – 10 years.
- Need a plan.

Comment 17
- Coordinate with farmers to fix up cohesion that is missing.
- A broker might be appropriate for this task.

Comment 18
- Something is missing from the picture.
- Example of tea tree – too many uncoordinated growers, flooded markets and the price dropped.

Comment 19
- What about creating a service company to coordinate this?

Comment 20
- Need to organise the industry around IP – entrepreneurs and single companies do this well.

Comment 21
- Potential products with IP possibilities do exist in Australia.
- A short R&D period is required.
- Companies need an investment portfolio.

Comment 22
- Need someone like a Venture Capitalist.
Comment 23
- If current companies (e.g. Blackmores) support the offer, there would be increased support for VCs etc willing to take part

Comment 24
- Allows diversification of risk
- Time to revisit the previous plans

Comment 25
- Visited parliament last week – 18 backbenchers all positive about the CM/HM industry

Comment 26
- Need to capitalise on the current funding trends for knowledge creating industries

Comment 27
- Discovery ARC grant applications are out – Nutraceuticals and alternative medicines are a top research priority

Comment 28
- These research priorities are still being pressed

Comment 29
- Blackmores has pushed for 2 or 3 years for an industry marketing and promoting campaign for alternative medicines
- We need an organised, concerted push at all levels – the following three points will be pushed:
  i. Natural therapies benefit all – they are cheaper, and allow us to live longer and in better health whilst costing less to the economy.
  ii. We need to understand CM properly – CM should be a first choice for physicians where appropriate, once we know CM is safe and effective. A physician might be proven negligent if they prescribed a pharmaceutical that is more dangerous, for a result that could be achieved with a less harmful HM.
  iii. CM is the right of all Australians – as such, it deserves a fair share of tax support.

Question
- What about getting money out of the USA Government?
- How much does the USA support CM research?

Response
- NIH puts $USD 4 million into CM research
Comment 1

- One Australian company is a collaborator and co-recipient of two major NIH grant projects, one with The University of Wisconsin and the other with The University of Oregon
- Jefferson University is also involved in the CM scene
- The problem is that you need a USA based collaborator to receive a USA grant
- The good thing is that there are not that many people in the industry at this time

Comment 2

- Who would be willing to participate in further discussions or workshops?

All participants indicated their willingness to participate in further forums.

Comment 3

- Should anyone else be here?
- Maybe liaise with State Government, Queensland Department of Primary Industries, AusIndustry, IP Australia, Queensland Investment Commission etc?

Other suggestions from the floor

- Brokers
- Venture capitalists
- Federal Government

Summary

1. New industries require a sales outcome
2. There are other options than just in primary industry
3. Marketing / PR issues are first priority
4. Adopt a chain orientation, for security and long-term competitiveness
5. Examine IP and IP management
6. Build partnerships
7. What drives the chain? Is there a chain champion?
8. Education, starting at the consumers
9. Explore indigenous herb possibilities
10. Explore how to disseminate IP to “industry”
11. Fund development / capital
12. Mini CRC – manufacturing, processing, R&D focus. Develop IP around evidence based medicine. Maybe an equivalent service company would be more appropriate / effective?
13. A role exists for smart brokers

14. Portfolio’s versus industry products – would a cooperative be the best management model

End Workshop One
Time 3.50pm

Annex 1 – Group One Flow Chart

Notes:
1. Regulatory/Govt. assistance is seen as being applicable to all fields in the flow chart.
2. Evaluation R&D, in particular, is seen as a key target for Govt support.
4. Both evidence, and confidence, are seen as extremely valuable (3/3)
Annex 1b – Group One Flow Chart Notes

Key players
- Grower
- Marketer
- Manufacturer
- Processor
- Broker
- Retailer
- Wholesaler
- Consumer
- Health professional
- Regulator
- Infrastructure
- Media / communications

Aspects of Scientific R+D:
- Raw materials
- Efficacy
- Agronomics
- Processing

Aspects of Marketing:
- Market Research
- Promotion
Annex 2 – Group Two Flow Chart

Marketing Issues:
- Cost
- Quality
- Clinical Trials
Appendix 2.

Goals of Herbal Medicine Corporation
Goals of Herbal Medicine Corporation

The goals of establishing a herbal medicine corporation are several and varied, namely to:

a) Provide leadership to the herbal medicine industry with regard to standards, best practice
b) Develop and implement a code by which the herbal medicine industry can progress
c) Provide a seamless transition from intellectual property to commercial product
d) Provide authenticity of claim through analysis and certification
e) Create a lead organisation that can negotiate at a commercial level with multinational companies
f) Establish a single “brand” in the international market
g) Provide research leadership which will establish the Australian industry in its own right
h) Provide a mechanism and structure for competitive links/businesses to become a part of a competitive chain that will provide greater certainty
i) Develop the herbal medicine industry at the national level
j) Raise the status of herbal medicine to an acceptable level for validated products to be included on the pharmaceutical benefits scheme
k) Unite the herbal medicine industry, through membership, and generate a sense of industry “being”
l) Interact with Government to increase recognition of the herbal medicine industry and increased support through research grants and programs
m) Provide co-ordination and linkages for identified potential opportunities to be developed

Partners and Relationships

The herbal medicine corporation will need to include and/or involve a number of organisations to achieve its goals. Consideration needs to be given as to who these organisations are and what level of involvement is required.

Organisations that need to be considered include but not restricted to:

- The Therapeutics Goods Administration
- The Complementary HealthCare Council
- Australian Institute of Commercialisation
- Universities
- State and Federal Governments
- Commercial companies
- Healthcare industry associations
- NHMRC

Also how links and relationships are established. Who decides?
Appendix 3.

Herbal Industry Workshop No. 2 Minutes
Thursday 19 June 2003
Australian Herbal Medicines Feasibility Study  
Workshop No. 2

Minuted by Marie Seeman BA Arts (Hons)  
Australian Herbal Medicines and Ancillary Industries

Thursday, 19 June 2003

ACCMER – Mater Health Services, Brisbane

AGENDA

09:30 – 10:00  Coffee for 10:00am start
10:00 – 10:25  Session #1 Introduction and Review Workshop #1 (Phillip Cheras)
10:25 – 10:55  Session #2 Discussion – Post PAN implications for CM (Stephen Myers)
10:55 – 11:10  Morning tea
11:10 – 11:30  Session #3 Presentation of Corporate Entity development options and strategies (Bruce Rich)
11.30 – 12.00  Session #4 Corporate Structure for Commercial success (Ross Blanch)
12:00 – 12:30  Structure for Investment (Tracey Howley)
12.30 – 12.40  AIC Case study (Tracey Howley)
12:40 – 13:15  Lunch
13:15 – 14:15  Session #5 Group and general discussion to reach consensus on the optimum corporate structure and strategy (Facilitator Wayne Delaforce)
14:15 – 14:20  Infrastructure and financial support for the industry body - Introduction (Bruce Rich)
14:20 – 14:50  Session #6 Venture capital investment – (Janette Stephen)
14:50 – 15:20  Session #7 Support options  
RIRDC programs (Tony Byrne)  
State Government programs – Gold Coast consortium (Alastair Kane)
15:20 – 15:35  Afternoon tea
15:35 – 16:25  Session #8 Summation and ratification of the Corporate Entity and Development Strategy – (Stephen Myers)
16:25 – 16:30  Conclusion and close – (Stephen Myers)
Introduction

Development potential for the Australian Herbal Medicines and Ancillary Industries exists and is generally acknowledged by industry associates. However, recognition of how this may be achieved requires clarification.

An initial review of the herbal industry in Australia revealed an industry that was fragmented, basically small scale, minimally oriented towards exports and deficient in strategies to achieve future development. The review also identified a key subgroup of companies that were successful – in both production and processing, progressive and niche market aligned.

During the review and at the industry workshop held on the 27 February 2003, sentiment was expressed that supported the concept of developing an industry strategy and a structure to achieve strategy objectives. In order for such a strategy to be developed and a structure identified that is acceptable to industry members, a consultation process is being followed.

The following minutes are part of the consultation process for developing this strategy.
INTRODUCTION AND REVIEW WORKSHOP #1

by Dr Phillip Cheras

The Australian Medicinal Herbs and Ancillary Industries

Workshop #2: 19 June 2003

A collaborative project between
The Australian Centre for Complementary Medicine Education and Research (ACCMER)

A joint venture between
The University of Queensland and Southern Cross University

and the
Centre for Social Change Research
Queensland University of Technology

Workshop #1 (27 Feb 2003): Overview

Current total Australian CM industry (herbal + others) approx $AU 1 - 2 billion in a global herbal market valued at $AU 100 billion in 2001
Workshop #1 (27 Feb 2003): Overview

- WHO forecast - global market for herbal products will be $US 5 trillion by year 2050

(HocSearch 2002)

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Workshop #1 (27 Feb 2003): Overview

Pharmaceutical Benefits Scheme (PBS) for 2001 - 2002 was $4.108 billion = 12.9% increase over previous year

(Dept. Health & Ageing, 2002)
Workshop #1 (27 Feb 2003): Overview

In year ending March 2002, anti-inflammatory and anti-rheumatic products alone were subsidised by the Federal Government to the value of $205.3 million – add 40% for AEIs

Workshop #1 (27 Feb 2003): Overview

On current trends expect PBS increase to approx $10 billion by 2020 - unsustainable

CMs (herbal) could make a significant contribution to reducing PBS blow out – contribute to “wellness” with safe, effective CMs

(ABS category no – 3222.0)
Workshop #1 (27 Feb 2003): Overview

In EU countries such as Germany, CM is primary mode of healthcare.

Increased acceptance of CM in developed countries has led to increased demand for quality raw materials and particularly value-added products.

Reviewed Industry Models

Key to success identified as competitive value chains with INTEGRATED R&D STREAMS addressing products, technology, markets and people.
Workshop #1 (27 Feb 2003): Overview

Value Chains:  loyalty / relationship chains linking producers to consumers
Share information systems
Share logical functions and product development
Superior value for customers
Improved competitiveness and resilience

Workshop #1 (27 Feb 2003): Overview
Considered Existing Australian Industry Inter-relationships
The Australian Herbal Medicines Industry Feasibility Study

Workshop #1 (27 Feb 2003): Overview

Considered Existing Australian Industry Inter-relationships

Value Chains – Australian components

(reneed to think globally)

Raw materials ✓
Farmers / suppliers ✓
Processors / manufacturers ✓
Wholesalers / retailers ✓
Consumers ✓

Value adding / R&D / IP enhanced products X
(value adding / R&D / IP performed outside Australia)
Workshop #1 (27 Feb 2003): Overview

Value Chains – other requirements / issues

Brokers (national & international levels)
QA – research into standards needed
Branding issues

Workshop #1 (27 Feb 2003): Overview

Identified Need

A Corporate Entity – functions would include
• R&D / IP development (all levels)
• National focus – champion role
  • facilitate IP through to commercialisation at international level
• Broker role (national & international)
• Upholding a “standard of excellence” ? branding
DISCUSSION

Comments made regarding the Australian Industry are listed below:

- Australians are ‘Little Players’ in a global scene
- There exists huge potential to develop ‘right’ products
- Pharmaceutical benefits scheme = $4.1 billion
- Subsidies by Government for a range of pharmaceutical agents e.g. anti-inflammatory products which are known to have adverse side effects (e.g. gastric ulcers, deaths associated with products)
- Unsustainable PBS blowout, predicted to be $10 billion by 2020 based on current trends
- Safe, effective CMs – major advantage over synthetics
- Increasing acceptance of CM in Europe e.g. Germany
- There is a need for integrated R&D streams (products, technology, markets and people)
- Loyalty/relationship chains linking producers to chains can provide advantage
- Value adding, R&D, IP enhanced products – mostly conducted outside Australia
- Identified need – Corporate entity
POST PAN IMPLICATIONS FOR CM IN AUSTRALIA

by Prof Stephen P Myers

The issue is about Good Manufacturing Practice (GMP) – the recall was based on an OTC pharmaceutical agent and was a manufacturing issue. The issue of safety and efficacy of complementary medicines (CMs) was then inappropriately brought into question by the media.

The GMP problem would not normally be caught by general audits. There needed to be an additional trigger such as an adverse event to flag that something is amiss. It is extremely difficult under normal circumstances to detect inappropriate processes when they are being deliberately concealed. The regulatory body needs a trigger to initiate action. This particular event has resulted in:

- approximately 1600 medicines that have been withdrawn from the market
- decreasing consumer confidence in CM
- a variety of people making outrageous comments about CM
- a greater public awareness of issues including ethics and quality of ALL medicines.

However, the focus directed on the CM sector by the mainstream media is viewed as an opportunity to aid in carrying the industry forward.

This highlights the need for the CM sector to have its own specific regulatory mechanisms. The Federal Government has convened an expert committee to review the CM sector and to recommend how the CM sector should operate – covering quality, regulations, advertising.

The CM review committee report is due by 15 August 2003.

The expert committee has met twice and is due to meet six times over the three month period.

The relevance of the PAN issue on our agenda is to contribute to developing processes that are needed to underpin the herbal and CM industry in the supply and development of quality products in Australia and for the export market.

Comment: There is a clear message that there is a potential for stricter standards – this may result in having to register CM – there is a real concern that the pharmaceutical model will be slavishly followed. There was general consensus that the CM area needs a different model to that used for evaluation and regulation of pharmaceutical agents.

It is acknowledged there is a need for the background of CM traditional use and historical data to be recognized by Government and regulatory bodies.

The message that should be conveyed is that you cannot take a round peg, that is CM – and force it into the pharmaceutical square hole. Different tests are required. There are different histories of CM and pharmaceutical medicines (e.g. St Johns Wort may become labeled using standard tests for one purpose however it has multiple uses).
A fascinating study by John Farnsworth on 165 pharmaceutical products derived from plants showed they had the same use as a pharmaceutical as they did as a traditional medicine.

Comment 1
There is an assumption that the pharmaceutical model is the only valid model for CM medicines. However, CM medicines are very complex with multiple activities – not just single activity. There are different assessments – need to come to grips and make Government aware of the complexity and the milder side-effects of CM. CM is different in philosophy and outlook.

Comment 2
There is a current shift in consciousness which is fairly destructive to CM, however it will benefit eventually – higher respect, increasing awareness, proper processing (not like Pan), issues clarified by Doctors and Pharmacists – this should result in increasing confidence.

The “witchcraft” label continues. Research needs to be increased in the HM sector.

1. Need to jump forward – rebound from Pan or be crushed.
2. Industry R&D appropriate manner – avoid tyranny of pharmaceutical model – complex compounds could waste enormous amounts of money going towards the pharmaceutical model. Enhance good manufacturing, monitoring, complaints process, and champion herbs as the third tier, e.g. food regulated. CM needs own regulation.

DISCUSSION

Comment 1
- CHC is on “the radar” and recognized as vehicle for CM with significant interest by parliament. There is good support at the backbench level from both sides of politics. CHC is building associations and access.

Comment 2
- Politicians say nearly all publicity is good publicity. The spotlight is on the CM sector and this provides us with an opportunity to move the sector forward.

Comment 3
- There have been dangerous statements made by well known identities, which is damaging future prospects of the industry. Need to contact lobby group to find out process of making issues known.

Comment 4
- We need products that work and do what they are supposed to do.

Comment 5
- There are rumours about Pan and products that differ – no one lodged a complaint and the TGA audited Pan on an 18 months basis and did not pick up anything – therefore the audit system needs improving.
Comment 6

- Spotlight is on CM industry and therefore the Industry needs to pick itself up and put themselves at the cutting edge of R&D – this is the attitude – take the lessons and get on with it. Need to stimulate industry – be careful about the manufacturing process and look at the positives.

Comment 7

- Need to generate some positive response from media. The HM industry needs to learn from the recent ethanol experience e.g. ethanol demise through mainstream media. Consumer confidence changed and market died. Assist industry to improve and pick some winners and put in media – do not underestimate public perception – don’t be naive that Government doesn’t respond to media cases. Use a lobbying campaign.

Comment 8

- NATA may have a role in raising standards of laboratories used by the HM industry.

Comment 9

- Current labs within the CM Industry are not being accredited by NATA. There is different testing between companies – proprietary knowledge, Therapeutic Goods Administration Laboratory (TGAL) is not at the point of providing guidelines for organizations.

Comment 10

- Pan has caused a seismic change with the industry and put CM under the spotlight, something that CM hasn’t been able to achieve in the past. We can use this focus on CM to assist future development efforts.
11.10 – 11.30 SESSION 3:

PRESENTATION OF CORPORATE DEVELOPMENT OPTIONS AND STRATEGIES

by Dr Bruce Rich

HERBAL MEDICINE

CORPORATE STRUCTURE OPTIONS

Workshop # 2
June 19 2003

Goals of Herbal Medicine Corporation

The goals of establishing a herbal medicine corporation are several and varied, namely:

a) Provide leadership to the herbal medicine industry with regard to standards, best practice ...
b) Develop and implement a code by which the herbal medicine industry can progress.
c) Provide a seamless transition from intellectual property to commercial product.
d) Provide authenticity of claim through analysis and certification.
e) Create a lead organisation that can negotiate at a commercial level with multinational companies.
f) Establish a single “brand” in the International market.
g) Provide research leadership which will establish the Australian industry in its own right.
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i) Develop the herbal medicine industry at the national level.
b) Raise the status of herbal medicine to an acceptable level for validated products to be included on the pharmaceutical benefits scheme.

c) Unify the herbal medicine industry, through membership, and generate a sense of industry “being”.

d) Interact with government to increase recognition of the herbal medicine industry and increased support through research grants and programs.

e) Provide co-ordination and linkages for identified potential opportunities to be developed.

Partners and Relationships

The herbal medicine corporation will need to include and/or involve a number of organisations to achieve its goals. Consideration needs to be given as to who these organisations are and what level of involvement is required.

Organisations that need to be considered include but not restricted to:

The Therapeutics Goods Administration
The Complementary Healthcare Council
Australian Institute of Commercialisation
Universities
State and Federal governments
Commercial companies
Healthcare Industry associations

Also how links and relationships are established. Who decides?
The Australian Herbal Medicines Industry Feasibility Study

Mechanistic model

Functionalist operational structure
DISCUSSION

Bruce Rich: From the first workshop three broad categories of issues were identified: Risk management, supply chain and corporate entity. The first two can be overcome in part by addressing the third category, corporate entity. Before a structure can be determined we need to focus on what are the goals and objectives? The champion role – provide leadership.

The corporate entity is a lead player that will assist classification – endorsement – recognition. It will assist in a seamless transition from raw material to retail product – brokerage role (goals and objectives). A single brand – QA product in an integrated market. “Brand recognition” would help industry and individuals within Australia. A single brand managed through shareholders or a company – produced to a certain standard and code giving customer reliability. The code needs to apply beyond raw materials it needs to ensure that products are obtaining a set standard – at the moment – marginal products are confusing the market.

Comment 1
- CHC has developed a code for industry. Don’t reinvent the wheel.

Comment 2
- What we missed – IP (e.g. Ginkgo) people could buy into. The development of IP to a validated product at the international level are the things we could do.

Comment 3
- HM efforts need to encourage the medical industry in Australia to broaden their attitude.
- It was clarified that the ‘single brand’ of the corporate entity would compete in the market place. However, this competition would be based on IP that has been developed or a code and certification that have been adopted.

Comment 4
- Problem of competing products. Sophisticated product market, single brand could exert some control e.g. growers can market raw material anywhere in the world. Identifies as Australian – logo.

Response
- A brand or logo that ensures a guaranteed level and quality of material, endorsed line, auditable trail of what you are buying is what you are getting

Comment 1
- R&D – how it may occur. e.g. shares recognizable components of products

Comment 2
- An example of an industry logo-citrus processing – logo has to go on label and is promoted separately in advertising.
The Australian Herbal Medicines Industry Feasibility Study

Comment 3
- Difficult to see company in industry providing industry-wide leadership when it is driven by its own commercial interests.

Response
- The corporate entity would raise image of herbal medicines – help to ensure credibility.

Comment
- Think laterally and get support for use of HM without being boxed in pharmaceuticals subsidy. Increase responsibility of people looking after their own health.

Response
- Partners and relationships need to be developed. In regard to commercialising of IP a number of models need to be considered – hybrid, mechanistic or organic model.

Comment 1
- There is a place for an institution to maintain code and develop code apart from raw material and labeling. Struggling for anyone to pay you to do it. Education, training on code for organization is one whole facility needed in Australia. Need to resolve this before going on.

Comment 2
- Code of practice ACCC launched September – the idea is to have agreement with 80% to sign on to Code of practice and planning to target USA. All work together for compliance. Eventually get whole industry working under code of practice.

Comment 3
- Need funding – part Government and other funding. For example Horticulture sector with opportunity for industry partners to come in and leave. Lots of other models to look at. e.g. Food industry anti-oxidant fits into industry band.

Comment 4
- Need someone to kick-start it.

Response
- Commercial entity with commercial ready IP could be the initiator.

Comment 1
- Lots of little companies around Australia could come into this. They are stuck at different stages of IP or non IP and need someone to bring it together.

Comment 2
- 3 or 4 corporate objectives to fulfill. Provide vehicle for IP – Magnet for people through
which IP and R&D products can be produced – not been done previously – cohesive coordinated process is required.

Comment 3

- Funding issue – entity requires funding, e.g., horticulture industry, obtains a levy from growers and Government funding. This is now set up as an industry company. Prior to that it was a statutory body – this is very difficult to do – has to go through parliament. A road that will lead to a dead end.

11.30 – 12.00 SESSION 4:

CORPORATE STRUCTURE FOR COMMERCIAL SUCCESS

by Ross Blanch and Tracey Howley

Processing
1. Processing - Coordination
2. Doesn’t need infrastructure - Joint Venture
3. Bring experience together - Develop own IP
4. Ownership of IP - Income Stream

Government Funding
- Not for Profit
- Risk Management
- AIC Model

COMMERCIAL SUCCESS RELIES ON A NUMBER OF POINTS:

- Identify mission or goals of business
- Leadership and commercial success
- Legislative issues – tax, R&D, concessions
- Stakeholders – who are they?
- Present situation
- Where is IP delivery – raw material or commercialisation of product or new products brought to market

Comment 1

- Existing products R&D: There is a need to do checks on existing products in the market. No one is doing this at present.

Comment 2

- An Australian plant based product has been developed and commercialised with international patents for processing.
Comment 3
  • Majority of companies don’t have cash to do the required R&D.

TRACEY HOWLEY / ROSS BLANCH: POINTS FOR CONSIDERATION:

• Make or buy decisions – coordination and centrality of information
• Who are the parties?
• Negotiate where IP rests

Comment: The HM industry is interested in the input and output.

CORPORATE STRUCTURE FOR COMMERCIAL SUCCESS

General discussion:

Comment 1
  • Simplest IP arrangement – lodge IP shared with project owner who can determine how it is used.

Comment 2
  • Depends on Business Plan. Commercial model and goals (e.g. pursuing for the good of industry).

Comment 3
  • The model needs to attain self funding and advance development of IP through to commercialisation.

Comment 4
  • Industry is too small to do solely, need Government to kick-start funding.

CORPORATE STRUCTURE FOR COMMERCIAL SUCCESS

The AIC Structure and how it came into being:

The Australian Institute of Commercialisation (AIC) came into being with substantial backing from the Queensland Government. During the formative stage effort was focused on the IP sector and strategic partner identification. AIC is a not for profit organization. It is basically set up to ensure a higher degree of R&D obtain a commercial outcome. The AIC is controlled by a board of directors with a high profile chairperson with access to decision makers in Government and private sector.
Comment

- The HM industry could develop a model where R&D is through university, Government and commercial arms that provide funding arrangements.
- AIC – Australian Institute for Commercialisation – Government department – biggest problem. Focus – Be commercial, IP, Government funding, external grants. Got to get structure right or funding bodies walk away. Need to attract companies.

Response

- Investors – Industry specific investors. Focus on investor and what they can bring to the table and their alliances “smart money”.
- What is the latest fad? Australia is very unsophisticated in strategic investment. Another model e.g. Tritan foundation corporate structure – need company and plan of what to achieve. 1 in 80 to 1 in 100 get invested. AIC trying to increase from 1 in 80.

11.30 – 12.00 SESSION 4:

CORPORATE STRUCTURE FOR INVESTMENT

By Ross Blanch and Tracey Howley
The Australian Herbal Medicines Industry Feasibility Study

The Game – unfair advanced investors

- VC's achieve their return as a capital gain
- Their exit mechanism is generally by IPO or an acquisition by a larger corporation
- Typically invest in companies with a value of up to $10m
- Can usually only manage 6 investments - resource strapped
- 1 in 60 are invested in with smaller funds and 1 in 80 plus is invested in by the larger funds

Considerations

Before entering into a new business structure, consideration should be given to:
- Ease and expense of setting up
- Stability and permanency
- Ownership of assets
- Legal actions
- Transferability of the business
- Limitation of liability (security)
- Ability to raise funds
- Management and control
- Taxation
- Freedom from external regulations
Introduction

- What types are there?
- Advantages and Disadvantages
- An investors view
- Other Options
- What the structure looks like

What types are there?

<table>
<thead>
<tr>
<th>No Separate entity</th>
<th>Separate Entity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sole Trade</td>
<td>Partnership</td>
</tr>
<tr>
<td>Trading Trust</td>
<td>Limited Company</td>
</tr>
</tbody>
</table>
Types of Structures

- **Sole Trader**
  - Suitable for a small business and not for an enterprise that intends to grow rapidly

- **Partnership**
  - Relationship between or more persons carrying on a business with a common view of making a profit, major drawback to investors is the joint and several unlimited liability of all partners for firm’s debts and obligations.
  - An investor who invests under the auspices of the partnership has an individual liability for the debts of the partnership and the actions of the other partners, and can be personally sued for the liability of the partnership.

Types of Structures Cont.

- **Proprietary Limited Company**
  - A more complex form of structure,
  - Requires setting up under the Corporations Act
  - Company Directors have legal obligations,
  - A business with this structure:
    - Is considered as a separate entity from the business person running it
    - Has different profit distribution, taxation and legal responsibilities than a sole trader or partnership
Types of Structures Cont.

- Trust

There is an obligation imposed on a person to hold property or income for the benefit of others (beneficiaries). Income generated by the trust for the beneficiaries is taxable. If the beneficiary is a person, individual tax rates apply.

Advantages and Disadvantages

<table>
<thead>
<tr>
<th>Structure Type</th>
<th>Advantages to Investors</th>
<th>Disadvantages to Investors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partnership</td>
<td>Able to claim any losses made by the investment as a tax deduction by treating the loss as an expense against other forms of income</td>
<td>Limit the potential for a capital gain because of the small market for selling a share of a partnership.</td>
</tr>
<tr>
<td></td>
<td>“the objective of venture capitalists is to accumulate wealth by capital gain”</td>
<td>Severely restricts the potential capital gain. It is also an unsound structure because investors will often invest on the basis of an expected income tax deductions during the start-up period.</td>
</tr>
</tbody>
</table>
## Advantages and Disadvantages

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</tr>
</thead>
<tbody>
<tr>
<td><strong>Trading Trust:</strong>&lt;br&gt;&quot;If the goal of the venture capitalist is to publicly list then this is the wrong structure.&quot;</td>
<td><em>Were attractive due to taxation structures in the mid-80s - the trust paid no income tax provided all the income passed to beneficiaries.</em>&lt;br&gt;<em>Trustee company could operate on a normal profit basis.</em></td>
<td><em>New taxed therefore removing their prime reason for existence.</em>&lt;br&gt;<em>Directors are jointly and severally liable for claims made by creditors if there are insufficient assets (unless contracts exclude liability).</em></td>
</tr>
</tbody>
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## Advantages and Disadvantages

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<th>Structure Type</th>
<th>Advantages to Investors</th>
<th>Disadvantages to Investors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Company Structure:</strong>&lt;br&gt;&quot;Forming a public company is a key task in raising equity.&quot;</td>
<td><em>Company is liable for any debts incurred.</em>&lt;br&gt;<em>Up on liquidation, maximum shareholders loss is their shareholding.</em>&lt;br&gt;<em>Generally creditors have no recourse on personal assets of shareholders.</em>&lt;br&gt;<em>Dividend Imputation - franked dividends.</em>&lt;br&gt;<em>Availability of group tax relief and access to R&amp;D tax breaks.</em></td>
<td><em>Administration Costs - but financial benefits outweigh admin costs.</em>&lt;br&gt;<em>Onerous duties on Directors – an investor will usually require at least on directorship and tax board position.</em></td>
</tr>
</tbody>
</table>
An Investors View

 Investor Profile

 VC’s:

- Are higher risk investors
- Desire a higher return on their investment.
- Manage the risk/reward ratio by only investing in businesses that fit their investment criteria
- Complete extensive due diligence
- Have differing operating approaches (location of the business, the size of the investment, the stage of the company, industry specialisation, structure of the investment and involvement of the venture capitalists in the company’s activities)

An Investors View

 Investor Profile

 Venture capitalists typically seek:

- Superior Businesses
- Quality and Depth of Management
- Corporate Governance and Structure - VC’s are put off by complex corporate structures without a clear ownership and where personal and business assets are merged
- Appropriate Investment Structure
- An Exit Plan
Other Options

- **Joint Ventures**
  
  Due to the escalating costs associated with research and development, joint ventures have become the preferred structure for commercialisation.

- **Co-operatives**
  
  A structure that has corporate liability status - it is a separate legal entity and has the advantages of limited liability. The main difference between cooperatives and companies is that under a company structure there is a profit motive, returning dividends to the members of the company, whereas a cooperative operates on a service motive, providing adequate services to its members and any return of capital is limited.
SESSION 5: GROUP DISCUSSION ON COMMERCIALISATION ENTITY

Facilitated by Mr Wayne Delaforce

Notes were recorded from two groups known as Group One and Group Two. Groups were divided as evenly as possible based on type of organisation that the participants represented. Discussion focused on identifying the aims of the commercialisation entity and the good, bad and gap characteristics of the existing industry.

GROUP ONE

Aims:
Provide platform for industry, research provider, Government Agency interaction
1. Innovation: Drive an innovation Industry and viable one.
2. Self Sustainable: to produce commercially viable intellectual property.

Good:
• Consumer demand
• Safety of product – low risk
• Clean and green
• Lower barrier to entry
• Established historical use – traditional
• Emerging science
• “passionate” industry – commitment and dedication
• Economic opportunity – huge
• Domestic and overseas market opportunity
• High standards in Australia recognized internationally
• Technologically advanced practices in Australia

Bad:
• Fragmentation
• Low incentive for research
• Small economic base
• No lead company
• Lack of market awareness – education of public
• Poor perception of decision makers of industry, integrity (against pharmaceutical/ medical/perceptions)
• Poor quality starting materials
• Reselling of foods as vitamins etc
• Some questionable industry practices
• Identifying appropriate industry standards
• GST on products

Gap:
• Lacks independent knowledge assessment
• Insufficient efficacy data
• No Government funded research body
• Lack of Government support and recognition
• Facilitation of industry involvement in Government practices
• No Government R&D corporation
• Insufficient validation of product quality
• Scientific resources
• Lack of global presence due to few global products

GROUP TWO

Aims:
i. Internationalisation of the Australian CM industry
   • Maximise Australian primary product content in processing
   • Maximise development of Australian indigenous herbs
   • Develop an international commercial presence
ii. Networking – Industry cohesion role
   - Body to support Australian native plants
   - Foster R&D
   - Coordinating/facilitating
   - Raising money

iii. Plan
   - Venture capitalists
   - Motivation for bringing group together
   - Project basis (need funding, clinical trials, business plans, partners, R&D, develop IP)
   - Government support to assist commercialisation

Good:
   - Lots of interest
   - Loads of IP
   - Traditional herbal applications can become part of industry
     - For example Broome – Indigenous community development through native Australian products
   - Money for ideas – take it to the next step
   - Matching up research and entrepreneurs
   - Clean and Green Image
   - Powerful resources in Australia (land, native products)

Bad:
   - Small farms not viable
   - Embryonic industry – scattered and unorganized
   - Lack of support for CM industry in Australia in comparison to other countries. For example NZ representation at trade fair
   - No global presence
   - Global herbal companies going into developing countries
   - For Australian industry to grow and prosper it needs encouragement
   - Lots of IP not being done in Australia

Gap:
   - Need funding to commercialise ideas
   - Who is going to fund it? Government or other grants
   - CM research falls between the cracks
   - Do we need a global player?
   - Herbal companies going off-shore
   - For Australian industry to grow and prosper it needs encouragement from Government, R&D bodies and the media
CREATING AN ENTITY FROM A NATIONAL PERSPECTIVE

The Structure: What should it be?

- Attract funding (before Pan reluctant and after Pan less interested)
- Experienced people throughout chain and provide advice to industry
- Loose or formal structure
- Industry is too small at the moment
- Steer into commercial mould to attract investors – closer relationship with universities but stands outside of university. Find a balance of attracting investors and being a peak research body.
- Research done by best person to do job at the best price – to be commercial
- Come together through entity

Aims:

- Integration – Innovation – Self-sustainability

Profits?

1. Reinvest
2. Greater good and to increase the perception of industry
3. R&D – depends on makeup of group e.g. stakeholders might want money back. Should be Government funded to begin with because small fragmented industry.

P3 Pharmaceutical program $150 Million

Points for consideration

- Classify activities
- Looking for partnerships and new IP
- Begins July 2004
- No funding at state level
- Commercialisation
- Networking
- An entity that develops IP
- Create a body to work for CM
- How do we get issues on table for regulatory change?
- Is it required?
- Driving IP!
- Common language driven by history and products
- Community to understand language

Profile and changes post pan era, essential for survival. Need a viable and respected industry.
VENTURE CAPITAL INVESTMENT

A representative from the Department of State Development and Innovation gave a presentation on venture capital.

What is Venture Capital?
- Basically superannuation funds provide money for venture capital companies that then invest these funds in companies that have the potential for high growth.

For a company to attract venture capital funds they need to be able to demonstrate:
- High growth
- Equity position for 4-8 years
- Place on the board of directors for venture capital representative
- Usually need a minimum investment of $1 million

Similarly investors look for:
- Business opportunity which offers a superior product or service
- High growth potential (particularly like global market prospects)
- Sustainable competitive advantage can be demonstrated
- In-place quality management systems
- A review of the existing state of the company

Another means of obtaining investment funds is via Business Angels.

What is a Business Angel?
- They are high net-worth individuals
- They invest at the lower range of $10,000 to $1m
- They mostly invest at the early stage of company commencement
- They take a hands-on approach
- They have considerable business experience
- They require as a minimum due diligence

The Department of State Development and Innovation has a venture capital unit that can advise companies interested in exploring this area.
14.50 – 15.20  SESSION 7:

SUPPORT OPTIONS: RURAL INDUSTRIES RESEARCH AND DEVELOPMENT CORPORATION

by  Mr Tony Byrne

Rural Industries Research and Development Corporation (RIRDC)

- One of 13 statutory research funding bodies in the federal Agriculture portfolio
- Role:
  - Foster new industries
  - Manage R&D investments for established industries
  - Invest in cross-sectoral rural R&D
- Budget $26 million in 2002-2003

RIRDC Research Program Structure
### New & Emerging Industries

<table>
<thead>
<tr>
<th>New Industries</th>
<th>Emerging Industries</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New Plants</strong></td>
<td>Asian Foods</td>
</tr>
<tr>
<td>Bush foods</td>
<td>Agroforestry</td>
</tr>
<tr>
<td>Herbs</td>
<td>Cashews</td>
</tr>
<tr>
<td>Fruit, veg &amp; nuts</td>
<td>Deer</td>
</tr>
<tr>
<td>grains &amp; pulses</td>
<td>Essential oils</td>
</tr>
<tr>
<td><strong>New Animals</strong></td>
<td>Organic produce</td>
</tr>
<tr>
<td>crocodiles</td>
<td>Rare natural fibres</td>
</tr>
<tr>
<td>ostrich &amp; emu</td>
<td>Tea tree oil</td>
</tr>
<tr>
<td>kangaroo</td>
<td>Wildflowers</td>
</tr>
<tr>
<td>milking sheep &amp; goat</td>
<td></td>
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</tbody>
</table>

### Essential Oils and Plant Extracts Program

- Boronia, dill, fennel, lavender, parsley, Tasmannia lanceolata, eucalyptus, citrus, lemon myrtle, peppermint, sandalwood oil.
- Echinacea, licorice root, skullcap, dandelion root, golden seal, valerian
Essential Oils and Plant Extracts Program

Budget $400,000 in 2002-2003

Essential Oils and Plant Extracts Program 5 Year R&D Plan

Objectives
To underpin industry development by:

- improving understanding of markets to better focus research efforts and to foster efficient industry development;

- improving existing products and encouraging the development of new crops and products to take advantage of market opportunities;
Essential Oils and Plant Extracts Program 5 Year R&D Plan

- supporting the development of sustainable and profitable production systems, continuing on from the objectives in the previous plan;
- facilitating regulatory approvals;
- promoting post harvest and extraction technology to improve yield and quality; and
- improving the flow of information to the industries.

Funding Process

- Annual call for projects in early August
- Two stages:
  - 2 page preliminary applications - November
  - full applications - March
- Expert panel
Funding Process

• Contributions from RIRDC, the research institution and industry (25 per cent of project cost)

• Strong emphasis on commercial partners and pathways to adoption

15.00 QUEENSLAND Government STATE DEVELOPMENT

Mr Alastair Kane

The State Government along with support from the Gold Coast City Council have been instrumental in bringing together a consortium of CM processors from around the Gold Coast. This consortium has registered a company – Queensland Nutraceutical Industry Association, Inc. (QNIA). Its main focus is on:

• Environment and Health & Aged Care
• Economic leakage $50 million of products
• Establishing manufacturing basis at Gold Coast
• Steering committee formed in March and 26 members
• 326 sponsors and 50 manufacturers
• Queensland nutraceutical
• Brainstorming, research, surveys
• Develop and maintain industry e.g. Gold Coast Council support
• Assist and promote nutraceutical industry
• Promote association trade shows
• Lobby groups
• Assist with TGA and local authority
• Assist members funding


Networking is part of the supply chain
• Consultants (GMP)
• Industry Association
• Subsidy
• Quits program

Federal Money
• Venture capital, Comet scheme, got to have IP as an asset, to get funding from Comet smaller companies are better to go through than larger organisations. Work in with CHC.

**QNIA RULES OF ASSOCIATION**

Queensland Nutraceutical Industry Association Inc

1. A word or expression that is not defined in these model rules, but is defined in the associations Incorporation act 1981 has, if the context permits, the meaning given by the Act.
2. The name of the incorporated association is “Queensland Nutraceutical Industry Association Inc”.

Definition of Nutraceutical

A Nutraceutical is a substance that may be considered as part of a food or as a substance that is sold as tablets, pills, syrups, powder, cream, lotion or cocktail that provides well being, health benefits and prevention of disease. This includes complementary and alternative medicinal remedies, as they are based on natural products such as homeopathic, herbal and botanical products. Food supplements (Vitamins, minerals) and Aloe Vera products can also be regarded as nutraceutical.

**QNIA OBJECTIVES**

3. The objectives of the association are:
   A. To develop and maintain the integrity of the industry
   B. To assist in the promotion of the Queensland Nutraceutical Industry
   C. To provide a means of promoting the nutraceutical industry through developing market awareness and education
   D. To promote the association by attending as a group to both domestic and International trade shows
   E. To assist in the export marketing of nutraceutical products
   F. To act as a lobby group to promote the best interests of the industry and its members
   G. To provide to the members assistance in dealing with TGA (Therapeutic Goods Administration) AQIS (Australian Quarantine Inspection Services) and other Government Authorities
   H. To assist members in applying for Government funding
SUMMATION AND RATIFICATION OF THE CORPORATE ENTITY AND DEVELOPMENT STRATEGY

by Prof Stephen Myers

Stephen Myers: IP generation in Australia. The two groups came up with similar aims – integration, developing a network, and sustainability including commercialisation.

How should the process proceed?

How do we create something with IP value? Options range from a loose network to a corporate model.

Discussion

Discussion raised a number of issues and comments which are listed as follows:

Comment

- Partnerships are the way forward

Issue

- Few Industry groups have the requisite funding

Comment

- ACCMER should establish a commercial relationship with industry.

Response

- We have clients and have relationship with industry people but not a consortium of industry partners. We could generate income from a data package.

Comment

- ACCMER should be part of network executive group.

Response

- The entity needs to be able to source those institutions that can best perform the research. The entity needs secure funding otherwise will dissolve.

Comment 1

- Australia has the tools for world class complementary medicine. We could take a range of potential herbal development proposals and establish laboratory and clinical data that could be promoted in Australia and internationally. Perhaps ACCMER could play a significant role in this process. How can industry assist in this process given that there is not much philanthropy in Australia?
Due to the high risk nature of the research initial support will be required from Government, Industry and Academia. Blue Sky ventures have a small success rate but high returns from successes. In order to interest companies with a global focus a sharp business plan is required for the corporate entity. This could be the entity that achieves this in Australia and could be based in Brisbane. Here is a Post Pan opportunity to focus the attention of Government and the public on the future potential of Australia to develop complementary medicines of international standard.

Comment 2

- A CRC model as a possible example for consideration.

Issue

- Concern that the industry is currently too fragmented to be able to source Government backing. Already have catalyst and knowledge of what is required. Huge sums of money are spent by the Australian public on self medication and over the counter products. This sector is rapidly expanding with large blowouts in the PBS.

Comment 1

- A mix of projects should be targeted ranging from low to high risk. This would probably require $5 million over 5 years to support with the aim of one project being highly successful and thereby mitigating the impacts of less successful outcomes.

Comment 2

- CRC model is not appropriate – not viable. Universities love them but no one else does. Venture capital by way of pooled development funds (PDFs) offers tax incentives and could be an ideal vehicle for the proposed corporate entity. The Entity could initially focus on ten projects over five years, requiring five million dollars to be raised. This will involve high risk but also a strong commercial feel which should appeal to investors. Each project provides a sharp end point. Create PTY LTD – 10 IP projects – talk to investor people.
  - The PDF structure is commercially approved
  - 2nd round of PDFs are being presented with better models
  - Good for ACCMER
  - The corporate entity needs a sharp business plan
  - Need to select an IP portfolio that can deliver a positive result.

Comment 3

- To access PDF funds they require 3 years of verifiable research involvement. For the corporate entity, this would mean an entry point at year four.

Comment 4

- A range of companies would be able to buy in under this concept. These investors are not necessarily part of the nutraceutical community. The corporate entity needs to
convince Government of the value in the CM industry and could highlight potential benefits to the PBS due to cost effective complementary medicines.

Comment 5

- Comparison of cost benefit of CM products to pharmaceutical products needs to be highlighted.

Comment 6

- The benefits of developing IP can be demonstrated by the bitter plum product where the company has generated $200,000 directly into the community at Broome. These sorts of benefits should be pointed out to Government.

Comment 7

- An industry / ACCMER alliance could potentially maximize the CM industry in Australia and expand international opportunities. Can lead the world – keen to see flexible structure for the corporate entity.

Comment 8

- Queensland Health, Centre for Food Technology through DPI and Queensland based has scope to develop activities under wider umbrella. ARC may offer opportunities linkage grants – becoming more ambitious. Useful to have large supporting partners but they don’t last forever. Need ongoing income as well. Support in cash and in kind.

Issue

- There are two issues. One, we need to create something now due to PAN and current climate opportunities. Secondly, we need to develop a couple of scenarios on a model based on today’s comments.

Comment

- Don’t use label “herbal” use “natural products”.

Issue

- Where to now?
  Come back to this reference group to discuss ideas further.
  Urgent need to decide on the most appropriate model before we go to a general stakeholder forum.
  We should keep our minds open to broader definition of the industry to include ‘botanicals’, marine resources (currently not our brief).

Stephen Myers

- Thank you for your participation. We will circulate the minutes and corporate scenario proposals for your feedback.

End Workshop Two
Time 4.30pm
Appendix 4.

Herbal Industry Workshop No. 3 Minutes

Wednesday 5 November 2003
Objective 1: Decide on Structure for CM Commercial R&D Entity
Objective 2: Decide Funding Structure for the R&D Entity

AGENDA

12.00 – 12.30 Lunch
12.30 – 12.50 Dr Phillip Ceras
   Brief Introduction and background
12.50 – 1.10 Dr Jaydeep Biswas
   A commercialisation model for the
   Biotech/Complementary Medicine Industry
1.10 – 1.40 Questions
1.40 – 2.40 Mr Greg Beaver
   Pooled Development Funds (PDF) model
2.40 – 3.00 Afternoon tea
3.00 – 4.30 Dr Phillip Cheras / Dr Bruce Rich / Prof Stephen Myers
   General discussion and decision regarding
   Commercial R & D entity, structure and funding
**Brief Introduction and Background**

Dr Phillip Cheras

The focus of the workshop is to identify what the type and structure of the complementary medicine research and commercial entity should be.

The previous workshop concluded with the need for a whole of supply chain approach i.e. raw materials, farmers, processors and consumers. Each link would be at a global level of efficiency. However, what was missing from the whole scenario is that in this country we tend not to spend money on R&D and IP development.

In future complementary medicines are going to have to have their claims underpinned by hard data. Release of the report by Expert Review Committee underlines necessity for the type of organisation we are trying to put together today.

A body such as that which we are proposing is deserving of Federal Government assistance.

Today we will be listening to Dr Jaydeep Biswas speaking on a commercialisation model followed by a presentation by Mr Greg Beaver, on how PDFs operate.

With this information and what we have previously heard, a decision on the structure of the IP company and how it will be funded should be able to be made.
XYZ Ltd will be owned by UQ and private, noteworthy individuals. Activities under discussion are likely to include bringing herbs from China and India and following approval by the TGA re-exporting internationally. It will play a role of putting together ventures in different countries by a private unlisted company. The venture has guaranteed funding each year for development of new ideas. Step from research into commercialisation.

SLIDE 1
SLIDE 2

**Deal Flow/Research Pipeline**
- Medical/herbal technology opportunities brought through strategic relationship with SCU and UQ

**Investment Analysis**
- Potential opportunities are screened on following basis:
  - market
  - unique features
  - risk balance in portfolio
  - stage of development
  - competitive advantage
  - consistency with chronic disease treatments, herbs or diagnostics
  - IP position/proof of concept
  - Formal investment proposal to executive directors

**Deal Negotiation/Approval**
- Negotiate farm-in with minimum 40% with IPO rights
- ‘Clean IP’
- Clear milestones for farm-in investment
- Technical due diligence
- Research contracts
- XYZ must be manager
- Board approval requested
- Execute agreements for technology SPV

**Investment Exit**
- Active market testing of trade sale, partnering, licensing, dilution or IPO for product manufacturing and marketing

**Investment Management and Partnering**
- Active participation at Board level with
  - strategic planning
  - financial reporting
  - research expenditure
  - key decision making
  - goal setting
- Supply position on natural medicines while local alternatives are found
- TGA/clinical testing in ACCMER for herbs

SLIDE 3

PRIVATE AND PUBLIC MARKETS

CASH → XYZ Ltd
  ASX/AIM
  Board

CASH → Executive

UQ Biomedical Pipeline

IP Project 1 → IP Project 2 → IP Project 3 → IP Project 4

- Project companies initially 100% owned by UQ and researchers
- XYZ secures equity in each project company by project finance on ‘earn-in’ basis
- Active market testing of trade sale, partnering, licensing, dilution or separate project IPO for product manufacturing and marketing
SESSION 1: DISCUSSION

Issue

- If everything is coming through this University, you get first rights in exchange for guaranteed funding

Response

- Investment process and asset/IP management company – XYZ will not produce anything
- Not stuck with one or two drugs, managed like property portfolio, like an investment bank
- The project decides whether to sell out or does its own listing
- Same model that has been previously used by ABC Capital raised $25m two years ago for a non-biotech venture
Issue
- 100% UQ-aligned company initially
- If a private company has its own success overseas in terms of product and export, can they come into that model?

Response
- Primary goal is to link with UQ
- XYZ would own shares in different companies

Issue
- Establish Chinese and Indian herbs, do you mean by rebranding?

Response
- Have been working on a Chinese herbal medicine and would like to take it through TGA testing and clinical testing. SCU is well positioned to do that
- When asked if these processes can be patented, were advised that they are protected by commercial trade secrets
- Looking for strategic investors and strategic industry partners and when everything is signed up will be keen to talk to State Government about it
- What we would like at the seed capital stage is CM companies to go with us
- The plan needs people on advisory board
- If it gets going it will likely be the largest biotech float next year
- Keen for a large CM company, or a friendly pharmaceutical company, to come in at seed stage

Issue
- In the future all companies are going to have to provide proof of herbal active ingredients and where they are sourcing them
- There is probably a need for a national register. The TGA could probably assist Governments to set it up

Issue
- Herbs from India and China, will they be grown here?

Response
- To be grown here
- In the case of Chinese herbs, we can import large quantities. However, cannot guarantee business with such a long supply chain
- Have to try and re-create it here and test it
- Mention was made of a multivitamin firm from India who wants to enter the Australian market. They want to take it through TGA trials and get a market in the USA and Europe through Australia
Session 2: Pooled Development Funds (PDF) model

Time: 1.40pm – 2.40pm

Mr Greg Beaver
Pioneer Development Fund (Aust) Limited

Greg spoke on pooled development funds (PDF) and capital raising and organizational strategies.

SESSION 2: DISCUSSION

Discussion took place on Venture Capital in Australia. Points made include:

- Australians very good at looking over back yard fence
- Current legislation makes it very difficult to recommend early stage investments
- Venture capital funds, almost no venture capital in this country
- Pooled development funds controlled by venture capital markets
- Benefits of PDF capital gains
- Found no issues with Pooled Developments Funds Act provided requirements are met
- Tax free
- Strong relationships throughout the world
- Took advantage of the 12/20 rule – will make 20 shareholder offers in a 12 month period with a maximum of 50 shareholders
- It is difficult to raise money but have raised $14m the hard way

Issue

- PDFs equal venture capital funds
- How is it tax free?

Response

- Fund pays 15% tax but it is tax free to investors

Issue

- No shortage of good ideas in Australia
- A model like this could have relevance but have to consider who will run it and who will start it
- How to harness coverage back into this model?
- How do you kick start it?

State Government comment

- For this to work and for a model like ACCMER the State Government is looking at research on new product development
- Will need to provide investor money from the companies that would use them and the universities that would be partners as well
Issue

- No R&D - IP being put into the industry at this stage, currently operate at an individual level
- What we want to do is to develop an IP and R&D ethos, what vehicle do we need to merge that and what is the underpinning mechanism

Response

- If someone has a good product, it is how to wrap a business around a product
- If we like the people and technology, wrap a business around it and try and get early funding for them
- Not bound by convention
- Saw opportunities and worked out how we could organize them
- See how to implement this in your industry
- Ask what they need and what is required to take them through each step
- Use every network available
- Talents of people on the Board can become redundant
- Get technology through incremental hoops

Issue

- If we brought you a herbal medicine deal, how long would the process be to get it to market?

Response

- 3 – 6 months to get an investor ready then another couple of months to put a business around it
- Each product is different, might take 3 months, might take 12 months
- If someone came up with an idea – there must be large network from people around this table
- If you can put a good product out to network, at least put some structure to it
- Character assessment of individuals as much as technology

A prospectus on Pioneer Development Fund (Aust) Ltd was made available as a guide.
Session 3: Capital Raising Models

Dr. Jaydeep Biswas

- ABC Ltd PDF an example of raising capital. Raised $25m

**DIAGRAM 1**

Institutional

$25m within 6 months

ABC Ltd PDF

Retail

$5m

ABC Ltd

Listing

mining shell

**Investment**

- for ACCMER – there may be a combination of both sides of ABC Ltd

**Comment**

- A suggested option is outlined in diagram 2

**DIAGRAM 2**

Inventors → Companies → PDF → VC → Company (Local)

* seed $ * marketing options

Company (OS)

R&D (ACCMER) (PBR)

Growers Processors

Horticulture Aust

RRDNC

Govt Bodies

ARC
Issue

How to get a commercial entity operational

Comment

- PDFs are ahead of any other structure because of tax benefits
- Things to address are whether the market will be successful, is the market ready, where in the timeline are we – 0-2 years, 0-3 years
- Most of the time 3 or more years to the product being in the market place
- 18 month investment timeline
- If cannot show it has potential within 18 months it will be out
- 12 months to market is market ready

Comment

- 12/20 – 20 investments in 12 months. A potential investor might get 10 of the 20 making an investment:
  - 10 investors making an investment of $20-30K gives $200 – 500,000 total
- Up to $5m based on any number of investors as long as you have a prospectus type document (a degree lower)
- Cost $20 – 70,000
- Dedicated investor partner or take it to IPO

Other possible models suggested
Bruce Rich

DIAGRAM 3

- Go to industry for $500,000 and the Government match the dollar value, then $1m. Then seek Federal funds
• The Government was prepared to put up dollars for restructure in the sugar industry. This industry is of similar value
• Expert Report indication there should be more funding into research

DIAGRAM 4

An explanation of the R&D tent model

David Catsoulis

Note: A more complete model is given on page 50.

Comment
It could be a PDF or non for profit organisation. Would assist in trying to secure national research arm for complementary medicine in Queensland. ACCMER is already here. We accept this model, expect its going to work. It has to be Australia-wide.
Also biotechnology links with New Zealand and Asia.

Within the research tent companies do end up sharing IP. Everyone has exclusivity within the tent as well as sharing it, only within the tent. Also capacity to share royalties, maybe 10% of overall could be kept aside, therefore potential for self-funding.

Question
- How is your model different?

Comment
- It is a herbal pipeline

Question
- Is there a place to crystallize ACCMER within the framework of what you are doing?

Comment
- The bank community surprisingly has been very supportive of herbs

Comment
- ACCMER should be shepherding into existence a commercial framework to take to industry
- It is a good basis to move on from here, an ideal framework to identify an opportunity, to identify a mechanism and it can incorporate PDF
- Need to have individuals, actual drivers. It doesn’t come from academics. It will come down to a balance sheet, cash flow analysis
- There is a need for someone who can say we want to do this because we see returns for investors and ourselves
- Commercial people are interested in this area which has been a revelation

David Catsoulis indicated that he would be happy to put out a 2-3 page summary, including the tent model diagram, to be circulated. (Presented as discussion Paper 3)

End Workshop Three
Time 4.55pm
Appendix 5.

Herbal/Complementary Medicines Industry Workshop No. 4
Wednesday 9 December 2003
Objective 1: Decide on Structure for CM Commercial R&D Entity
Objective 2: Decide Funding Structure for the R&D Entity

AGENDA

09:00 – 09:30 COFFEE FOR 9.30AM START

09:30 – 09:45 Phillip Cheras
Brief Introduction and Review of Workshop #3

09:45 - 10:45 Jaydeep Biswas
A commercialisation model for the Complementary Medicine Industry

10:45 – 11:00 MORNING TEA

11:00 – 12.45 General discussion of the commercialisation model

12:45 – 13:20 LUNCH


13:30 – 15:15 Group and general discussion

15:15 – 15:30 AFTERNOON TEA

16:10 – 16:25 Phil Cheras / Bruce Rich / Stephen Myers
General discussion and decision regarding commercial R&D entity, structure and funding

16:25 – 16:30 Conclusion (Stephen Myers)
MAKING THE FUNCTIONAL AND FASHIONABLE FEASIBLE

The Australian Herbal Medicines Industry Feasibility Study

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Venue: Room 34
Level 1, School of Medicine
Royal Brisbane Hospital, Bramston Terrace, Herston, Qld
Minuted by: Judith McKinnon

1. Phillip Cheras - Brief Introduction and Review

Because several people here were unable to attend previous workshops, I will provide a brief overview of where they have brought us to today and after that, I intend to hand straight over to Jaydeep. Jaydeep will present to us what we hope is the final model for the commercial entity that will be associated with commercialisation of herbal medicine products, specifically, Australian products.

We have had three previous workshops. The first was held on 27 February. This was not a response or knee-jerk to Pan (it preceded Pan). The second workshop was held in June and the third held early in November this year. To avoid losing momentum we decided we would have resolution by the end of the year and that’s why we are holding this workshop. Unfortunately, because of the time of the year, a few people can’t make it because of other commitments.

As you all probably know, the total Australian complementary medicine industry is valued at between $800m and $2 billion. Statistics are indicating that by 2050 the herbal industry alone will be valued at $5 trillion. Even if this is an exaggerated estimate, this industry is well worth our participation, particularly if we have the right kind of products. We all know the pharmaceutical benefits scheme in this country has blown out to a 60% increase over the past four years and we also know that complementary medicines have a potential for impact in this area.

By 2020, if nothing changes, the PBS will blow out to a situation which is unsustainable.

We also know that complementary medicines are increasingly accepted in developed western countries and that in some of these countries, such as Germany, complementary medicines are a primary method of treatment.

At the first workshop, we used UQ’s School of Natural and Rural Systems to review the entire industry from primary producer right up to the consumer and what was identified was that across each level of the industry there was good technology in this country and good people but when we looked at the industry as a whole, there was no R&D effort and no real IP input coming out of this country. This was identified as a major shortfall in relation to complementary medicine in this country.

At Workshop No. 1 we looked at the industry and how it fitted together, as well as the relationships between the different levels of the industry and the Government agencies such as the TGA.
We identified good raw materials, good farmers and consumers in this country are extremely well-educated and probably lead the world in their knowledge and acceptance of complementary medicines. What was missing was R&D and IP enhanced products. At that time we asked ourselves What can we do about that?

We concluded that what was needed was a corporate entity that could commercialise herbal medicine in this country. It should have a national focus and this should have, potentially, an international and national brokering role, whilst upholding standards of excellence.

In Workshop No. 2 we then brought people from outside – the Australian Institute of Commercialisation, QUT Development Office, State Development Office, Ernst & Young and a group of people from State Development based at the Gold Coast to present concepts as to how the commercial model could fit together and operate.

We had intended at Workshop No. 2 to reach consensus on the structure of such a corporate entity but each of these people presented a different concept and we simply ran out of time on 19 June and decided we needed to have another one or two workshops to put this concept to bed.

In the meantime, expert committee on Complementary Medicine in the Australian Health System report was released and what was absolutely evident following that release was that complementary medicines will require a much greater depth of scientific rigor to ensure a basis for claims, than is presently required.

For us, I think this is very good, because there will be a necessity for scientific underpinning within the complementary medicine industry both from a laboratory and clinical trials perspective. Australia is already one of the most regulated countries in the world in relation to complementary medicine and with the release of the Expert Committee’s report it will become even more regulated. However, because of the extremely high standards of laboratory and clinical trials research performed in this country. I believe this situation can be turned to our advantage in accessing global markets.

Undoubtedly, as I said, this Government’s insistence on increased levels of evidence is going to provide increased work for ACCMER and will provide the rationale for an entity such as we are proposing here.

So again, in Workshop No. 3, we were considering options for the structure of a commercialisation entity and Dr. Jaydeep Biswas and Greg Beaver both presented potential structures and options. Yet again, we ran out of time just prior to sewing this up.

What we will do today is have Jaydeep and David Catsoulis outline the proposal they have been working on over the past several weeks. We finally have a proposal we would like to pass by you people here who are mainly from the cutting edge of industry, to make sure that it is right as far as you are concerned. If so, and we get general acceptance here today that this is the way forward we can then decide who will join the commercialisation entity. So Jaydeep will now give you his presentation.
2. XYZ Presentation

It is always easy to come in at the back end of a large project like this which has been managed and pushed forward over the last ten months.

This is a market opportunity you must have foreseen. The story I want to talk about now is really a project which UQ and private investors have been developing in the biotech arena over the past four months. It is basically signed and about to go to market. I will describe that soon.

What we feel basically privileged about is that Phil has allowed us to look at that model to see whether there is a chance to roll up into that industry with the support of the medical industry. That is where we are.

The company is called XYZ Ltd. 50% owned by UQ and 50% owned by private investors at this point in time, prior to large fundraising. It will have exclusive access to the whole biotech pipeline through UQ. To give you dimension on that pipeline, the university invests $200m a year in that area and will have first right to any project out of that pipeline over the first ten years. On average there are fifty to a hundred patents per year.

This model is very well accepted internationally. It has been going in the States for years and years and is the fundamental commercialisation process for the universities and most recently and most poignant, this has been implemented in the UK with a group known as IP2IPO. This company has raised a significant amount of cash and has a development arrangement with three universities in the UK to continue this same process. The model is not new but very effective and becoming more accepted as we speak.

Question

- Is this the only application of that model in Australia?

XYZ Comment

- Yes, the only application in Australia. The universities in the UK are Kings College and Southampton University and they have put their future intellectual property rights onto the Stock Exchange. That company is now valued at half a billion dollars. After four weeks it doubled its capital. This will give you an idea of how the market values intellectual property. It was listed on 5 October. The company is IP2IPO.
- In exchange for the right to access and choose, it will put also a minimum amount of guaranteed funding into the university pipeline to develop projects post-patent, so that the university using its internal and Government funds will develop all the projects to patent. Our goal is to commercialise – get things to market.
- The other thing this company will do as an example, we have an area in the university called Telemedicine and that is a business you cannot patent but is cash earning if you can get it out there. So we get these into cash earning entities and would like to facilitate putting those out into the market, rather than just sitting in a corporate structure.
We have a personal interest in the herbal industry, having seen what it has done for our children. The other element in this is that it is good business. The biotech company by nature has cash flows which are five years out. We can develop a herbal business which builds business on traditional herbs and then goes toward the indigenous herbs and use some of the funds to facilitate a spin-off company. That is the proposal we have put forward here, which is really a subsidiary. I don’t think XYZ, as a parent, would want to own more than 51% of it.

We would like to target the knowledge in ACCMER for this process. If we had access to the intellectual property in ACCMER, then in exchange for that IP we would commit substantial funds for its development and take some of these things to market.

3. General Discussion on the Commercialisation Model - Led by XYZ

Figure 1 represents the proposed model for IP development and commercialisation.

Figure 1 HYPOTHETICAL COMPANY
(based on 5 projects)
XYZ Comment

- The strength of this approach is that the UQ brand, is one of the biggest in medical research and one of the largest in the country. It is of tremendous benefit if you make a move into complementary medicine.

Question

- What about private inventions? They are often a great source of IP.

XYZ Comment

- Absolutely, and as you look further into this later on – there will be opportunities.
- Basically, it is initially a subsidiary owned by XYZ Ltd, and XYZ Ltd has a stake in it and then we bring in other investors. Investors in this may very well be different from those in the parent company.

Question

- So XYZ is the commercialisation entity for biotech IP. Is Natural Healing Products the commercialisation entity for natural product IP?

XYZ Comment

- Correct. XYZ is the commercialisation entity for the IP related to biotechnology for diseases. Now, the market here and the financial markets are telling us that the industry players in the herbal area are different from the biotechnology industry players. So they asked us to quarantine it into a separate part of the drawing (see Figure 2). That's the way I have drawn it and I am quite keen to hear your ideas. We will come to fundraising for that later.
- Now, the initial projects for XYZ (the parent) are projects from the university pipeline. One example is portable MRI machines, ready for development and fully patented. They are able to make ECG machines now that are the size of the screen on a mobile phone. Another example is test kits for meningococcal that are the same size as a pregnancy kit. A five minute test shows whether your child has meningococcal or not. There are also opportunities for investment in the stem cell area. Herbs are very much in our minds and what we are proposing here is to do it through a spin-off company that we will help seed.
- The strategy for the parent company is to secure about five biotech projects from the pipeline of the university to start investing in. Biotech products have a long lead time, so we need to secure early cash flows by developing and building business. For other projects in the biotech pipeline that we choose not to invest in, we set up trade sales or licenses. The herbal subsidiary company would be formed anywhere between two to nine months but within the nine month period. The parent company will go to the stock exchange within nine months, so a spin-off has to occur before we go to the stock exchange.
- At any point in time it is a business so you always look at your position in intellectual property to maximise value to shareholders. What we are moving towards is an asset value company, not a biotech company. We manage assets.
Question

- So what you are saying is that you want to use cash flow from the herbal subsidiary to bolster the basic company?

XYZ Comment

- No. The parent company will be raising its own capital in the stock market.
- It will be other way round, basically. We will be investing from the parent company to the herbal company.

Question

- And when you say spin-off dedicated herbal subsidiary do you mean that the subsidiary will market herbal products?

XYZ Comment

- No.
- The company is not about getting into marketing and distribution of products but will assume a middle man role. For instance, you might have a herb for cancer which may be initially 100% owned by the inventor, but as you invest money into developing it, the company is buying equity.
- The other advantage is that at this level you may bring in additional investors, as well.
- As we said, it is an asset management company. It is about research pipeline, analysing the investment, and negotiating your way into that piece of intellectual property. Manage that investment and report it to the shareholders and then exit. We are not to be a producer, marketing or distribution organisation.
- We will be raising seed capital to seed the first five biotech products and also to put some money into the herbal company.
- UniQuest – the commercialisation arm – makes sure the projects are patented as they come out of the lab, and presents the project to XYZ with a rough business plan. This goes to XYZ’s investment committee. This committee will have external people from the scientific community on it. If XYZ accepts that project then it negotiates with UniQuest to buy in to the project. They might say it will cost $5m to buy 70% equity and being in this position you will usually get to agreement. In a situation where you don’t agree UniQuest has a right to go outside and try to get equity themselves in the market. If they do that, we still have a right to buy back 50%. So we always have a right to go into any project, up front or in the future and also a right to look back. So, all the successes in the past, XYZ has a right to buy into those.
- That model, whilst it looks very simplistic, has taken months to develop and I think at the end of the day it is a very good model for all industries. If potential projects don’t make it first time, they go back into the pot and then come back again for another breath.
- It allows the market full access because there is still 50% there for the market but we are a safety net, so to speak, for those projects that should come to market.
Figure 1 relates to a capital raising process, while Figure 2 that Bruce kindly put together depicts the herbal side and ACCMER packages.

**Figure 2 Herbal IP Company**

**XYZ Comment**

- Now (Figure 2) this is where we look at the herbal company on its own. We are bringing herbs from India and China and bringing them into Australia for short term cash flow. The goal is to invest in the indigenous botanical herbs to benefit from the biodiversity of this country. That will take a bit more time but the analogy is exactly the same as biotech because we help fund the pipeline bringing these options to market but we also get early cash flows to satisfy the market.

- There is another point here and that is the markets have always been available to anybody to assist in the commercialisation of product. Certainly the eastern markets are undoubtedly more aware of the opportunity base outside the east, today more than ever and in discussions with a number of senior players, there is intense interest to see a western country help them commercialise their medicines. They would love to work with Australia. I think the process is well underway anyway, but there is a view that Australia is a potential to be one of the homes for the “east meets west” as it is called. If we get this opportunity running, that is the biotechnology aside, but the herbal industry nucleus running then there is a base there for that to happen in this country.

**Question**

- Is it likely that Indian and Chinese companies will want to invest in the Australian herbal industry.
XYZ Comment

- I met the Regional Director of an international pharmaceutical company two nights ago and she is responsible for the middle east and South Africa. They have been busy in Australia getting TGA to approve facilities in India – an American company – for the European market. They will be emailing me the names of the pharmaceutical companies in India for re-export to the European market.

Question

- Are the Indian companies investing?

XYZ Comment

- The Indian companies will invest.

- I will give you an example. I am from the mining industry as you know. One of the former senior pharmaceutical representatives from the Under-Secretary in that field said that even though he has been out of the pharmaceuticals industry for two years he receives over 100 emails each week from interested parties in India looking for external opportunities and Australia is one of them. So, the interest is enormous.

- To summarise: major targets are generating the first cash flow and developing a portfolio of indigenous botanical products that will come out of this. I will come back to this issue of formulation and marketing because investors might have different rights.

- **Capital Structure**

  Put $1m on the table as part of the company seed money, raising funds. I would be happy for industry players to join us in this process to provide investors. Then we do a private placement in another four months to inject another $4 million. $2 million will come out of XYZ, as I said, and $2 million either from a rights issue to investors or placement in the market by an IM (Investment Memorandum). Once we have a track record of bringing the herbs to market, we IPO it in 2005 and raise $10-20 million for a herbal bio-discovery company.

- Now, coming back to the issue of marketing and distribution. If you are a shareholder of this company and a private shareholder, not an industry player you would like herbs to be manufactured by contract manufacturing and then distributed under a brand but we also recognise that either at the herbal company level or at the parent they all want certain rights so we are assuming that an example of the type of rights we could consider are “first look” rights. For when things come out of testing they have a first look right to take that product under their brand in exchange for a royalty. I haven’t discussed it but I am sure this will be an important ingredient in this debate.

XYZ Comment

- I would see it as difficult to give any one group that right unless they were taking all the equity in the company. If there was a real industry spread in the investment group I would see this as a normal part of negotiations.
Question

- How would you handle the issue once we got it to the table and had it funded to different levels. How would you manage those different rights?

XYZ Comment

- If a party took up the whole process that is a separate situation. But that is not necessarily healthy for the industry. I think there should be a spread of investments. What we are really talking about is getting the industry going in the strongest possible direction and that needs support.

Comment

- If we could refocus and ground this discussion. The place where this whole thing started off at was when Bruce and Phil and I began these workshops early in the year was what we needed to do was to actually build a primary industry in Australia, given we are major importers and not major exporters of herbs. How do we kick that off and create an international market opportunity and for people at the agronomic level growing herbs?
- Not just a return out of the intellectual property by this entity. The idea is that we generate Australian-based IP that is one part of the value chain to create these international markets for Australian endeavours. Instead of buying the IP value-added from overseas we can supply herbs to the international market. The reason we have ended up focusing at this end was that the first workshop defined this as the missing link in Australia. We have growers, manufacturers, wholesalers, marketers but the thing we are missing is the people to add the IP value to the industry. We don't have a gingko biloba or St Johns Wart in Australian industry that turns over $USD 100-200 million a year for the country that developed that intellectual property.

XYZ Comment

- This is definitely a goal for this business even though we have to get there. How we get there is part of the business plan.
- Yes, there are two aspects. One is in isolation because if industry is going to invest but we have to see the missing part and that is the part that generates the intellectual property is what is need to kick-start the value-added industry we don't have in Australia.
- The other point I wanted to make is that we have been very keen to get other herbal companies into the parent bit because I have so many opportunities in biotech that the solution may be herbal related on those disease cell lines and not therapeutic and to have a university pipeline with disease cell pipelines, disease discoveries, proteins, etc., to have people who will work with us in that parent company to exploit that. If a herbal company came in at the parent level they might well ask for different rights.
- So as a purely single form of investment, it is not a bad investment. Nobody should lose. So, you are benefiting from the cash flow which benefits you guys.
Comment

- The organisation that manages the botanical resources for the world’s largest supply of pyrethrum is looking at the possibility of diversifying into the medical area. One of the challenges facing that company was getting pyrethrum to grow commercially and develop proprietary seed technology. One of the products on the table is taking a particular plant crop that doesn’t grow effectively. Using proprietary knowledge to make it into a commercial crop and finding a varietal type, getting a data package right - there may be projects you push from the agronomic side but there will be a lot you would push from the efficacy side where you can see a market. There is biological data to suggest you could build a product. Once you have this, you can look for agronomic product. I would like to see each product on its merits and I see products that could start at the agronomics end.

XYZ Comment

- In terms of developing to market, the agronomic package might take forever. There has to be a portfolio of products and some will fall off.
- I think it is either/or. I think you have the ability to invest in that individual opportunity but the safety net is there for the array of opportunities coming through. These guys have their threshold set of processes that they decide at any point in time that it is ready for investment to take it to the next level and that’s what we are talking about.
- I don’t know how you protect the IP around a natural product. I know the processes you can go through but I think it might hold the industry back. I am just airing this as a view - when I looked at a Chinese herbal product which grows in the gut of a caterpillar. It sells for more than gold per gram in China and is available in Bali. The Schuller corporation has invested in it. My research is that it is being grown in wheat crops in the USA so how do you stop it? You could get on with the business of marketing it and making it commercial instead of spending millions defending it.
- Branding it and marketing it. There is a strong push to bring in data protection in Australia for this sort of knowledge in complementary medicine and the Government has agreed to look at this as a practice. In Europe if you get trade knowledge this becomes protected as IP for a number of years and if someone wants to use it they have to buy it from you or recreate it.
- To get back to investment. As with the parent company we have strategic plans for the herbal company that helps to bring in industry knowledge and drive it. We need to go through a process of who wants to come in. I know in Phil’s case he is getting approaches from international companies looking for a vehicle to exploit Australian biodiversity. We would like to have Australian companies based here to be strategic partners before we go around the world and bring somebody else into the market.

Comment

- My sense of where the industry is at today - it would not be hard to get a bunch of companies such as ourselves putting in $200,000 or _ million dollars maximum -
enough to lock and hold a good idea and see if it will work. If a particular industry member picks up one and runs with it, we still have $250,000 in it as first end of the stick and if we all decide we want to get in it is not unusual to have 17 different glucosamines on the market!

XYZ Comment

- The emphasis needs to be that you can invest in individual products and I think there is an opportunity there. I think the first emphasis needs to be getting Australians to invest in the herbal company first off (the herbal carrier). You need to have your investment across a portfolio of projects because some of them will have shorter return on investment, some high or low risk and the difficulty is that you might back the wrong horse.
- There is risk in any venture. It comes to biting the bullet.
- We are saying that for minimal risk you guys will be the major beneficiaries of what will come out the back end because it will be an IPO. You can continue to invest. The bulk of the money will come from public markets which will underwrite the success of the deal flow which you will benefit from. So we are only talking about seed capital v opportunity. I wouldn’t get too worked up about where the money takes you.

Comment

- There were a number of things that Southern Cross has in the IP area.
- We are tying up the aspects of this legally, at the moment, but we have also been given an opportunity for a plant that is known to have significant cognitive benefits throughout Asia. A well-recognised plant. Chinese immigrants came here during the gold rush and planted this plant where they were and we have discovered and have access to a new varietal type of this plant which has been in Australia for 120-150 years. It varies from its traditional plant in Asia. The chemotype is potentially different - and it is a quite potent anti-inflammatory. We have done all the laboratory work and we’re going into clinical trials next year. It has both anti-inflammatory and cognitive functions and the benefit is that we might be able to dually prove it in terms of a data package and you might be able to market it as a plant that enhances a person’s cognitive capabilities and enhances well-being. It has potential value in the geriatric market. It is one of the Blue Sky products. We (ACCMER) have a number of projects on our back burners. We have been given funds to develop an organisation that primarily in the first instance has to service contract research opportunities because that is our core business. With what limited funds we have available we are working on products and over the past couple of years have been looking for a commercial partner for these ideas to take them from slow developers to rapid developers.
- That’s where the model comes in. You guys can come and have a cherry pick.
- In the biotech side of it, the first five projects, the investment community may decide to take one and look at what else is there. So that is fail safe area. You are funding against the pipeline. They recognise partners such as yourselves and that is what the money is being raised against, not just a project.
• We are actually looking at the moment in the laboratory to find synergy between the plants that actually have specific activity for the three bacteria involved in acne to capture an intellectual property position we can patent on a natural product that can be used for acne. This is another example of what we consider to be a rich one and we have a Masters student working with us on this.

4. General Discussion and Decision Regarding Commercial R&D Entity, Structure and Funding.

XYZ Comment
• We are at a point whereby the beachhead has been set. We know what has to be done and the missing bit is the time tested and true dollar and it needs a hand on the heart to say are we in or are we out at some stage in the next couple of weeks.
• On the parent company we have a draft IM for that company which articulates an investment in the herbal area already up to $1m and then $2 million. That seed raising is $5m and will be all taken by mid January. In fact the first $3m is already underwritten. In this process over the next few weeks there will be a similar document on the herbal side which will be 4-5 pages. 20 private investors. We don't want to go outside this group.

Question
• With the herbal company what are you setting up to raise.

XYZ Comment
• $3m in total.

Question
• You are looking for $2m more?

XYZ Comment
• What I put there initially is $2m for the herbal company - $1m + $1m. It is a capital raising situation. If we can get another $1-2million in the process. If other investors come in, XYZ's equity goes down. The core remains XYZ and the industry.

Question
• What is ACCMER's role? UniQuest takes 50% of XYZ at the beginning. Is ACCMER going to be an agent at arm's length that is used for R&D?

Comment
• In a sense, what has happened is that two ideas have dovetailed. When Bruce and Phil and I started this early in the year I had no idea that we would end up discussing an IP generated company. David and Jaydeep had approached Phil and myself with the idea of developing herbal products and since then it has become a much larger opportunity and these two ideas have, in a sense, collided.
One of the things we have to work out with Blue Sky and XYZ is the role that ACCMER should actually play. We are in a situation where we have enough intellectual property in our pipeline that the ACCMER Board has recommended that we develop this opportunity. The Board has actually put forward the thought that we actually move towards something similar to this with the opportunities that ACCMER has.

My feeling is that from the point of view of the herbal company I would like to see ACCMER having a significant role to play but not an exclusive role. I think it would be inappropriate for us to say we would like to exclusively provide R&D but we would like to see that we have a significant R&D role in the way the company is structured.

XYZ Comment

- You are, no different from any other investor. You can bring whatever you want to bring. We have an infrastructure of $5m I don't want to see that burnt up supporting an institute that is generating ideas because that is not the idea of a commercialisation vehicle. You would be basically saying this is a contract institute for the projects that come out but you could also bring IP in to commercialise.

- You have such strong IP today apart from the opportunities you have just discussed. You can say the IP is such a strong position you might be able to create an equity position for ACCMER in exchange for tipping that IP in but that is up to the shareholders. That is what the UQ has done.

- You can either take that value in cash or take it in equity.

Question

- Is it a good thing to have research involved in the equity? Does that confuse issues or is it in fact an added stressor. Or should they be objective?

XYZ Comment

- We had this same debate with UQ. Their brand and track record and reputation was overriding the investment community. In a similar way, we have to assess this. A lot of other global companies approached ACCMER because this is one of the few institutes in Australia with all the skills, phytochemistry and so on. It provides links you might not normally get so that is another aspect.

- The most important thing is to remember you have to crawl before you walk before you run in these sorts of businesses. We would like to see the opportunity come to market. If we can get that opportunity rolling. We have some products we will continue to run trials on and I am sure others will, as well.

- We need to consider how you cut up the cake and who does what and how does equity sit in it? If you have some rapid paybacks, it will swing the deal.

Question

- How formal is ACCMER. Do you have restrictive Articles of Association?

Comment

- It is a joint venture between UQ and SCU, so in a lot of ways we represent both
universities. In contractual arrangements we have one university acting as an agent, which is UQ.

Question
- What are your objectives?

Comment
- Primarily to be an international research centre in the field of complementary medicine, with a primary focus on herbal medicine.

Question
- So, can we extend that? I am talking now in practical terms. Can you extend your Articles and such into a commercial activity?

Comment
- Absolutely. From my perspective ACCMER has a portfolio of projects that can be put in front of investors to have the potential to do what we are actually talking about at the moment.
- If the projects stack up, they stack up. And that is the very important and crucial role of the investment committee. ACCMER, as part of this process would certainly have a front row seat in having their projects reviewed and dealt with. There has to be a commercial process and the committee decides, irrespective of anyone’s perspective whether the projects are valuable and worthwhile and whether the markets are going to be attuned to the outcomes. I can’t see any reason why your projects would not be evaluated as part of that process and being brought to market. If we are successful it should encourage the researchers based at ACCMER to keep the projects flowing.
- I would agree with you. I would be the first person to say don’t invest in a product that is not commercially viable.

Question
- Can I just pursue where I was about ACCMER? XYZ is a merchant bank. They have a committee of review called the investment committee. They are reviewing material that has been fully prepared under UQ through UniQuest. Does ACCMER have the same facilities to prepare fully a project for evaluation?

Comment
- We are an entity of UQ.

Question
- There is one investor I think I could bring to the table who would be interested in developing native Australian plants. He has a real passion for them. You said that would be one of the things you would like to expand into. At some stage that will be a blue sky opportunity. You don’t have to go back to a group and say “let’s look at where opportunities lie in this and where we would put x amount of seed funding to look at
a series of opportunities for native Australian plants”. One of the things I would like to see in regard to this is the herbal company makes decisions for doing work they believe needs to be done on a research basis, that ACCMER would have the opportunity to first right if it had the facilities and capacity to do that sort of work.

**XYZ Comment**

- If you bring something to the table and you are developing an opportunity it is your baby.
- I understand exactly where you are coming from. There are two approaches to this. No. 1 is the herbal entity. We can lock into and do everything to help. We can say “here is our dedicated market research institute” that might fly or not. The other alternative is to say we have a preferential relationship with ACCMER to do research where it could be accommodated within the auspices of the job to do researches through ACCMER.
- All I am very conscious of is to do the best I can to get the best assistance to facilitate the outcomes at the end of the day. The door is open. XYZ and UQ developed its relationship by saying “if there is a better opportunity” It is not so much about taking research from UQ, it is about attracting other interests to the XYZ cupboard so we are presenting the best opportunity base to the commercialisation opportunities of the world, whether international or local IPOs. We will spread the interest far and wide to secure the best.
- As I understand it, Herbal Co. has an investment panel. It needs a commercial manager and also needs a research manager and these might be the same thing. Regarding the public investors. These people want to know that clever decisions will be made. We need someone who can drive this intelligently and commercially. It needs to be handed to the right people to research.

**Question**

- Why do you see Herbal Co. being involved in that research arm? Do you see it as a merchant bank?

**XYZ Comment**

- We, as a merchant bank, have an obligation to provide funding for these things but we certainly don’t see ourselves managing it, we see ourselves in the end result.

**Comment**

- So, OK. You are not managing the research. You are investing in the research.

**XYZ Comment**

- Yes. Not actually having anything to do with the research until it gets to a point of commercialisation.
- Each of the products in UQ has a research manager in place. XYZ gives them money which is monitored by XYZ. They do all the research under contract. You would have to be happy with the guy managing the research. A milestone setter. Do we have
a research manager inside the company or do we trust ACCMER or outsource the whole.

- The problem with this model is that we have private investors and that UQ model won’t work. ACCMER would definitely have to have a formal role there but you can’t say it is the only role.
- To be frank, to go to market, you have to say who is going to do this work and at this point it is ACCMER because it is the only entity at the table.
- You would need more than one research player I would have thought. ACCMER would have to have a primary role there.

Question

- Could ACCMER fulfil the role of who does the research? If there is a type of research we don’t have facilities for and you go to India, can you manage on behalf of the entity. If you don’t, who does?

Comment

- We, in a sense, do that already. There is at least one group which takes responsibility for the portfolio and if we can’t do it, we outsource it.
- ACCMER is one source of intellectual property. You need a preferential relationship. I was in Melbourne recently and I ran into someone who is a mining investor at Changi airport. He tried a herb and reduced his cholesterol by 70%. What he wanted to do, is import this into Australia and get into the USA market. We have to test this and get TGA data approval for that product. That showed me the benefit of the relationship with someone like an ACCMER. They have the facilities and the people to do the clinical trials.

XYZ Comment

- We have to be careful of conflict. If you are an equity holder in this herbal company and you are producing data for the marketable products coming out of that company, then there is the potential for serious conflict of interest in assessing external innovations of competitor products. You might want to think about taking financial remuneration rather than having an equity interest.
- If an external person comes to the party (an external investor) with an osteoarthritis treatment we would have to make sure there is nothing in our portfolio. There could be a conflict there.
- Within the camp, that IP is protected.
- There is perception and there is reality and that will always be a problem.

Comment

- In situations like that then we need to find resolutions for them. We had such a situation last year where two different companies approached us to do research on the same biological end point, simultaneously. The way we resolved it was to do the research in two different settings – one in Brisbane and the other in Lismore. So, we
had two different groups of people and there was no possibility of mixing them or for one project to compete against the other. I think we have to deal with those sorts of conflicts as they arise. In terms of commercial research, all I have to offer is our integrity and our capacity to be able to maintain confidentiality with the companies we work with. The minute we beach that confidentiality we might as well do something else because we don’t get any further work.

XYZ Comment
• You would sign agreements, too.

Comment
• Regarding equity, part of the commercial strategy that has been strongly suggested to ACCMER as part of our business plan, is to look for equity partnership where we are not simply doing things for a fee but have a stake in what we are doing. Part of what we put on the line is our credibility.
• I would hope that we would be able to, on an ongoing basis, to demonstrate that we had the integrity and nous to call a spade a spade. On a number of occasions we have had to go to sponsors who have invested a large amount of money and tell them what they had put on the table did not work for this or other reason.

XYZ Comment
• There are corporate guidelines in relation to these types of conflicts and we have to be aware of them and deal with them.

Comment
• It would have been better for some people who have invested large amounts of money in research that I have done, that we did have an equity partnership, because on a couple of occasions we actually warned them before they started that this was not a good investment to fund and it would not have gone on.

Question
• What is stopping ACCMER from going directly to Blackmores or a TPL or a Mayne and commercialising something ACCMER has? Why go down this path when we have three separate players. ACCMER has a good idea, goes to Blackmores and Blackmores commercialise it.

Comment
• We need to determine the projects to be funded. We should fund projects which have the best opportunities or where you think the risk is worth investment. In a portfolio you will have some low investment, low risk and you will have high investment and high risk ventures and you will have different timelines. You will have short term returns and long term returns. You should have a good mix of all of those things in a diverse portfolio.
XYZ Comment

- You are right. There is this area whereby the individual company can do its own research and bring the product to market. The concept with Herbal Co, as it was with XYZ, was to assist and facilitate those products with some value i.e., the research has been done by the founder or the inventor through to getting it to market. You share some of that risk around. At the UQ we take the product from IP registered stage onward to commercialisation. So, the concept was that we would have a research tent where it wasn’t that we were doing a lot of research but adding to the value of the research already done. Within the tent, there are things coming in and going out all the time and what is left is an array of quality products that these guys or others might be interested in taking to market. A super league concept rather than having a plethora of parties talking about products to be commercialised by one entity. Getting back to how the entity would function. From start up you would want to, in relation to seeding of additional capitalisation raise initial seed capital. XYZ will be part of that.

The balance I would see as a $3m dollar exercise but to start with, $2m. This is about where we need to be to benefit from opportunity to go forward ($2m). I would see the other $1m come from industry and how that would be broken up is a topic for negotiation with the initial seed capitalists in the process. We will probably put our money in as a nominal amount, say 20c shares x five million shares. So let’s say if there are another five million shares that need to be issued to seed that initial outlay. $2 million would provide for some opportunities and we would progress those opportunities with the $2 million. With the valuation that would take place, already it is valued at $2 million regardless of anything else. A valuation would take place on the selection of projects. Let’s say 5 projects we want to progress – 2 or 3 might come from ACCMER or elsewhere. Those 5 projects have a value, based on UQ, we have $80 million worth of value on those projects. Let’s say we got $20 million of valuation as a lower estimate (hypothetically) then that $2 million might buy us 50% of those projects which might value our equity in this company at $10 million. By adding a second round of capital we might be able to bring the projects to market which will then change the valuation of the assets to double that. At $40 million our 50% might have risen to $60-70 million. We may now have $20 million capitalisation in our companies with an investment of $3 million.

It is around that time we would need to go to market and raise funds again somewhere between $20 - $40 million worth of value in a seeded outfit. We could then raise $10 million by issuing stock at an agreed value for around 50% of equity of the company. If we raised $10 million for that venture at 50c or a dollar it comes back to what portion of the company you want to give away. You have 10 million shares so another three million added would come to 13 million shares on issue to the seed. After that again you might issue another 13 million shares to the market at $10 million so you are going out at about 70c a share. So that is the basic model we have brought to capitalise the company and get the $12-13 million into it and then it can go and create its own destiny. That’s how we would see it.
• It is all about valuation of the early opportunities and capacity and capability to take it to market and raise the additional funds that will allow it to go forward. We have probably most of those components, already, in this model with the exception of knowing which other projects are there.

Comment
• So, you really need an investment committee right now to pick the projects you want to run with in the portfolio. That is a role that ACCMER would be very happy to assist with to put forward opportunities we would see as projects.

XYZ Comment
• Each project is a separate model here.

Question
• How does that work?

Comment
• We put all intellectual property and data into a company. For example Company A which is 100% owned by ACCMER. As Herbal Co. invests into Company A, it gets equity.
• Rather than getting its money back it is getting the opportunity to market. We would rather see that money go into getting that product to market. The researchers would have residual equity in the project and be the people doing the research.
• Yes, this makes sense.
• It is up to you to negotiate. If you want funds back.

Question
• What kind of entity do you see Herbalco being? In terms of management and board structure, how much of a critical mass is there and what is needed?

XYZ Comment
• It is all open to discussion. The best person for the job should get the job.
• As with XYZ we are looking for the best person for the job to take up the CEO position and drive this. The market will want to see who that person will be.
• The emphasis on the CEO will be much more commercial than technical, in other words. It was interesting to see the CVs of the people in IP2IPO – the executive – you can trace his background – he is a merchant banker, happens to be an international chessmaster!
• That’s what it is all about. You buy now for future return. We add value. We spend $2-3 million dollars to take a product valued at X – doesn’t matter what its value is and take it forward. The proprietor of the opportunity will want to think it is worth ten times more than what we think it is worth. What we have to do is to get both parties to agree to a value and then take that value to an exponential level by spending wisely. The $20 million dollars was an arbitrary figure I just picked out. It could be worth $5
million or $50 million. In the case of the meningococcal test, the university is selling that opportunity to XYZ. Very low value. By taking it and spending a million dollars in relation to commercialisation of the process we believe the upside is $10-15. We have to mitigate risk by having other projects in the pipeline.

Comment

- Today, we wanted to ensure we extinguish the need for conversation because at the last meeting we thought that would be the last meeting and people wanted another one. The agenda goes to 4.30pm. I don’t think, given it is now 12.30, that we have four hours of discussion in it.
- I would hope we are probably going to be finished sometime between 2 and 3pm. Some people want to leave by 3pm. What I want to do is keep the conversation going until we are satisfied we are as far as we need to be in this process. Having said that, let’s open it back up again.

XYZ Comment

- I think you have a real opportunity for a biotech bank in this country which will develop the biotech industry as it should be, supported by the university and a couple of investment banks. I think the owners of the company want to promote development of a herbal company in parallel which is linked to the medical community, which is something we want given what has transpired over the past year or so in relation to the industry. The point is that a subsidiary or spinoff company will be funded one way or the other and the process is moving. What we would like to get today is agreement that this is the preferred model by the industry and agree on total number of funds to be requested from the industry, with timelines. The process is moving.
- I would add that the commitment that needs to be made should be done expeditiously. I would like to suggest that part of the process is that we co-ordinate the interest of the relevant parties around this table to start with and then beyond that having declared that interest. I know Christmas is a terrible time but there are still two weeks before we go on leave. If in that two weeks people can talk to their respective powers that be and get a response in writing from each individual here to indicate what their potential is. We will send out a 5 page Executive Summary, within the week, of what the Company is and what capital structure is likely to be, given it is not capitalised at the moment, indicating it is a subsidiary of XYZ and that XYZ will be investing $1 million. I think if we can kick off on that basis this will provide an impetus. I am not expecting anyone to make a physical cash commitment but just have it starting to be built for how it will be structured. That will allow us to go forward into the New Year knowing who is in and who is out.

Comment

- My understanding, following discussion with colleagues who need board approval, generally, you capture people within the industry who have the capacity as key people key in research to go back to their managers to say “here is an opportunity”. You have
to look at the capacity to make a number of presentations to their general managers to show an opportunity but you have to look at a number of presentations before this happens.

**XYZ Comment**
- Yes. Indicative interest so that we know the potential is there. Also, if we could get a quantum attached to that so we know if we are in for _X_ million or such and such. At this point in time, we are not looking for cheques.

**Comment**
- Yes, I am aware of that but we are going to have to present this twice to the company if not three times to get a basis.

**XYZ Comment**
- No doubt about that but to get through to the core message in what we are presenting is that it is not about the five key projects that are going in today. It is about the concept of whether this could be done and if we are in agreement, then what physical commitment will be made by the individual parties. We are sticking our neck out and saying we are in now. The process doesn't need to be over months, needs to be more like a month.

**Comment**
- My company would probably say it is in and the amount would be determined by the scope of the projects. We wouldn't give a specific commitment but say we are in.

**XYZ Comment**
- I have asked Phil to put together a portfolio of what you would like to see put forward.

**Comment**
- If a company said it was coming in, would that be to the parent company, XYZ, or into a totally separate subsidiary, which will have individual investment into it.

**XYZ Comment**
- Correct.
- I need in principle who wishes to be in and who does not and if you don't end up making a commitment that's fine. We understand. I can put the time and resources and effort to carry it through. The market is very aware of lead times that go to bringing a biotech story through to fruition. That is coming through loud and clear. There is definitely a move away from biotech as an investment, from the public's perception.
- Our offer is a totally different risk model. We are offering an array of products - a replacement for any product that doesn't make the grade. It is the merchant bank concept we are pushing but it is a biotech company. The pot will be full when we start with $30m of seeding and IPO funds. That pot, in my view, should not get below
70% because when those initial investments go out they will be invested into an array of near term to long term investments. The near term things are 12-18 months away but we have had expenditure but at the end of that period we have been bringing in funds whether they be spinoff IPO, which could raise $5-10-20 million on a particular project, of which XYZ will take its due recourse which might be that it sells its own equity position in that particular project. It might be a trade sale or that we decide to go to meningococcal development and take it to market and within 12 months you could expect return on investment. This is the critical zone. You don't let it get below a certain level. Any successful merchant bank will want to know it has allowed some leeway or runway in its business plan.

- Also, we have an opportunity with XYZ to invest in products that are already phase 2 or phase 3 FDA trial. So, whilst there will be significant opportunity as far as resources required for the company to take an investment position, it is up to the company to negotiate what equity we can secure from the university in relation to those particular projects out of that residual pot. We would not be doing that unless we saw a return on investment within a reasonable time so as to not reduce the pot.

Comment
- If you are going to apply the same principles to Herbal Co, so if you are not going to reduce the pot below 70% it suggests the first $2m you raise you will spend $600,000.

XYZ Comment
- No. I am talking about the total pot, not the seed capital. The total pot in this case is $15m. So we might spend $5m of that over time but would expect to see something coming through within a time frame. This is a principle where the business should not be running itself down to the bones without a plan.

Comment
- One of the things you have to do in this first component is that XYZ puts in $1m and industry will put in $1m. How much of that $2m would you be prepared to spend on real, on the ground research to double the opportunity?

XYZ Comment
- Most of it will be spent in gaining the $20m valuation. It's not turning it from 20 to 40 it is turning it from something to $20m. Taking you up to that next level of value.
- As soon as you have industry intention locked in, we can go to private investors and they will feel comfortable. So it's not just $2m, it is $3-4m.
- The initial $2m is the critical $2m. That is from ourselves. Now, we would like to think the industry would back it up. The industry might say we want to do $1m or two or three. Most of those early funds would be used to commercialise.

Comment
- Let's say you had 5 projects and raised $2m. Some percentage of that will be spent on
accountants, a board. What percentage?

XYZ Comment

- About 30%.

Comment

- So, the initial $2m is sitting now at $1.4m. You have $1.4 and 5 projects. That seems to be less than $300,000 for each project.

XYZ Comment

- There might be 3 projects.

Comment

- But what I am trying to do at the moment is take the idea forward. If it is half a million dollars a project then you are looking at 3 projects. I am not sure if that is a big enough portfolio to start off with. My understanding by talking to venture capitalists is that “you give me 10 ideas and one is crackerjack, one to two will be OK and 7 will be also-rans”.

XYZ Comment

- We have to get away from the idea of talking about individual projects. We are talking about opportunities that will come through this company and we are developing the pipeline.

Comment

- I hear that. If you pick 3 projects and you spend $0.5m on each, and that doesn't double the potential opportunity, then how do you go to the marketplace to raise the funds. The first projects you bring to the table have to be projects that have a high degree of commercial success associated with them so that when you spend that amount of money you value add significantly to generating intellectual property so you have a story to take to market.

XYZ Comment

- In the UK a business called Oxford Natural Products was based on a similar model and they had things from Asia and India and there were a range of things they were looking at and nothing was getting there and they called for more and more funds to kick a few goals.
- This has to be a very commercial animal and I think you are talking about risk diversity.
- $2m is just to seed it. Those funds won't do anything until after the IPO.

Comment

- Comment from industry is saying that investment will be dependent upon projects you put on the table.
XYZ Comment

- As it should be. But the principle of investment into the company will not be dependent upon any one particular project.

Comment

- The model you put up before is dependent upon there being an increase in the value of intellectual property initially invested in. If the $2m you invest does not increase the value then I am not sure how you go out to market to raise the $10.

XYZ Comment

- I think you are talking about a research valued or related investment. We are taking something from the university which has X value and we are taking it from the university. I don’t think we necessarily will make that value appear overnight but how do we get that value to the marketplace. It has to have a very thorough business attached to it, it has to have trade secret intellectual property and weighted value attached to research prowess and has to have a good strong commercial message as to where the revenue is going to come from. Maybe one of the parties at the table will stick up their hand and say they will commercialise it. To finish the process off, there will have to be a couple of million dollars early on in the seeding of the concepts.

- We are getting a million from industry and a million from XYZ. Suppose there were only three companies here. This is the only vehicle of its type in this country which has industry players working in the herbal area. If you were sitting back as a private investor looking at $2m going into this company, researching a pipeline which will potentially go to market, how do you believe the share prices will go? As soon as you announce it the value of the company is going to double, not even on the stock market yet. As soon as you begin research to get in the next layers of funding of $1-2m, it won’t be difficult and then we have to get it to the point where the board believes in a year or two’s time that we should Initial Public Offering (IPO).

Comment

- I think the critical focus of Steven’s point, which is how you take something worth X and take it to $20m. That is no different from the model we use for XYZ to having identified a value and agreed that value with the university. We will sit down with you and say celery seed is worth $10-15 – or $5m or whatever the number is. We will take out of that $1m of expenditure that will expedite that particular project. So, we take $1m of the first $2-3m and expedite celery seed. For that what do we get? Again, that is a negotiation process – a fixed part of the process of the XYZ business plan as it would be for the Herbal business plan. It might buy 30% or 50% or 15% or wherever we get to with it. But the opportunity is there to develop that investment over a period of 18 months or 2 years, with regard to having been successful with the IPO, which is a given in this process. It is not that all of the funds are coming from that initial $2-3m. That wouldn’t work for the situation we were just talking about where you had to go back to your investors. You would have to raise enough funds initially in this IPO process to seed those projects.
IPO is Initial Public Offering. Once you have raised those funds from the market you have sufficient wherewithall to run with it and add value.

Just going through that process adds value.

That is the ideal but we don't necessarily have to see them make the next Quantum leap in the market. That will happen out of the post-IPO scenario. We are going to develop these projects to the next level.

Question
• If you are coming up with $1m and industry comes up with $1m, why can't we go to the Government and get additional funding.

XYZ Comment
• Absolutely!

Question
• How does ACCMER get its funding now?

Comment
• It is a mixture. A combination of contract research where someone wants to do particular pieces of research and then someone else comes with pieces of research. We quote for it and we enter into a contract to do it. With some of it, we enter into equity opportunity with someone with an idea and does not have the capacity to progress it. We take it on to do the research by taking a stake in it. With some of it we actually generate from other sources than research.

Question
• Do you have funds from the university allocated to you?

Comment
• Yes but I don't have pipeline funds from the university. I can depend on the university paying me if my centre has PhD students or courses where students enrol but I can't depend on the university saying here is $2m a year to pay staff and keep running. My centre is basically a small business.

• Some of the people at this table would like to see ACCMER bedded down and solidified because at the moment we are the only bridge between complementary medicine and orthodox medicine but the bridge is very tenuous. The Pan crisis this year put a major hole in the budget.

XYZ Comment
• It is in all of our interests to have ACCMER here.

• I have another idea that may soften the blow a little in relation to one of the questions you raised before about locking in a relationship. We initially started talking about how ACCMER can be funded. We are paying a pipeline service fee to UniQuest to provide the services it provides. If we conceived that ACCMER can be an integral part of this process and has a role to play, and accept that, I could see nothing wrong with,
similarly, providing a service fee arrangement, apart from any other thing that happens to ACCMER to provide the role that it is providing.

- You could look at providing a large chunk of that through Herbal Co. to provide the base level of services.

Comment

- The minute we get some funding behind us we will have lots more opportunities. We have a lot of opportunities already available. We have a portfolio of about ten projects which have capacity to provide significant intellectual property.

XYZ Comment

- Once you have a level of funding, the university might be more likely to make funding available.

Comment

- We have been given a seed funding opportunity. We have been set down a path that we have to be fiscally independent. We are not going to stop tomorrow but if we don’t get onto pathways that are financially viable, then the opportunity represented by ACCMER will not continue.
- People in the industry have told me they are glad a group like ACCMER has come along and I think we represent real value to the industry.

Question

- How many projects would come through your operation in a year? How many potential commercialisations?

Comment

- Probably, we are doing 50 to 60 projects. We have nearly 20 graduate students.

Question

- How much of that is driven by outside commercial interests?

Comment

- Probably in the vicinity of 10 to 20 commercial projects, some big and some small.

Question

- So, a third is commercially viable?

Comment

- Yes. A third would be graduate student projects and a third be developed of our own accord.
- The reason we are sitting around this table is that we believe this is the right partnership.
XYZ Comment

- We can make the pipeline fee or service fee or whatever you want that can be paid to ACCMER to have it there to manage the research management capacity of this entity.
- If you were willing to offer the projects that you have (I don’t know what they are or how much they are worth). If you offer them into the start up vehicle and we have them valued and channeled through the pipeline, in exchange for access fee for future projects.

Comment

- One of the difficulties is to get practicalities organised. Some of the ideas we are working on and some of the intellectual property is just an idea and when you put it down on paper and show it to people some of the value is automatically lost.

XYZ Comment

- That’s the process we have gone through with UniQuest. Every single party we have spoken to has signed a confidentiality agreement otherwise they don’t get the document.
- There is no secret on Cordycepts and probably half a billion Chinese have taken this in their life. Where are we in relation to that process? We are developing an aspect of that Chinese traditional herbal medicine that doesn’t seem to have been taken up by any Western organisation and so, the opportunity to develop this is there.

Comment

- In terms of these projects, how many do you want us to put on the table to start off with? Only projects where we have significant leads to start off with?

XYZ Comment

- Sometimes the good projects are projects in that biomedical pipeline which were put on the table. They suggested a group they believed were their best but we refine that down to the best five.

Comment

- We have a list of about 10 projects but some of them are blue sky opportunities. There is one we have data on and I am more than happy to be candid with is a fantastic opportunity for a herbal product that eradicates helicobacter pylori, (a bacteria associated with ulceration gastric ulcers and duodenal ulcers) and is a fantastic opportunity for the Japanese market.

XYZ Comment

- I think we can give an in principle agreement and then in January a pipeline list which will include an update to the original 3-5 pages which will include ACCMER’s dozen best pipeline projects and we would have a selection based on that on what we view as near to market or commercially viable. It might be that you guys have a different view and we can get the industry input for the process.
Question
- What about the rest of us, with projects.

XYZ Comment
- There is no exclusivity on projects.
- What I want to get to you by the end of this week is a 4-5 page description of the opportunity, which is putting what we have seen today to work.
- The privileges are to the foundation members.

Comment
- Is there a willingness to indicate a possibility of putting funds on the table to provide a person (or persons) to form part of the initial committee that gets the projects.

XYZ Comment
- I will take it further. Those people should form the original Board of the company to take it forward because without that input it won’t successfully go forward.
- It is important because Government and the public will want to know there is industry representation on that Board.

Comment
- We talked before about the CEO of IP2IPO is a merchant banker. There needs to be this filter process to determine which projects are of highest priority.

XYZ Comment
- These things are really part of the overall process toward IPO.

Comment
- One of the things I wanted to see first was to offer these guys the opportunity to actually help assess which projects you would start with.

XYZ Comment
- They will nominate who is on the investment committee. It will be either themselves or their nominees.
- You will want about five real hard headed types.
- Once something like this has publicity it will attract investors and the right people to it.
- If we back it, the university system backs it, the Government backs it, it is unstoppable.

Question
- Have you heard of the Anthill magazine? It has ideas about innovation and Australia has fantastic ideas but commercialisation is not our forte.

XYZ Comment
- Yes. We got a copy of it yesterday. A properly placed PR consultant will have us in
every journal and magazine in the country.
• If you have a good story, you will get the investors.

Comment
• You guys represent the big end of the industry and go out there and target the partners you think would want to work with this. There is an opportunity to initially do this by invitation.

Question
• XYZ will keep it a closed entity regarding shares?

XYZ Comment
• Assuming the model is that we go to IPO there will always need to be a minimum amount of liquidity in the company. Less than 20 million shares would probably be unworkable for the market. I would be targeting something between 30 and 50 million shares on issue at IPO at that stage. Where does that leave everybody? I think any individual or corporate could take a larger stake either at IPO or on the way through, via one of the seed raisers, so that doesn't inhibit them in any way in taking a larger position. The opposite is applicable. We would rather they took a larger position on the way through and keep their interests going up with the opportunity that is arising.
• I don't think I would want a $500,000 type of investment to stop anyone around this table going forward and we would like to see them up the ante and raise some more capital for us as part of that forward process. If someone took between 30 and 50 million shares as a corporate capital structure to go to market with is about what we would target.

Question
• On the issue of data protection, will we come across that as a herbal. If you come up with a super duper herb what is stopping someone from popping that tomorrow and therefore making that not worth anything?

XYZ Comment
• The answer to that lies in the process. We have identified, given the nature of some of these products, that it is going to be more difficult to secure the IP. We are all going to need to sign something more substantial than a two page confidentiality agreement to go forward so that we are protecting each other's rights and the original concept is protected.

There was a research tent in which all the participants in that tent, had their IP or concepts protected under the Charter of that tent and all parties signed it.

End Workshop Four
Time 2.45pm
The Australian Herbal Medicines Industry Feasibility Study
Appendix 6.
HERBAL Co. Ltd.
December 2003
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Summary
Herbal Co. will generate profits via commercialisation of complementary medicine products. Herbal Co. will fill the void in the value chain between biodiscovery of botanicals (by universities, herbal and other natural industry players and inventors) and marketers and distributors. The burgeoning growth of Australia’s billion dollar complementary medicine industry (and global trillion dollar industry) provides an insatiable need for new, proven natural products for common and chronic ailments. Herbal Co. will be owned by industry players with branded marketing and distribution, universities and clinical institutions (who have strategic assets for the complementary medicine industry), and private and public investors.

Given the tightening regulations in the Australian complementary industry, alignment of the industry with key research assets (universities, TGA-approved testing facilities) will provide Herbal Co. with a strategic advantage as a product developer.

The larger herbal companies, inventors and universities will have a ‘one stop shop’: facilities, skills and risk-management systems to assess and develop opportunities to market such as indigenous botanicals and traditional Eastern medicines. A Herbal Co. Investment Committee will recommend to the Board which opportunities are the best for toxicology and efficacy testing, clinical trials and product formula preparation, provide budget and milestones, and then monitor the development and commercialisation of the product.

Herbal Co. will make money by having licensors of products as shareholders (i.e. industry partners) with the license exchanged for royalties to Herbal Co. If any product is not licensed, Herbal Co. will be free to either trade-sale the intellectual property or market the product under its own brand internationally via partner distribution channels.

Herbal Co. will have a significant competitive advantage difficult to replicate, because of first-mover advantage, industry partners, pipeline from universities/private players/industry, existing multi-million dollar university facilities, credibility provided by university clinical trial facilities, access to disease conditions through university medical schools, university alliances with major metropolitan and rural hospitals, and market interest in exploiting Australia’s unique biodiversity (Figure 1).

Herbal Co. may extend its mandate in the future to veterinary medicines, cosmetics and the broader field that includes all types of complementary medicines, once it has a sustainable business in the development of herbal medicines for human use.

Herbal Co. will lobby for expansion of Australia’s herb farming industry to produce ingredients locally, thereby reducing imports.
Industry Background

The complementary medicine industry in Australia is undergoing dramatic change:

- The complementary medicine market for common ailments and chronic diseases is growing exponentially in Australia (multi-billion $) and internationally ($5 trillion in 2050) (Figure 2).
- The Pan Pharmaceutical demise has highlighted the need for strong regulation in the industry for safety as well as proof of efficacy to protect the interests of producers and consumers.
- Ideas and species from Australia’s extensive biodiversity are not penetrating the market because of the lack of seed capital for testing research concepts. The major players in the industry are marketers and distributors who consider investment in commercialisation only once the concept is proven.
- Industry, Government and researchers appreciate that a sustainable and growing industry taking into account Australia’s biodiversity will require early stage capital for ‘proving up’ research concepts, capabilities to test the safety and efficacy of complementary medicines for market credibility and to conform to an expected stricter TGA regime.

The lack of early stage funding to test credibility of claims has until now severely restricted the
opportunities for new entrants to bring Australian products to local and international markets. This concept discussion paper for the establishment of Herbal Co. will address these issues by providing capital to catalyse these opportunities.

Figure 2: Forecast Increase in the Value of the Global Complementary Medicine Market

![Graph showing forecast increase in the value of the global complementary medicine market](image)

- Williams, F., WHO global health plan will give boost to alternative medicine. Financial Times; May 17, 2002; London; Industrial and Technical Consultancy Organisation of Tamil Nadu Ltd (ITCOT) in Business line; Report to aid medicinal plant sector May 21, 2002; Islamabad
- Zhen-Gang Wang and Ren, J. (2002) TRENDS in Pharmacological Sciences 23;8;347-348
- RocSearch Ltd. Herbal Remedies Global Market.
- Based on 7% growth per annum

**Business Plan**

The business model will be implemented around a five stage plan that involves:

1. Early cash flows by product re-engineering and securing TGA approval of traditional Indian and Chinese herbs for Western markets. Herbal Co. would use ACCMER and UQ to assist in gaining Herbal Co. TGA approval and medical credentials for these well known herbs, for which Eastern (but little Western) research evidence for efficacy exists. Since these traditional medicines have been used over centuries, TGA hurdles are far less compared to bringing new unknown, indigenous herbs to market.
2. Early cash flows by importing and marketing natural multi-vitamins from India and China manufactured in TGA-approved facilities in those countries.
3. For Herbal Co. products which are not taken to market by Herbal Co.’s industry partners, formulate a new manufacturing and distribution joint venture (JV) with an existing manufacturer and distributor of complementary medicine products both in Australia and/or internationally under a new Herbal Co. Board-sanctioned Brand.

4. Capitalise upon the existing Herbal product research undertaken at ACCMER and other research institutions in the Asia/Pacific region. It is envisaged that Herbal Co. will review a variety of products sourced from these institutions and select those most ‘Ready for Market’ for introduction to Herbal Co.’s Brand. The indigenous products from Queensland’s and Australia’s biodiversity under development by ACCMER are a mixture of products with both short and longer lead times.

5. Using ACCMER and its credibility, expertise, networks, IP pipeline and ‘first-look’ relationship as one of the foundations of the Herbal Co. strategy.

The route to market for generic products is shown below (Figure 3). The registration of complementary medicines as therapeutics by the TGA is outlined in Figure 4.

In the case of all pipeline products requiring additional laboratory or clinical trial research, ACCMER will be offered the first opportunity to perform or sub-contract this research.

Figure 3: Route to Market for Generic Complementary Medicine Products
Figure 4: Elements of Complementary Medicine Product Development

Capabilities of Partner Universities

UQ is one of the premier Research Universities in Australia. It has a unique medical faculty which is based around the key hospitals in Brisbane with key clinical appointments in the hospitals being joint or adjunct between the hospitals and the University. This ensures that medical research has the benefits of clinical expertise and experience combined with large subject populations for clinical trials.

Together with the Institute for Molecular Biosciences which focuses on gene therapy, UQ has world recognition.

UQ has a total research and salary budget of $600 million, 32,000 students, 5,000 staff and it is one of the top commercially funded universities in Australia. It is #2 in PhD completions and has $200 million of total basic research expenditure (excl. salaries) annually. Its commercialisation vehicle, UniQuest has catalysed over 25 startups in the last 7 years and is ranked number 10 in the world. Total income for UniQuest from research contracts and commercialisation in 2002 exceeded $50 million and profitability of more than $5 million.

SCU, Lismore features world class research centres focused on research into medicinal plants. Herbal research facilities through ACCMER allow the investigation of the mechanisms, toxicology and chemistry of individual plant components as well as the conduct of clinical trials. SCU has been re-licensed by the Therapeutic Goods Administration in Australia as a Good Manufacturing Practice (GMP) facility. Natural medicines assessed and clinically trialed at ACCMER are ‘near ready for market’ subject to TGA approval.
The value addition by ACCMER and associated Universities to existing natural and traditional medicines from the East is to (a) screen the medicines under Western norms, (b) optimise dosage and strength to ensure efficacy, and (c) extract the active ingredients to reconstitute the medicine from local natural products in Australia.

The Australian Centre for Complementary Medicine Education and Research (ACCMER)

UQ and SCU have joined together to establish a unique collaborative research and education centre with the objective of providing an independent reference point built on substantial strengths in research, innovation and teaching. These strengths include:

- A leadership group with background and experience combining traditional and Western natural medicine qualifications with an extensive research and commercial expertise in complementary medicines
- The involvement of a research intensive university with a large medical school and access to metropolitan hospitals (UQ)
- The involvement of a regional university with extensive experience and commitment to the field of complementary medicine (SCU)
- A strong underlying industry and commercial focus

The ACCMER team contributes a broad laboratory science and clinical background and has extensive laboratory and clinical trial expertise.

The Centre for Phytochemistry and Pharmacology (CPP)

ACCMER has now combined with the Phytochemistry unit within the CPP to form the Natural Products Pharmacology Unit (NPPU). ACCMER/CPP’s strengths include the elucidation of the mechanisms of action and chemistry of individual plant components. This research is facilitated by state-of-the-art equipment in cell culture, cell analysis, chromatography, mass spectrometry and nuclear magnetic resonance spectroscopy. The team of scientists at ACCMER/CPP has over 50 years experience in academic and commercial research into therapeutic natural products. CPP is licensed by the Therapeutic Goods Administration as a Good Manufacturing Practice (GMP) facility.
Appendix 7

Participant list of attendees at Workshops
Mr Greg Beaver
The Pioneer Development Fund (Australia) Limited

Dr Jaydeep Biswas
Director
Strategic Development
University of Queensland

Mr Ross Blanch
Partner
Ernst & Young

Mr Phillip Brown
Partner
Australian Organic Herbs

Mr Tony Byrne
Research Manager
Rural Industries Research and Development Corporation

Mr David Catsoulis
Managing Director
Healing Power Ltd

Dr Phillip Cheras
Deputy Director
Australian Centre for Complementary Medicine Education & Research

Mr Chris Dean
Chairman
Thursday Plantation

Mr Wayne Delaforce
Assistant Director of Development
Queensland University of Technology

Mr Robert Forbes
Director
Robert Forbes and Associates

Mr Tim Groom
Manager, Agricultural Research & Development
Botanical Resources Australia

Ms Tracey Howley
Manager
Ernst & Young

Ms Val Johansen
Executive Director
Complementary Healthcare Council
Mr Alastair Kane  
Senior State Development Officer  
Queensland Government State Development  

Ms Paula McDonald  
Senior Manager  
Australian Institute for Commercialisation  

Mr John L Miller  
Divisional Regulatory Affairs Manager  
Mayne Consumer Products  

Professor Stephen Myers  
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