30th MAY 2002

IRISH MEDICINES BOARD

IRISH MEDICINES BOARD SEMINAR REPORT

Implications of the Proposed Interim National Licensing Scheme for Traditional Medicinal Products

Bord Leighseasra na hÉireann
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The Irish Medicines Board [IMB] hosted a seminar on the implications of the proposed interim national licensing scheme for traditional medicinal products at the Hilton Dublin Hotel on 2nd May 2002. A total of 111 attendees were present at the seminar including 10 IMB staff, 2 representatives from the Food Safety Authority of Ireland and 3 representatives from the Medicines Unit of the Department of Health and Children. Attendees included representatives from the health trade industry and representatives from all interested organisations including two consumer organisations [Consumers for Health Choice (CHC) and Consumers' Association of Ireland (CAI)]

The format of the seminar was a series of presentations from representatives of each of the key areas influenced by the proposed interim national licensing scheme [see Annex 1 for copies of slides]. The programme included presentations on the various implications of the proposed interim national scheme for consumers, the herbal industry, pharmacists as well as an update on the developments in the area of traditional medicines regulation in the EU [see Annex 2, Seminar Programme]. The seminar closed with an extended panel discussion, which provided the attendees with an opportunity to pose questions to any of the speakers.

Session 1: Introduction

Chair: Prof. Frank Hallinan, Chief Executive, IMB

Prof. Frank Hallinan, CEO of the IMB, opened the seminar, welcoming all attendees and speakers to the first IMB meeting on traditional and herbal medicines. Prof. Hallinan highlighted the long standing concern of the IMB [formerly the National Drugs Advisory Board (NDAB)] with regard to the need for appropriate regulation in this area, drawing particular attention to the NDAB annual report of 1976.

Dr. Dairine Dempsey, Herbal Medicines Project Manager at the IMB provided the attendees with an overview of the proposed interim national licensing scheme.

Mr. Richard Woodfield, Herbal Policy Manager at the Medicines Control Agency in the UK spoke about the draft EU Council Directive on Traditional Herbal Medicinal Products, which will ultimately supersede the interim national scheme. Mr. Woodfield opened by drawing the attention of the audience to the recently published White House

Complementary and Alternative Medicine Policy Report, highlighting that many of the recommendations of this report were consistent with the European proposals in the herbal area. He went on to discuss the advantages of a regulated system for traditional medicinal products and highlighted that such a system would provide long-term stability to the market and would remove the current disincentive for responsible companies to market quality products in Europe. He also drew the attention of the participants to the many reports of poor quality products including reports of products that contained undeclared prescription-only medicines and suggested that a regulated environment would eliminate such problems and therefore increase public confidence in herbal medicines as well as enhance consumer safety. This issue was particularly relevant to ethnic medicines he said. Mr. Woodfield was also confident that through regulation consumers would have the advantage of buying products which could legitimately make agreed medicinal claims allowing a more informed and effective use of herbal medicines.

Mr. Woodfield highlighted some of the key issues of concern in the draft Directive including the limited scope of the Directive to herbal medicinal products. However, he highlighted that there was now a provision for the scope to be extended at some time in the future and he welcomed this recent amendment.

Mr. Woodfield spoke specifically about the industry concern with regard to the possible limitations of the proposed definition of traditional use. He suggested that the key area of concern is that this definition does not adequately define a traditional medicinal product in terms of its true tradition of use and acknowledged the herbal industry fear that it might limit the number of products that would ultimately fall within the scope of the Directive. He also acknowledged the industry concern that this definition might unfairly discriminate against medicinal products from ethnic traditions, which in some cases have thousands of years of documented use in their country of origin. However, he was confident that there was a sufficient degree of flexibility within the Directive to reduce if not eliminate these concerns. Mr. Woodfield also suggested that medicinal use by herbalists, including practitioners of ethnic medicine, could be presented as evidence of traditional use.

Mr. Woodfield refuted the contention by the some sectors of herbal industry that the proposed quality requirements were 'unrealistic and inappropriate' arguing that the

proposed quality standards were developed specifically for herbal medicinal products in conjunction with European herbal experts and the herbal industry.

Finally he highlighted that the MCA and IMB views were often similar and he welcomed the initiative taken by the IMB in its proposal for an interim national licensing scheme for traditional medicines.

Session 2 : Implications for the Consumer

Chair: Dr. Joan Gilvarry, Medical Director, IMB

Ms. Helen McCormack, a medical herbalist focused on the potential implications for herbalists of the proposed interim national licensing scheme. She highlighted the unregulated professional environment for herbalists across the EU and the current initiatives, particularly through the European Herbal Practitioners Association, to address this issue. Ms. McCormack strongly advocated the possibility of statutory self-regulation for herbalists.

Ms. McCormack welcomed the IMB proposal for an interim national licensing scheme for traditional medicinal products. In addition, she highlighted that the proposal included a recommendation that herbalists should be exempt from the requirements to hold a Manufacturer's Licence and to hold individual product registrations for products dispensed to patients under their care. Ms. McCormack stressed the importance of such provisions and concluded that these exemptions were essential in order to ensure that that the proposed regulatory framework could operate effectively while allowing herbalists to continue to practice.

Ms. Breda Dooley, the consumer representative on the Irish Medicines Board, presented the consumer perspective. She discussed the advantages of the proposed scheme and highlighted specifically the fact that through regulation there would be a guarantee for the consumer that the product they buy is of good quality and is safe for use for the specified indication. Ms. Dooley went on to discuss some of the potential areas of concern such as the possibility of an increase in the price of traditional medicinal products. She acknowledged that this was difficult to predict at this stage but suggested that consumers are generally willing to pay for quality. She clarified that this scheme was

developed for over-the-counter products and was not a mechanism for making herbs prescription-only medicines. Ms. Dooley stated that consumer choice would be maintained, that products would be labelled clearly and honestly and that there would be a mechanism for product traceability, in the event of a problem. Ms Dooley finished by posing a number of questions relating to the '30 year rule', the proposed definition of a traditional medicinal product, the possible removal of products from the market in Ireland and the possible need for a separate regulatory agency specifically for traditional medicinal products. Ms. Dooley was confident that these issues would be clarified during the course of the day.

Ms. Geraldine Lavelle, a community pharmacist, spoke about the impact of a regulatory framework on the retail pharmacist. She highlighted that the current unregulated environment leaves the pharmacist with no assurance of the quality, safety and efficacy of herbal medicinal products. Ms. Lavelle highlighted that regulation would ensure that the available products are of appropriate quality and are safe. This would allow the pharmacist to confidently recommend such products as valuable and appropriate medicines for the treatment of minor self-limiting conditions. She particularly welcomed the fact that, through regulation, pharmacists and consumers would have access to all relevant product information including information with regard to potential interactions with other herbs as well as with conventional medication.

Ms. Aideen Hurley, a health food store owner, made a presentation on behalf of the Irish Association of Health Stores [IAHS]. Ms. Hurley first introduced the IAHS outlining its code of ethics, staff training procedures and sales protocols. She then focused on the positive aspects of the proposed interim national licensing scheme for traditional medicinal products acknowledging that through regulation consumers would have access to 'good quality, safe products' and that registered products will be officially recognised and would therefore be preferred to those sold by mail order or over the internet. The IAHS welcomed the fact that products would be able to make legitimate medicinal claims and that consumers would have access to full information on the product they buy. Finally the IAHS welcomed the assurance for them that the products offered to them for sale would be 'above board' and highlighted that it is already an integral part of the IAHS code of ethics only to sell products which they believe have been manufactured in accordance with good manufacturing practices [GMP]. Ms. Hurley

suggested that the above positive implications would only be considered valid if the negative implications were addressed.

The IAHS called for a definition of a 'traditional medicinal product' rather than the existing definition of 'traditional use' and was particularly critical of the implications for traditional medicinal products from outside the EU. In addition the IAHS expressed dissatisfaction at the European definition of a herbal substance and at the scope of the proposed interim national licensing scheme suggesting that it was a.) too broad in including non-herbal ingredients such as royal jelly as well as herbal teas and juices and b.) unclear in its distinction between medicinal herbs and foods. The IAHS questioned the status of combination products and products containing vitamins and minerals in excess of the recommended dietary allowance [RDA]. In addition to the above the IAHS are unhappy with the proposed quality requirements as they consider that some enterprises will not be able to afford to upgrade their facilities and/or procedures to manufacture traditional medicinal products so that they meet the required EU quality standards. The IAHS are pleased that the products registered under this scheme would be available over-the-counter but are not happy that this designation can be divided into pharmacy-only and general sale. The IAHS were critical of the proposed organisational structure and called for the establishment of an independent agency. Finally the IAHS highlighted the potential problem with the issue of 'health enhancement' in the existing advertising regulations [Medicinal Products (Advertising) Regulations, 1993].

Dr. Desmond Corrigan, the Director of the School of Pharmacy, TCD and Chair of the IMB *ad hoc* Scientific Committee on Herbal Medicinal Products, presented the keynote address entitled 'The National Licensing Scheme for Traditional Medicinal Products in Ireland'. Dr. Corrigan focused on the work of the SCHMP in developing the proposal and the terms of reference within which that proposal was developed. He first highlighted that it was not within the remit of the SCHMP to make recommendations on the regulation of herbal practitioners, review herbs currently restricted to prescription control or to devise a completely new scheme requiring an independent agency to implement it. Dr. Corrigan highlighted that the proposal was an 'interim' one which should by definition lead, with minimal disruption, to the proposed EU Directive as discussed by Mr. Richard Woodfield. He stressed that there would have been no advantage, particularly for the herbal industry, in ignoring the EU proposals.

Dr. Corrigan was positive about the proposed organisational structure including a unit for traditional medicines within the IMB and an independent Sub-Committee on Traditional Medicinal Products. Both of these would be appropriately staffed, would include herbalists and would be multidisciplinary in their approach he said. Dr. Corrigan likened the proposed Sub-Committee to the Committee on Herbal Medicinal Products mentioned in the draft Directive and emphasised the need for appropriate scientific representation on both committees.

Dr. Corrigan acknowledged the difficulties expressed by many interested parties, including the IMB and the SCHMP, with the proposed definition of traditional use but again highlighted the need to be consistent with the EU. To develop an appropriate alternative is a much more difficult task that one might first imagine he said. Dr. Corrigan went on to discuss the scope of the proposed scheme highlighting that it was broader than the draft Directive because the original request from the Minister for Health and Children was broader as was the initial draft of the Directive.

Dr. Corrigan stressed the importance of the implementation of quality standards, highlighting that these would do much to reduce adverse reactions caused by herbal medicinal products. He rejected the notion that these standards were too onerous and suggested that the many companies who comply with, or are willing to comply with, these standards should be rewarded for their commitment to protecting consumer safety. Dr. Corrigan discussed the simplified nature of the safety assessment emphasising that clinical trial and toxicology data would not be required where the safety of the product could be proven by reference to long-term use and experience. He also highlighted that the traditional indication claim could be justified by reference to bibliographic data, thereby eliminating the need for clinical trial data.

Dr. Corrigan concluded that 'despite inaccurate and wild claims that the scheme would result in all traditional medicinal products being banned, the only products which could be threatened by this scheme are those which do not meet minimum quality standards or which are unsafe under normal conditions of use or where the label or advertising is untruthful'.

Panel Discussion 1: **Dr. Dairine Dempsey**
Mr. Richard Woodfield
Dr. Desmond Corrigan
Ms. Helen McCormack
Ms. Breda Dooley
Ms. Geraldine Lavelle
Ms. Aideen Hurley

1. A member of the ICGP, speaking on behalf of GPs, asked for more information to be made available to GPs with regard to herbal medicinal products and recognised suppliers. She suggested that it would be useful to have a seminar for GPs in this regard.

2. The Consumer Association of Ireland representative asked if the proposed patient information leaflet would contain a statement to the effect that the individual should consult with their doctor if they were concerned. Dr. Dempsey said that it was a requirement of both the interim national proposal and the proposed Directive that the patient should be advised to consult their doctor or healthcare professional if symptoms persist. She also indicated that the package insert would contain full information on potential interactions, contra-indications and side effects.

3. A question was asked how this proposal would influence the potential use of herbs as ingredients in food products. Dr. Dempsey indicated that many herbs have and will always have a very obvious food use as well as a potential medicinal use. She indicated that regulation would provide a framework within which any potential problems that might arise with regard to the food/medicine borderline, which will always exist, could be addressed.

4. A member of the audience asked about the '30 year rule' and suggested that there was no obvious solution to this problem. Mr. Richard Woodfield indicated that with the existing flexibility in the proposed definition as outlined in his presentation, he felt it would be less of a problem than anticipated.

5. The important issue of the 'backward looking' nature of the Directive and the possible implications of this on future innovation in the herbal sector was raised. Dr. Corrigan agreed that this might be problematic but suggested that in the absence of the '30 year rule' it would be necessary to require toxicological data, which would be far more onerous for industry. Dr. Dempsey added the proposed Directive was only one part of a continuum of medicines legislation and that novel or innovative products could apply for full authorisation in accordance with standard medicines legislation, although this would require full clinical trial data.

6. A member of the audience acknowledged that the safety of the consumer was of paramount importance to everyone involved in the industry but expressed concern at the potential cost to the industry if the interim national licence did not translate into an EU licence and more specifically if such a licence was needed in each Member State. Dr. Dempsey assured him that an additional fee would not be charged once the EU Directive came into force. However, she acknowledged the difficulty with regard to sale throughout the EU but suggested that ultimately the aim of the proposed Directive was to facilitate a single market.

7. Finally the panel was asked if a raw herb was the traditionally used form, could an extract of that herb also qualify for inclusion? Dr. Corrigan indicated that if the extract were enriched or concentrated it would not reflect the phytochemical composition of the raw herb and would therefore not qualify. Dr. Dempsey added that in principle a simple extract could qualify provided the applicant could show that their extract 'corresponded to' the raw herb in accordance with the proposed interim national scheme and/or the proposed Directive.

Session 3: Implications for Industry

Chair: Ms. Sue Rattigan, Chairperson, Irish Health Trade Association [IHTA]

Mr. Jonathon Griffith, speaking on behalf of the IHTA opened the third session with an industry perspective on the proposed interim national scheme. Mr. Griffith highlighted

that those companies involved in the manufacture, sale and supply of traditional medicines fell into two distinct categories: a.) those that exist within the pharmaceutical industry and b.) those that exist within the health trade. Mr. Griffith suggested that the former category were in a better position to accept and work with the proposed regulatory framework as they already manufacture/wholesale to appropriate standards. In terms of cost the latter group, who operate in accordance with food law, will find the introduction of new legislation particularly challenging. However, the potential advantage of having permitted medicinal claims for legitimate traditional medicines was welcomed. Mr. Griffith also touched on the possibility that some products may be lost to the market because of safety concerns and agreed that this would be to the benefit of the consumer and the industry. His overall cost:benefit analysis indicated that those companies already operating to appropriate standards would stand only to benefit while those outside that sector might not. Overall, however, Mr. Griffith welcomed the proposed scheme and suggested that in the absence of regulation traditional medicines may be lost altogether. Finally he finished by suggesting that we are moving towards a 'Modern Science of Traditional Medicine', which he felt was the best way forward.

Mr. John Lynch, Director of Inspection at the IMB then made a presentation outlining the requirements for holding a Manufacturer's Licence or a Wholesaler's Licence in accordance with the interim national proposal. Mr. Lynch indicated that holders of such licences would have to adhere to the existing European guidelines on good manufacturing practice [GMP] or good distribution practice [GDP], as appropriate. He stressed that in the former case, a specific annex for herbal medicinal products was part of the guideline. He highlighted the advantages of licensing focussing specifically on the guaranteed quality of the product. Mr. Lynch encouraged companies to liase with the IMB Inspectorate Department at an early stage in order to facilitate compliance with the legislation.

Dr. Elaine Breslin, Senior Medical Officer at the IMB, outlined the process of applying for a product registration under the proposed scheme. Dr. Breslin drew particular attention to the fact that the proposed registration scheme is a simplified scheme designed to take due account of the established tradition of use of many of the products eligible for registration. She outlined the types of products that would be included within the scope of the proposal including traditional herbal products, traditional non-herbal

products and traditional combination products. Dr Breslin discussed the details that would be required as part of an application: administrative details, a full quality dossier and bibliographic data in support of the safety and traditional use if the product. The latter information would replace the extensive clinical trial and toxicological data required as part of a conventional product authorisation application she said. Dr. Breslin indicated that the assessment process would involve pharmaceutical, herbal and medical expertise and emphasised that there would be on-going dialogue between applicant and assessor throughout the process. Finally Dr. Breslin provided some detail on the regulatory systems currently operational in Canada and Australia highlighting specifically the similarities in requirements between those systems and that of the Irish proposal. She specifically addressed the proposal for an agency independent of the IMB highlighting that the requirements of the regulatory framework would be similar irrespective of whether the regulator was the IMB, the Department of Health and Children or an independent agency. Dr. Breslin finished on the advantages for industry and the consumer of a regulatory framework for traditional medicinal products and emphasised that the proposed scheme would ensure the continued availability of quality products.

Ms. Niamh Arthur, Pharmacovigilance Co-ordinator at the IMB made the final presentation of the day. She indicated that pharmacovigilance, or adverse event reporting, was an integral part of an effective regulatory system but highlighted that it was a post-licensing activity. Ms. Arthur outlined briefly the actions that a company would need to take to develop an appropriate pharmacovigilance system and highlighted that such systems were designed to monitor the safety of the medicinal product throughout the life of the product and act as an early warning system where new safety issues emerge. In the case of traditional medicinal products where the tradition of use indicates that the product is safe, pharmacovigilance activity should confirm this she said.

Panel Discussion 2:	**Mr. Jonathon Griffith**
	Mr. John Lynch
	Dr. Elaine Breslin
	Ms. Niamh Arthur
	Dr. Desmond Corrigan
	Dr. Dairine Dempsey

1. A member of the audience asked what the current position was with regard to products containing vitamins and minerals in excess of the RDA particularly with the Food Supplement Directive under development, which might change the current RDAs to upper safe levels [USLs]. Dr. Breslin acknowledged the difficulty in this area due to the overlap between the Food Supplement Directive and the draft Directive on Traditional Herbal Medicinal Products and indicated that it was not the intention to require full product authorisation applications for such products until such a time as the European Standing Committee on Food had set USLs.

2. A question from the panel discussion at the end of session 2 with regard to new indications for specific herbal substances and/or new herbal substances from outside the EU was revisited. It was suggested that there should be a mechanism by which such products could gain legitimate access to the Irish market where the information presented originates outside the EU for example, by initial intense monitoring the safety of product. Dr. Dempsey agreed that this would a positive means by which the issue of innovation and development of the traditional medicines sector could be addressed but indicated that this would need to be raised at a European level.

3. A representative from the industry congratulated the IMB for hosting such a successful meeting and on behalf of the attendees expressed his gratitude for the opportunity to discuss the implications of the proposed interim national licensing scheme with all the key stakeholders in the traditional medicines area.

Feedback on the day and subsequent correspondence from a number of attendees has indicated that the seminar was considered to be both positive and successful in its aim to provide a forum for discussion for all interested parties. Indeed on the day an industry representative stated that he felt there was no doubt as to the committment of the IMB to this area.

Overall the IMB was pleased that there was significant agreement on the need for regulation in this area and on the key issues that need to be addressed in any regulatory framework. The seminar provided an opportunity to address many of the concerns of the industry and particularly to clarify any misinformation. It is significant to note that throughout the day no new issues or concerns were raised.

IRISH MEDICINES BOARD

Annex 1

Slides and Transcripts of Presentations

Bord Leigheasra na hÉireann
Earlsfort Centre, Earlsfort Terrace, Dublin 2. Tel: [illegible] Fax: [illegible]
Website: www.imb.ie

IRISH MEDICINES BOARD

Implications of the Proposed Regulatory System for Traditional Medicinal Products.

Prof. Frank Hallinan

Chief Executive

May 2nd 2002

'.....it does not feel it can take any action in the case of those medicines which have the sanction of traditional use, provided adequate assurance of pharmaceutical quality and safety are made available'.

NDAB Annual Report 1978.

"During the last few years there has been a number of new medicinal products containing herbal ingredients marketed in Ireland. The NDAB has been increasingly concerned at the potential for adverse effects arising from such products ..... which may not only exert undesirable effects per se but may interact with other medications or even foods'.

NDAB Annual Report 1979.

DESIRED OUTCOME.....

QUALITY

&

CHOICE

The Proposed Interim National Licensing Scheme – an Overview

Dr. [illegible] Dempsey
Herbal Medicines Project Manager
[illegible] May 2002

Introduction

- Herbal Medicines Project - June 2000
- Herbal Medicines Steering Committee – June 2000
- Herbal Project Manager - September 2000
- Scientific Committee on Herbal Medicinal Products [SCHMP] - December 2000
- Draft report - November 2001
- Final Report - January 2002

Herbal Medicines Project Final Report

- Definitions & Scope
- Product Registration
- Quality Assessment
- Safety Assessment
- Traditional Use/Traditional Indications Claim
- Final Provisions
- Additional Provisions

Definitions & Scope

- What is included?
  - [illegible]
- What isn't included?
  - [illegible]

Product Registration

- Hold a Manufacturer's/Wholesaler's Licence
- Submit an Application
- Comply with Additional Provisions/Final Provisions

NOTE: The [illegible] of all Product Registration Applications are highly confidential

Quality Requirements

- What is required?
  - A full quality dossier
- What does that mean?
  - Compliance with all existing quality guidelines
  - Note: Active ingredient = Whole Herb
  - Guidelines for "Non-herbal Medicinal Products"
  - GMP
- Why?
  - To ensure the products are of appropriate quality
  - Implications for safety
  - What you see is what you get

Safety Assessment

- What is required?

Traditional Use/Traditional Claim

- What is required?
- What claims can be allowed?
- What additional data may be required?

Final Provisions I

- Organisational Structure
- Assessment of Applications

Final Provisions II

- Timelines

Additional Provisions I

- Labelling

Additional Provisions II

- Patient Information Leaflet (PIL)

Additional Provisions III

- Advertising
  - [illegible]
  - [illegible]
  - [illegible]
  - [illegible]

Additional Provisions IV

- Site Licences
  - [illegible]
- Pharmacovigilance
  - [illegible]

Purpose of this Seminar

- Discuss the implications of this proposal
  - For the Consumer
  - For the Retailer
  - For the Industry
  - For the IMB
- Enjoy the day


The Directive on Traditional Herbal Medicinal Products
A presentation by
Richard Woomble
Medicines Control Agency
IMB Seminar Dublin
May


Summary


Current UK arrangements


Regulating herbal remedies as medicines? (1)


Regulating herbal remedies as medicines? (2)


US experience (1) - White House Commission on CAM

US experience (2) - White House Commission on CAM

- "Dietary supplement manufacturers and suppliers should be required to maintain records and report serious adverse events to the FDA."
- "Federal agencies responsible for enforcing current laws monitoring the quality of imported raw materials and finished products intended for use as dietary supplements and also [illegible] funding."

Progress on European Directive

- UK active in development work on Directive - UK and [illegible] make similar points
- European Commission published formal proposals - January 2002
- EU Presidency to decide on taking issue forward (Spain, Denmark ...) possible date?
- MCA public consultation on Directive launched before Easter (MLX 283)
- copy on MCA website, includes initial RIA

Directive - summary (1)

- Requirement for Member States to set up special registration scheme for traditional herbal medicinal products
- products intended for use without intervention of medical practitioner
- not applicable to products which could get marketing authorisation
- subsequent review of possibility of extending traditional use registration to other categories of medicines

Directive - summary (2)

- Evidence of traditional use of medicine or corresponding product(s) for 30 years in EU
- up to 15 out of 30 years may be made up of use from outside the EU
- no requirement to demonstrate efficacy - but can be refused if efficacy not "plausible"
- bibliographic review of safety with expert report
- regulatory authority could ask for additional safety data where justifiable

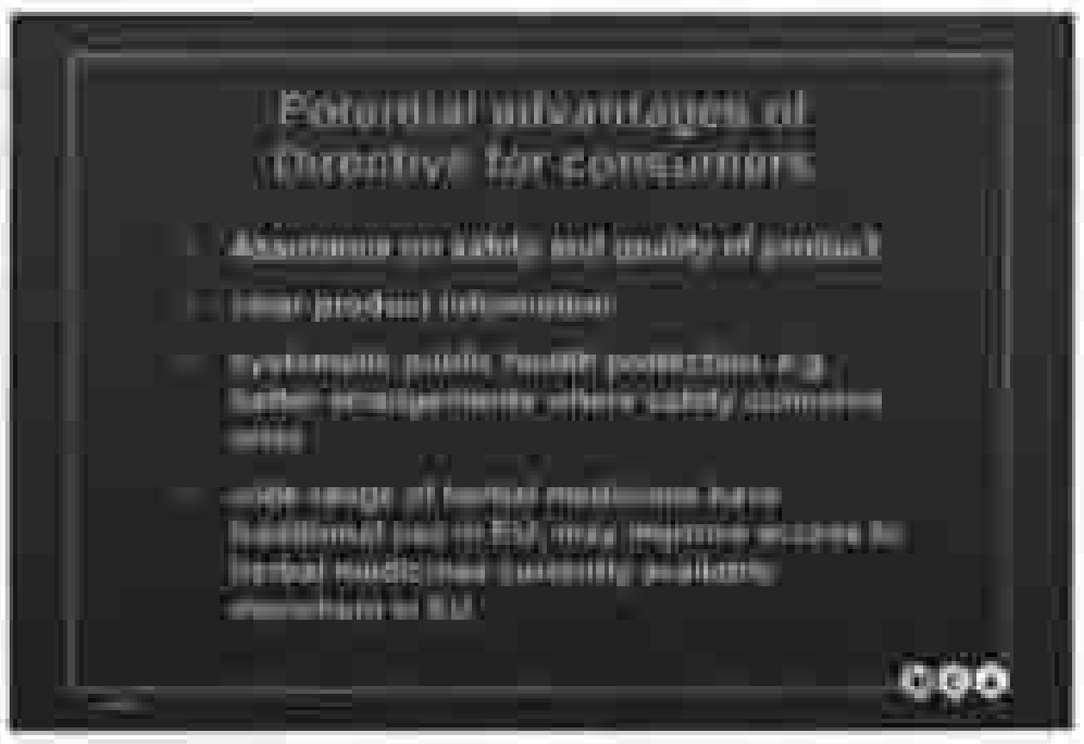
Directive - summary (3)

- Positive list of herbal substances with therapeutic indications, specified strength, route of administration, safety information
- if on list, no need for applicant to demonstrate traditional use and safety
- quality requirements as for licensed medicines: GMP required
- manufacturers and wholesale dealers licensed as applicable

Directive - summary (4)

- Systematic labelling requirements would apply
- traditional use of [illegible] indication: efficacy not proven but based on long use and experience
- can state nature of the herbal tradition
- European herbals committee: monographs and positive list
- Member States can make transitional arrangements for products on the market


Potential advantages of Brexit for business

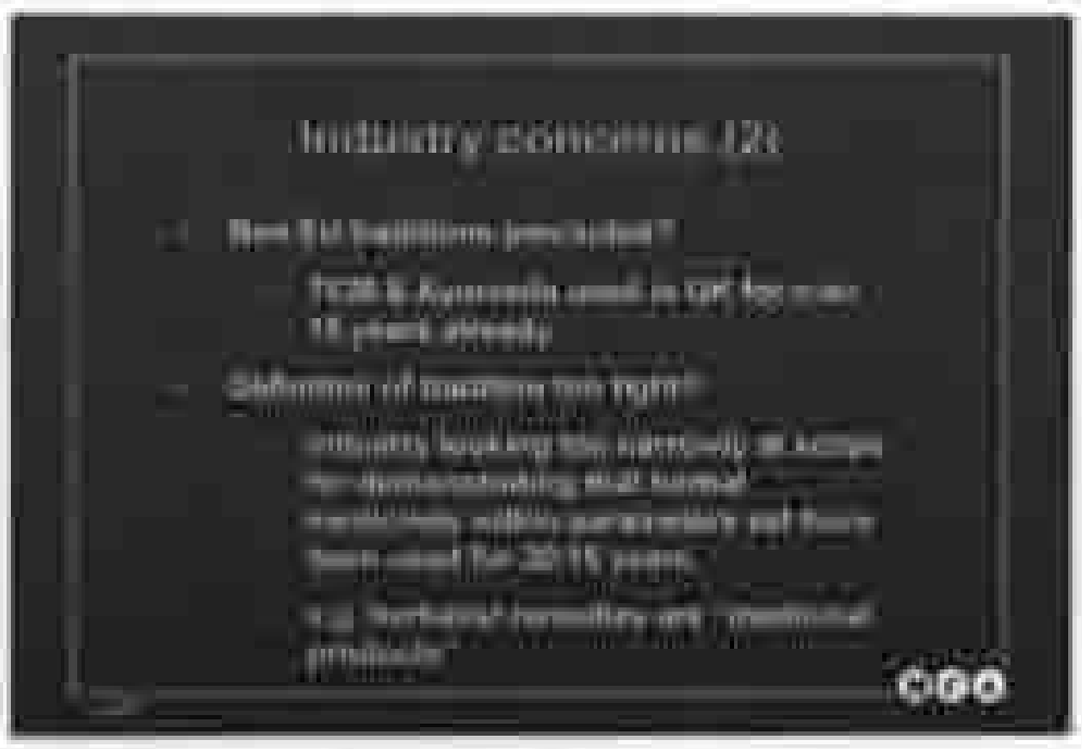

Potential advantages of Brexit for consumers


Potential advantages for consumers (cont)


Regulatory Impact Assessment (1)


Regulatory Impact Assessment (2)


Industry concerns (1)



Industry concerns (5)

- Taking "due account" of registrations or authorisations of other Member States: will it tie UK hands?
  - UK not bound by other Member States decisions (nor they by ours…)
  - not a mutual recognition system
  - means what it says - no more and no less

Industry concerns (6)

- Positive list of herbal substances
  - doesn't contain provision permitting national lists to supplement European list
  - MCA invited views on whether we should press for such flexibility
  - so far no agreed view from industry

Industry concerns (7)

- Position of existing licensed herbal medicines
  - likely to be an issue in many Member States
  - MCA held initial discussions with manufacturers to seek views
  - recognise importance of issue, will be further discussion with industry

Industry concerns (8)

- "Directive unrealistically demands immediate compliance with technical requirements" (Early Day Motion No 811)
  - Member States can have 7 years transitional period from date Directive comes into force for products on market when Directive comes into force

Conclusions (1)

- "An effective regulatory framework for traditional herbal medicines could do much to enhance the standing of herbal medicine and the strength and viability of the market. Responsible companies would no longer be undermined by less reputable operators following low standards, and public confidence in the safety and quality of products would be enhanced."

[illegible]

Conclusions (2)

- "…The bill undoubtedly entail more regulatory constraints than exist under the present inadequate and open-ended arrangements. However, subject to a successful conclusion to the negotiations, we envisage that such a Directive would permit a very wide range of traditional herbal remedies to achieve a secure future on the UK marketplace."

[illegible]

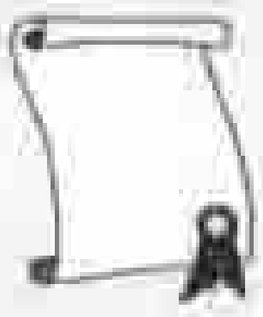
HERBAL TRADITION

- SMALL SCALE
- PERSONAL SERVICE
- CRAFT SKILLS
- AUTONOMY

PRACTITIONERS

- TRADITION
- TRAINING
- EXPERIENCE

UK REGULATION



- 1968 MEDICINES ACT
- SECTIONS 12 AND 56
- SI 2130 1977
- HERBALIST UNDEFINED

CURRENT DEVELOPMENTS

- PARTNERSHIP
- SSR
- QUALITY ASSURANCE
- HERB SPECIFIC EXEMPTIONS

EU REGULATION

- STRUCTURAL DISSONANCE
- DIVERSITY
- FREE PRACTICE

EHPA

- TRAINING STANDARDS
- COMMON ACCESS
- PROTECT TRADITIONS
- UNIFICATION

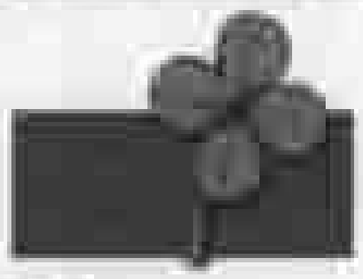
EU/EFTA STRUCTURE

- COUNCIL
- EDUCATION SUBCOMMITTEE
- RESEARCH SUBCOMMITTEE
- REGULATORY WORKING GROUP
- ACCREDITATION BOARD

IRISH PROPOSALS

- SCHMP RECOMMENDATIONS
- LICENCE EXEMPTION
- NON-MEDICAL PRACTITIONER
- SSR 7

[illegible] STRUCTURE



- COUNCIL
- 3 MEMBER REGISTERS
- IAMH
- IRCHM
- AMHI

Proposed Regulatory System for Traditional Medicinal Products

Implications for the Consumer

At the Shop Front

At the Shop Front 2

Areas of concern for the Consumer

Consumer concerns 2

Implications for the Consumer


Final Thought:

Irish Association of Health Stores

IMB Seminar:

"Implications of the proposed Regulatory System for Traditional Medicinal Products"

Retail Implications ~ Health Stores

Presentation by Ms Aideen Hurley IAHS

May 2nd 2002

Implications of the Proposed Regulatory System for Traditional Medicinal Products

Introduction

Good morning, ladies and gentlemen. My name is Aideen Hurley, I am a Committee Member of the Irish Association of Health Stores (IAHS) and have had been a retailer for 10 years now. I am delighted to be here, and I congratulate the Department of Health and Children and the IMB for having the initiative to organise this seminar. Furthermore, I am privileged to be able to present the IAHS position on the IMB/SCHMP proposals for the regulation of herbal medicinal products.

It is well known by now that there are many issues of concern to the industry arising from these proposals. I suppose it's fair to say that different issues would be more important to certain sections of the industry than to others. Health stores have been supplying herbal remedies to the consumer for the best part of 40 years, so for us, as retailers, our main concern is that herbal products and food supplements continue to be available to the public through our stores. We believe, with our long-standing tradition of retailing herbal remedies to the public, our high standards of training, and the personal belief in herbal medicine of all our members and staff, that health stores are the most appropriate retail outlet for traditional herbal products.

Let me state categorically that we are in favour of regulation, but that regulation must be appropriate, equitable and workable.

Regulation requires a fine balance between protecting the public and assuring maximum choice, and the key to good regulation is to ensure that balance is correct.

I would like to divide this presentation into four parts:-

Part 1 ..... Introduction to the IAHS
Part 2 .....The Positive Implications of the proposals.
Part 3 .....Issues of concern to us in the IMB proposals, and some of the negative implications of them.
Part 4 .....Suggestions for moving the situation forward, and conclusion.

Part 1 ~ The Irish Association of Health Stores

- The First health store in Ireland opened in the 1960s in Parliament Street, Dublin.

- The number of health stores have grown rapidly particularly in the 1990's in response to growing interest in alternative medicine and natural healthcare.

- There are now approximately 120 health stores in the Republic of Ireland, and most towns, and even some villages, now have at least one health store.

- The health store is now established as a valuable member of the community and is seen as a very useful resource in terms of help, advice and guidance in the matter of diet and keeping healthy.

- Health Stores are very often the first port of call for customers seeking a herbal remedy, and as such they are an important link between the consumer and the regulators.

- The IAHS is a professional trade association established in 1986. It now has 74 members representing over 90 stores.

- Its main objects are to set standards in the retailing of foods and natural remedies, to run training courses and provide qualification for those employed in member stores, and to represent and protect members' interests.

- The IAHS is governed by a Constitution and a Code of Ethics to which all members must adhere.

- **The Code of Ethics** is a statement of standards expected in member stores. All members are required to sign up to the Code of Ethics and are regularly inspected by the secretariat to ensure that they abide by it. All new members are designated "provisional members" pending inspection and accreditation. It lays down standards in the following areas:-

- **The Storage, Handling and Sale of Foodstuffs**
- **The Storage, Handling and Sale of Food Supplements and Natural Remedies**
- **Training and Supervision**

Importance of Training

Training is probably our single most important activity. Because we are engaged in helping people to keep well, good training for our staff is absolutely vital. The IAHS is recognised as a Trainer by Fás and all our courses are eligible for Fás funding. The Certificate and Diploma courses are based on those offered by the UK National Association of Health Store's Training School, which are recognised by the UK Department of Trade. The IAHS courses are amended to reflect Irish law and trading standards and conditions.

It is a condition of membership that all staff must undergo the IAHS training program

- all staff must hold the IAHS Certificate in Health Food Retailing
- all staff must hold the Royal Society of Health's Certificate in Food Hygiene or equivalent
- all owner/managers must hold the IAHS Diploma in Health Food Retailing

Protocol of Selling

A crucially important feature of the training program is the Retail Protocol of Selling. This sets out guidelines for the safe retailing of food supplements and natural remedies. The Key Guidelines of the Protocol state that natural remedies must not be sold in the following circumstances without professional advice:-

- to young children
- in pregnancy or lactation
- to customers under medical supervision
- to customers concomitantly using conventional medicines

Part 2 ~ Positive Implications of the IMB/SCHMP Proposals

It is well known that the SCHMP proposals have been criticised by industry and consumer groups alike, for reasons which we will deal with in Part 3. However, the proposals do have many positive features, and I think it is only fair to acknowledge the positive implications as well as the negative ones:-

1. The public will be assured of good quality, safe products across the board.

2. This will give our products a good marketing advantage over products obtainable elsewhere such as mail order or the Internet which may not be subject to any regulation.

3. Manufacturers will, at long last, be able to make claims for their products, and supply further information about them and what benefits they have.

4. Likewise, consumers will finally have access to proper information about the product and what the product is intended for. For many years consumers had to speculate, or perhaps consult unreliable sources such as the Internet for information on the benefits of herbal remedies.

5. The position of traditional medicinal products on the market will finally be recognised and assured. The regulatory cloud which has hung over this type of product for as long as I can remember will finally be lifted.

6. The products will be protected from hostile criticism by detractors of herbal medicine. Claims by these sectors such as "they are dangerous", or "they don't work, or "they are unregulated", or "they are contaminated" will all be finally shown to be without foundation.

7. For retailers, we will finally be assured that a product offered to us is above board. Our Code Ethics states that all herbal remedies must be manufactured to GMP standards. It is fair to say that most retailers tend to stick with the well-known major manufacturers who are known to work to these standards. Nevertheless, it only takes one of us to be caught out by a rogue product such as the "Cherrydex" cream, with disastrous consequences for public health, together with a permanent slur on our good reputation.

Of course, all the above positive implications assume that the proposed system is amended appropriately to address some of our concerns which we now go on to discuss.

Part 3 – Negative Implications of the Proposed Regulatory System

In Part 3, I want to briefly set out the main areas of concern as we see them. I am NOT going to go through the whole document line-by-line, as I want you all to be still awake when I'm finished !

First of all, let me state that we acknowledge the constraints which SCHMP found itself under, namely to adhere to existing medicinal licensing parameters and also to conform as far as possible to the emerging draft directive on Traditional Herbal Medicinal Products. However, we are not entirely convinced that this was the correct approach, as we are concerned about the overall workability of the proposals. We would also point out that the EU directive on Traditional Herbal Medicinal Products is only a draft, and may change quite substantially as it goes through the various stages.

1. Article 1 – Definitions and Scope

Definition

When setting out to regulate a product or group of products, it is first necessary to define and delineate that which is to be regulated. It is acknowledged in the Final Report that the definition offered is inadequate. While we acknowledge that it is very difficult task, we feel that a good definition is absolutely essential to the success of this project, as you cannot even start to regulate such products without knowing exactly what they are, and indeed what they are not.

Scope

This leads me on to the question of scope, and we are somewhat surprised to find what are usually regarded as food supplements, products such as royal jelly, fish oils and kelp, among those which may be considered as a medicinal product. Products such as these will undoubtedly be accommodated under a later version of the EU Food Supplements Directive. It is not clear from the proposals whether these particular products would be considered as traditional medicines in **all** circumstances or if they would still be able to continue as food supplements provided they did not make any claims. However, the difficulty of having, for example two kelp products on the market - one a medicine and another a food supplement is plain for all to see.

The definition and scope as presently laid down in the proposals unfortunately has the effect of maintaining the food/medicine dichotomy, an issue which has dogged previous efforts to regulate in this area. Many herbs are both foods and medicines according to the use to which they are put. This is never the case with conventional medicines which are **always** medicines, and therefore any new regulatory system needs to recognise and address this unique duality. Garlic is a classic example of this dichotomy. Thyme, sage, dandelion and nettle are all examples of this duality that

spring to mind and strong guidelines need to be drawn up to clearly establish what exactly is a Traditional Medicine.

Implications
The most important implication of this Article is that substances usually thought of as foods or food supplements may become medicinal products. Now, because they are essentially foodstuffs, these substances may not readily be evaluated as medicines. They may not be amenable to certain GMP requirements, and many will certainly not be able to demonstrate 30 years of **medicinal** use. Therefore well-known substances such as royal jelly, kelp, garlic, propolis, blue-green algae may well disappear from the market.

Even if they can be registered as traditional medicines, another implication will be that when the Traditional Medicines Directive comes along. Because the Directive only covers herbal products, these products will not be accommodated, and will presumably be illegal.

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Article 2 The definition of "Traditional use"

Under this article "Traditional use" is defined as having been in medicinal use in the Community throughout a period of at least 30 years. The thirty-year period may also be in specified territories outside the EU, provided that it has been available in the EU for at least 15 years.

Let me quote from page 29 of the IMB Final Report:-
"It is the opinion of the IMB and the ad hoc SCHMP that this does not adequately or accurately reflect the essential nature of the concept of a traditional medicinal product. This 30 year rule fails to accommodate many traditional medicinal products that, for one reason or another, cannot provide evidence of continuous medicinal use in Ireland or in another EU Member State for 30 years".

Also from page 30:-
It is the opinion of the IMB and the ad hoc SCHMP that this provision might restrict the number of products from traditions other than the western European tradition that would otherwise be eligible for registration under the proposed Directive and by extension under the interim licensing scheme.

Implications
These are our sentiments exactly, but disappointingly, in spite of these reservations, these restrictive measures still appear in the IMB proposals. This Article is Eurocentric and discriminates unfairly against non-European traditions. Here's a

rather revealing excerpt from the Explanatory Memorandum of the EU draft directive on Traditional Herbal Medicinal Products:-

In principle, only medicinal use within the Community is relevant since it is very difficult to verify whether information on use outside the Community provides a reliable basis to conclude on the efficacy and especially the safety of the product.

How's that for a perfect example of Eurocentric arrogance ?

So, does this means that information on the safety and efficacy of products is unreliable if it emanates from countries such as the USA, Canada, Australia, New Zealand, Switzerland, Norway, Japan, India, China ? Many of these countries have much richer traditions of herbal medicine than the EU Member States.

The main implication of this Article is that many Chinese, African, Ayurvedic or American medicines cannot be accommodated.

Another implication is that this rule will not encourage innovation and the development of new products. Innovation is the lifeblood of any industry and must not be curtailed.

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Article 2.3

It is unclear whether herbal substances such as whole fragmented or cut plants, plant parts, algae fungi lichen in an unprocessed, usually dried but sometimes fresh are included in the scope of the proposed system. Would this imply that any plant or plant part would be automatically considered a medicine ? I can just picture a keen gardener saying to his friends " It's been very dry lately, I have to water the **medicines** every day !", or "I think I'll prune the **medicines** today !". Or what about a lady who's just been presented with a bouquet of flowers " What a lovely bunch of **medicines** !". Sorry to be flippant, but I think this clause is just plain ridiculous. Plants are plants. They are neither foods or medicines, until they are presented as such.

Implications

We note from Explanatory Note 4 that vitamin/mineral supplements containing nutrients over the RDA are considered as medicines and must be authorised according to the Medicinal Products (Licensing and Sale) Regulations 1998. This is, in our view, an over-zealous interpretation of 65/65EEC, and as such is unacceptable. Also, Explanatory Note 4 appears to rule out combination products especially those containing combinations of herbs with vitamins and minerals over the RDA, and combinations of herbs with homoepoathic ingredients. This type of product, which

there are many, would thus be lost to the market. We also note that in Explanatory Note 3, herbal teas and juices are considered to fall within the scope of the regulatory system. We do not agree that teas or juices are medicines.

We are not convinced that it is possible to manufacture foods and beverages to pharmaceutical standards of GMP as required by these proposals. Therefore the main implication of this Article is that herbal teas and juices will disappear from the market because they are essentially foodstuffs and beverages, and not medicines.

****

Article 7 Quality Assessment

Implications
Some SMEs (Small and Medium-sized Enterprises) have stated to us that they would find it very difficult to find the resources to finance the preparation of Quality dossiers and at the same time upgrade their facilities to pharmaceutical standards of GMP. Therefore these companies may decide to withdraw from the Irish market and continue to supply their home base. For those SMEs located within Ireland, this would mean closure and the loss of jobs.

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Article 9 ~ Evaluation of Traditional Use

The same concerns and implications as those expressed under Article 2 also apply here.

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Article 10 ~ Evaluation of Traditional Indication Claims

Under this Article it is stated that:-
"Medicinal products registered under these regulations shall be available in pharmacies only or will be available for general sale".

As it is our understanding that this registration scheme only applies to medicinal products intended for minor self-treatable conditions, restriction of any of the products registered under it to pharmacy is not only totally unnecessary, it is also totally unacceptable.

Implication
The criteria under which these decisions are made are not elucidated. Depending on what basis is used for making these decisions, removal of a significant number of products from the shelves of health stores, and their restriction to pharmacy only could occur. This is would be an unfair and restrictive practice, and would be unjustifiable for products intended for self-treatable conditions.

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Article 11

Article 11.6 states that a product would be refused registration if it would be classified as a medicinal product subject to medical prescription.

Implication
Bearing in mind that the Herbal Medicines Project was initiated in response to public concern about the restriction of St John's wort to prescription, we believe that the Herbal Medicinal Project will have failed if it does not address the issue of the prescription control of herbs in some way. In our view, there are too many herbal substances which have been confined to POM status. It is difficult to understand why some, such as gingko biloba have been confined to prescription at all. This is particularly worrying in the absence of a registration system for herbal practitioners, as it means that the acknowledged experts in the field of herbal medicines cannot prescribe herbal substances to their patients.

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Article 13 ~ Appeals Procedure

This makes no provision for an Independent Appeals Procedure.

Implication
Without recourse to a properly instituted independent appeals process, products could be unfairly refused registration. The Appeals Committee must be totally independent of both the IMB and pharmaceutical or competing interests.

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Article 14 ~ Traditional Medicines Unit

This is the body which will assess products for registration. The Article states that :-

"This unit will be adequately resourced and staffed so that it has pharmaceutical, medical and herbal assessors".

Implication
In our view this will result in a preponderance of conventional medical assessors, and may result in products being denied registration because the medical and pharmaceutical assessors may not be familiar with herbal products.

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Article 15 ~ Sub-Committee on Traditional Medicinal Products

The proposed Sub-committee is to be a sub-committee of the full Advisory Committee on Human Medicines, and not a full Advisory Committee in its own right.

Implications
We find this proposal disappointing as it affords insufficient autonomy within the regulatory structure to allow fair and balanced policy decisions to be made in relation to alternative or complementary medicine, because it will always be subservient to the Advisory Committee on Human Medicines (ACHM), the membership of which is taken exclusively from the field of conventional medicines. Furthermore the proposed membership of the proposed sub-committee does not contain any industry nominated experts, who would be needed to advise on quality assurance issues or other matters which would be unique in the manufacture of herbal medicines.

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Article 19 ~ Advertising

In Explanatory Note 24, under the heading "The advertisement shall not contain any material which :-
c) suggests that the health of the subject can be enhanced by taking the medicine".

Implication
This forbids the making of health enhancement claims, which is not acceptable, as the health trade regards many herbal and food supplements products to be useful in the promotion of health.

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Well I think that's enough to keep us going for the time being ! The above is by no means a complete study of all the implications of the Proposals. In Part 4 we now turn our attention to what, if anything, can be done to ameliorate or maybe even eradicate the negative implications at least as far as we are concerned.

Part 4 – Suggestions and Solutions

In this section we present some possible solutions to the problems that we have identified.

1 Definition and scope

It would be best if the term "Traditional Medicinal Product" be confined to *bone fide* traditional medicinal products which are or have been part of an identifiable tradition of medicine anywhere in the world, whether herbal or not. Thus if it is found that kelp or acidophilus is part of any traditional medicinal system, it could be registered as a Traditional medicine. Otherwise it remains as a food supplement.

Accordingly we formally propose that the following definition of a traditional medicinal product be adopted:-

"A Traditional Medicinal product is a medicinal product containing as active ingredients, generally herbal substances, herbal preparations, but also other non-herbal substances, that are supplied on the basis of their use in an established tradition of practice.

Traditional use refers to documentary evidence that a substance has been used for a period of over 30 years of recorded use ***anywhere in the world*** *for a specific health related or medicinal purpose.*

Using the above as a core definition, a set of guidelines should be developed in consultation with the industry, to clearly delineate between food supplements and traditional medicines.

2. Route of Sale (Article 10)

As these regulations cover only those traditional medicines deemed suitable for minor, self-treatable conditions, all medicines so registered should all be for general sale.

3. Independent Appeals Process (Article 13

An independent appeals procedure must be established.

4. Regulatory Structure (Article 15):-

The IAHS calls for the establishment of a separate **Natural Healthcare Authority** under the auspices of the Department of Health and Children, to take responsibility

for the regulation of all natural health products including traditional medicines as well as complementary or alternative practitioners.

We contend that there would be insufficient autonomy within the proposed structural changes within the IMB to allow equitable policy decisions to be made in relation to alternative or complementary medicine. We suggest that the proposed sub-committee will not have the power or sufficient autonomy to fairly adjudicate on matters of crucial importance to the industry, and will always be subservient to the Advisory Committee on Human Medicines (ACHM). The membership of ACHM is exclusive to members of the conventional medicine profession. Furthermore the proposed membership of the proposed sub-committee does not contain any industry nominated experts, who would be needed to advise on quality assurance issues or other matters which would be unique in the manufacture of herbal medicines. This could result in policy being decided upon which may be detrimental to the equitable evaluation of products.

Furthermore the proposed Traditional Medicines Unit of the IMB would seem to have a preponderance of conventional medical assessors, which may result in biased judgements against the registration of traditional medicinal products.

Conclusion

We live in a time of unprecedented demand on our public healthcare system, which is generally considered to be in crisis. The health system is overburdened as a result of a combination of factors including an ageing population, poor dietary habits, lack of exercise, unhealthy work practices, pollution, stress, and the over-reliance on medication.

The healthcare system is almost exclusively directed to the treatment of disease, rather than the promotion of health, which may have prevented the disease in the first place.

Thousands of people are now turning to lifestyle choices which include good dietary practices, stress reduction techniques, plenty of exercise etc. Many choose to supplement their diet with natural health products, and there is an increasing body of evidence to suggest that food supplements may reduce the risk of chronic disease. Rather than clogging up doctors' surgeries, many people choose to treat minor ailments with Over-The-Counter remedies. There is a very important role here for herbal remedies to contribute to the overall health of the nation, and on doing so may relieve some of the pressure from the health system.

We have been assured by the IMB, by SCHMP, and by Dr Corrigan himself that the purpose of these proposals is to legalise the position of products already existing on the market, and that it is not the intention to remove them. However we only have to look at Article 2.1 the contentious "30 year rule" to realise that while it may not be the intention to remove product, it will certainly have that effect.

Many of the problems identified in Part 3 emanate from the fact that these proposals merely seek to "shoehorn" traditional remedies into a regulatory framework which was designed for powerful modern pharmaceuticals. In the case of substances which are **always** medicines this does not present any problems. However, in the case of natural substances which may be either medicines or foods it becomes unworkable. Can products which are essentially the same exist on the market in two different guises i.e a traditional medicine and a food supplement, and if so, on what basis ? In our view this dichotomy presents almost insurmountable problems, which can only really be overcome by a change of tack. That is why we advocate the establishment of a new specialised regulatory authority.

We believe that herbal medicines need a different regulatory approach than conventional medicines which reflects their nature and characteristics. Sometimes totally new legislation is required. We feel that a golden opportunity has been lost to devise a unique regulatory system especially designed for Natural Health Products, such as the Canadian system, which would be the envy of the world. Ideally, this would be a system which would be more equitable, workable and appropriate recognising the nature of the products, especially their complex composition, and which would reflect their superb safety profile which is markedly superior to that of conventional medicines, and indeed, to that of food.

Maintaining a Sense of Perspective and The Dangers of Over-regulation

It is often stated that just because a substance is "natural" doesn't mean it's safe. According to the Journal of the American Medical Association, properly researched, regulated, prescribed and used drugs are the fourth largest cause of death in the US, killing an estimated 100,000 people per year, and injuring in excess of two million. 500,000 people are killed every year by aspirin alone. Non-steroidal anti-inflammatories (NSAIs) are responsible for an estimated 20,000 deaths per year. Zyban has killed over 50 in the UK. Paracetamol kills 200 people every year in the UK alone. We have no figures for fatalities in Ireland.

On the other hand, St John's wort has had no reports of deaths in Ireland, the UK or in any other EU Member State. Similarly with Gingko biloba. Kava kava has had no reports of any adverse reactions either in Ireland or the UK. Kava has a history of safe use particularly in the South pacific for centuries. Suddenly over the last two

years there have been 30 reports of liver damage, but most of these cases, subjects were also taking conventional medicines that can also cause liver damage or over-dosing on alcohol.

These three herbs have been taken off the market, while paracetamol, aspirin, zyban and NSAIs remain.

There is clear evidence that under current regulations, proper risk analyses of herbal products are not being carried out. The degree of regulation must be proportional to the degree of risk. If there is over-regulation of a particular sector, then the regulatory system becomes self-defeating and indeed counterproductive in that it gives rise to black market conditions, in which there are no regulations or standards whatsoever.

The hazard or the degree of risk that over-regulation presents is therefore greater than that which would prevail if there was no regulation at all. I would urge that a sense of proportion prevail so that a fair, appropriate, transparent and workable regulatory system emerges for this type of product that we can all have confidence in.

Thank you for listening.

IMPLICATIONS FOR THE COMMUNITY PHARMACIST.

- INTRODUCTION
- PRODUCT QUALITY
- EDUCATION
- PATIENT/CUSTOMER CARE

CONFIDENCE

- CHOICE FOR CUSTOMER/ PATIENT

- CHOICE FOR THE PHARMACIST

QUALITY OF PRODUCTS

PREPARED TO THE HIGHEST STANDARDS BY THE MANUFACTURES ENSURING

- CONSISTANCY OF PRODUCT QUALITY
- QUALITY OF PRODUCTS
- SAFETY OF PRODUCT

STORED AND TRANSPORTED UNDER THE CORRECT CONDITIONS FOR THE PRODUCT ENSURING

- QUALITY OF PRODUCTS
- CONSISTANCY OF PRODUCT QUALITY
- SAFETY OF PRODUCT
- NO DETERIATION IN PRODUCT FROM MANUFACTURE TO MY SHELF.

PRODUCTS PRESENTED TO CUSTOMERS

- QUALITY LABELLING
- QUALITY IMFORMATION LEAFLETS

SAFETY

- WHAT IS THE PRODUCT SAFELY USED FOR TRADITIONALLY
- CONTRAINDICATIONS
- SPECIAL WARNINGS AND PRECAUTIONS
- INTERACTIONS WITH OTHER MEDICATIONALS AND OTHER HERBAL PRODUCTS
- USE IN PREGNANCY AND LACTATION
- UNDESIRABLE SIDE EFFECTS
- OVERDOSE
- DOSAGE FOR ADULTS, CHILDREN AND THE ELDERLY.

ADVERTISING

- RESPONSIBLE ADVERTISING

PHARMACOVIGILANCE

- CONFIDENCE THAT ALL PRODUCTS ARE BEING MONITORED TO ENSURE THE SAFETY OF CUSTOMERS
- REPORTING BY THE PHARMACIST OF ADVERSE REACTIONS, INTERACTIONS WITH OTHER PRODUCTS AND ANY UNDUE DETORIATION IN PRODUCT

EDUCATION

- MYSELF

  - RELEVENT BOOKS AND JOURNALS
  - LITERATURE FROM COMPANIES
  - THE PREPESENATIVE OFCOMPANIES
  - INTERNET
  - TRAININGS
  - MAGAZINES
  - FEEDBACK FROM CUSTOMERS/PATIENTS

- STAFF

  - RELEVENT BOOKS AND JOURNALS
  - LITERATURE FROM COMPANIES
  - COMPANY REPESENATIVES
  - INTERNET
  - TRAININGS GIVEN BY MYSELF,OTHER STAFF MEMBERS OR RELEVANT COMPANIES
  - MAGAZINES
  - FEEDBACK FROM CUSTOMERS

CUSTOMER/PATIENTS

- PHARMACY STAFF AND HEALTH FOOD STORES.
- LEAFLETS AND IMFORMATION PROVIDED BY COMPANIES
- MAGAZINES
- INTERNET
- BOOKS
- ADVERTISING
- FRIENDS

PATIENT / CUSTOMER CARE

CONSULTATIONS WITH PATIENTS

- PRESCRIPTION MEDIACTION AND INTERACTIONS WITH OTC MEDICINES,HERBAL REMEDIES,AROMATHERPY PRODUCTS,HOMEOPATHIC REMEDIES ETC.
- SUPPLEMENTS, VITAMINS, FISH OILS, ETC
- CONTARINDICATIONS
- LIMITATIONS AND RECOMMENDATIONS

CONSULTING WITH CUSTOMERS AND PATIENTS

- MAINTAIN THEIR HEALTH
- IMPROVE THEIR HEALTH
- PREVENTATIVE MEDICINE
- MINOR AILMENTS
- LIMITATIONS AND RECOMMENDATIONS

PATIENT COMPLIANCE

- DOSAGE
- DURATION
- AFTERCARE

The National Licensing Scheme for Traditional Medicinal Products in Ireland

A Presentation by

Dr. Desmond Corrigan
B.Sc.(Pharm), M.A., Ph.D, F.L.S., F.P.S.I.
Director
School of Pharmacy
Trinity College Dublin

at the

Irish Medicines Board Seminar

Hilton Hotel
Dublin
May 2nd 2002

IMB regulations' potential to decimate herbal medicines

REPRESENTATIVES OF BOTH suppliers and retailers of herbal medicines have hit out at the IMB's new draft regulations.

The Irish Association of Health Stores and the Irish Health Trade Association have claimed the new legislation has the potential to decimate business in the sector.

"Tens of thousands of Irish people rely on safe traditional herbal remedies for their primary health care," said Aideen Hurley of the Irish Association of Health Stores, which represents 80 retailers.

"These people are spending their own money and making their own choices of the kind of health care they want — very likely saving the Exchequer money," she added.

Both organisations have been critical of the IMB's failure to offer a definition of a medicine. They do not agree with the legal definition of a pharmaceutical medicine being applied to traditional medicines, arguing that they should have their own category.

The Irish Health Trade Association said suppliers and manufacturers had been seeking regulations for more than a decade.

The organisation added that it has serious reservations with the format chosen to come up with legislation, but pledged to co-operate in the search for appropriate regulations.

"Our concern is that the regulations don't formally recognise traditional medicines," explained spokesman Jonathon Griffith.

"Without formal recognition, traditional medicines are in danger of being overwhelmed by the conventional medicine system into which they are being drawn," he added.

Phytotherapy Care

(with apologies to Hepler & Strand!)

"The responsible provision of Herbal Medicinal Products for the purpose of achieving definite outcomes that improve a patient's quality of life".

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.01.2002
COM(2002) 1 final

2002/0008 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending the Directive 2001/83/EC
as regards traditional herbal medicinal products

(presented by the Commission)

Irish Medicines Board Scientific Committee on Herbal Medicinal Products.

Chair:	Dr. D. Corrigan Director, School of Pharmacy, TCD.
Secretariat:	Dr. D. Dempsey Herbal Medicinal Products Project Manager, IMB.
Members:	Aromatherapist/Pharmacist G.P./ Medical Herbalist G.P./ TCM Specialist Medical Herbalist/Aromatherapist Medical Herbalist Pharmacognosist Phytochemist Prof. E. Ernst (External Advisor)
In attendance:	C.E.O., IMB Medical Assessor, IMB Pharmaceutical Assessor, IMB.

Irish Medicines Board
SCHMP
Terms of Reference

- advise in relation to an interim National Licensing Scheme pending introduction of EU Directive 2002/0008 (COD).

- the Scheme to be brought in by Regulation not Primary Legislation.

- adequately define the medicinal products to which it relates.

- adequately address standards of quality and safety.

- where standard proof of efficacy has not been met that,
  - the product should be identifiable
  - the medicinal claims made be appropriate
  - the interests of public health be adequately protected.

National Licensing Scheme
Institutional Framework

1. Traditional Medicinal Products Unit.
   - to include herbal assessors.

2. Sub-Committee on Traditional Medicinal Products.
   - Medical Herbalism
   - Medicine
   - Pharmacy
   - Pharmacognosy
   - Toxicology
   - Aromatherapy
   - TCM
   - Complementary Medicine

3. Chair of S-C on TMP to be member of ACHM.

Terms of Reference for S-C.T.M.P.

1. Monitor implementation of scheme.

2. Establish national listing of approved indication claims.

3. Establish list of approved bibliographic sources.

4. Approve any positive list.

5. Approve any negative list.

6. General advice and technical support to T.M.U.

Adequately define the medicinal products to which it relates.

- '30 year' rule ex Directive.

- Australian TGA.

- Canadian.

- IAHS.

Criticism of Directive

1. 30 year rule.
   - not definition of 'tradition'
   - extension of timeframe of "well-established use"

2. Exclusion of Ethnic Medicines
   - discriminatory on ethnic grounds
   - does not provide consumer protection
   - reduces licit consumer access

Contamination of Ethnic Products with Synthetic Drugs and Minerals

Steroids

Phenylbutazone

Benzodiazepines

Arsenic

Lead

Mercury – 'Shu Gan Wan'

Of 11 Chinese Herbal Creams for Eczema - 8 contained Dexamethasone

Australian TGA

Complementary Medicines Evaluation Committee

"Traditional use refers to documentary evidence that a substance has been used over three or more generations of recorded use for a specific health related or medicinal purpose".

Canadian Definition

Natural health products are products manufactured, sold or represented for use in:-

(i) The diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans;

(ii) Restoring or correcting organic functions in humans, or

(iii) Maintaining or promoting health or otherwise modifying organic functions in humans.

Specifically, medicinal ingredients of Natural Health Products are those set out below, alone or in combination.

(a) a homoeopathic preparation.

(b) a substance or substances used as a traditional medicine, including, but not limited to, a substance used as a traditional Chinese medicine, a traditional Ayurvedic medicine or a North American aboriginal medicine, and

(c) a mineral or a trace element, a vitamin, an amino acid, an essential fatty acid or other botanical, animal or micro-organism derived substance.

Submitted Definition

"A traditional medicinal product is a medicinal product containing as active ingredients, generally herbal substances, herbal preparations but also other non-herbal substances, that are supplied on the basis of their use in an established tradition of practice".

Definition of Complementary Medicine

(B.M.J 1999;319:693-696 (11 Sept)

"Complementary and Alternative Medicine (CAM) is a broad domain of healing resources that encompasses all health systems, modalities and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period.

CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being. Boundaries within CAM and between the CAM domain and that of the dominant system are not always sharp or fixed".

Possible Definition of "Traditional Medicinal Product"

A traditional medicinal product is a medicinal product used in a system of medicine (other than that intrinsic to the politically dominant health system of a particular society, or culture in a given historical period) which is self-defined by its practitioners or by its users as preventing or treating illness or promoting health and well being".

Republic of Ireland
Scope of Proposed National Scheme

1. Herbal Medicinal products that have a proven traditional use.
2. Additional classes of traditional medicinal products.

- Fish oils
- Royal jelly
- Kelp
- Activated Charcoal
- Chinese products
- Ayurvedic products
- Other ethnic products

(Anthroposophic products?)

Republic of Ireland
Scope of Proposed National Scheme

3. Products included only with medical claims.

- Essential oils for external use.
- Herbal teas.
- Topical Aloe Vera products
- Herbal juices

Republic of Ireland
Scope of Proposed National Scheme

4. Combination products.

- Traditional combinations.
- Combinations which are not traditional?
- Traditional plus vitamins?

5. Products to be excluded.

- Those covered by Poisons Act and Misuse of Drugs Act etc.
- Vitamin products.
- Mineral products.
- Homoeopathic products.
- Bach and similar flower remedies.

Adequately address standards of quality

- N.f.G. on Quality of HMP's
- N.f.G. on GMP for HMP's
- P.T.C. on Good Agricultural and Collection Practice for starting materials of herbal origin.

Herbal Medicinal Products

The purpose of Quality Control.

1. Proof of identity.
2. Proof of quantity present.
3. Proof of phytochemicals present.
4. Proof of purity
   - absence of other plants
   - absence of pesticides
   - absence of heavy metals
   - absence of bacteria and fungi
   - absence of mycotoxins
   - absence of rodent/insect filth
   - absence of fumigants
   - absence of synthetic drugs

QC/QA amenable to External Audit.

Pharmacopoeial Monographs

European Pharmacopoeia
101 Plant Monographs in 2002 Edn.

National Pharmacopoeia's
French, German
Swiss, Italian
Chinese, Japanese

British Herbal Pharmacopoeia

W.H.O. Monographs

[redacted]

MANUFACTURE OF HERBAL MEDICINAL PRODUCTS

Principle

Because of their often complex and variable nature, and the number and small quantity of defined active ingredients, control of starting materials, storage and processing assume particular importance in the manufacture of herbal medicinal products.

Premises

Storage areas

1. Crude (i.e. unprocessed) plants should be stored in separate areas. The storage area should be well ventilated and be equipped in such a way as to give protection against the entry of insects or other animals, especially rodents. Effective measures should be taken to prevent the spread of any such animals and micro-organisms brought in with the crude plant and to prevent cross-contamination. Containers should be located in such a way as to allow free air circulation.

2. Special attention should be paid to the cleanliness and good maintenance of the storage areas particularly when dust is generated.

3. Storage of plants, extracts, tinctures and other preparations may require special conditions of humidity, temperature or light protection; these conditions should be provided and monitored.

Production area

4. Specific provisions should be taken during sampling, weighing, mixing and processing operations of crude plants wherever dust is generated, to facilitate cleaning and to avoid cross-contamination, as for example, dust extraction, dedicated premises, etc.

Documentation

Specifications for starting materials

5. Apart from the data described in General Guide (chapter 4, point 4.11), specifications for medicinal crude plants should include, as far as possible:

   — the botanical name (with, if appropriate, the name of the originator of the classification, e.g. Linnaeus);

   — the details of the source of the plant (country or region of origin, and where applicable, cultivation, time of harvesting, collection procedures, possible pesticides used, etc.);

Medicinal Products for Human and Veterinary Use:

Good Manufacturing Practices.

Annex 7.

Manufacture of Herbal Medicinal Products.

8. Quality Control.

Quality control personnel should have particular expertise in herbal medicinal products in order to be able to carry out identification tests and recognise adulteration, the presence of fungal growth, infestations, non-uniformity within a delivery of crude plants etc.

(Eudralex vol. 4)

Quality Guidelines for Herbal Medicinal Products.

1. EU Guideline on Quality of Herbal Medicinal Products.
2. EU Guideline on Good Manufacturing Practice (GMP) for Herbal Medicinal Products.
3. Guidelines for Good Agricultural Practice (GAP) for Medicinal and Aromatic Plants.
4. European Pharmacopoeia Monograph. Products of Herbal Origin.
5. WHO Guidelines on Quality Control Methods for Medicinal Plant Materials.
6. WHO Supplementary Guidelines for the Manufacture of Herbal Medicinal Products (GMP).

BRITISH HERBAL MEDICINE ASSOCIATION (BHMA)

Code of Good Practice — *June 2000*

HERBAL REMEDIES EXEMPT FROM LICENSING

Definitions
Words and phrases appearing in italics shall be defined according to the meaning ascribed to them by the Medicines Act 1968, and, in the case of the term "Herbal Practitioner", shall be defined as any person who sells, supplies, manufactures or assembles a herbal remedy exempt from licensing in the course of a business in compliance with the conditions prescribed by Section 12 (1) (a) and (b) of that Act.

Members Declaration
The member agrees to uphold the objects, standards and requirements prescribed by this Code of Good Practice and to co-operate with the British Herbal Medicine Association (BHMA) and the United Kingdom Medicines Control Agency (MCA) in regulating and promoting compliance with the Code and relevant United Kingdom and European legislation and regulations governing herbal remedies exempt from licensing.

Object
To promote the safety and efficacy of herbal remedies exempt from licensing by prescribing a clear framework of Good Practice within the United Kingdom and applicable European legislation with the object of protecting the health and well being of the patient/customer when choosing an unlicensed *Herbal Remedy*.

Raw Materials
1 The use of all ingredients excluding excipients used in the manufacture of a herbal remedy exempt from licensing shall, in so far as such ingredients appear, comply with the status and category prescribed by the provisions of the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984, as amended and the Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977 and all other regulations, restrictions or requirements as may from time to time be applicable to the use of such ingredients.

2 All ingredients excluding excipients used in the manufacture of a herbal remedy exempt from licensing shall conform to standards prescribed in the relevant sections of the publications referred to in Schedule I.

Manufacture
3 All procedures followed and processes used in the manufacture of a herbal remedy exempt from licensing shall, save in the case of those prepared by a herbal practitioner, conform to the standards recommended by Her Majesty's Government (HMG) publication "A Guide to Good Manufacturing Practice" or such other HMG publication as may from time to time replace or amend the same.

4 The substances referred to in Schedule II shall not be included as ingredients in the manufacture of any herbal remedy exempt from licensing.

Labelling
5 The *labelling* of all *containers* and *packages* used in the storage of herbal remedies exempt from licensing for the purpose of marketing, sale or other provision to the public shall comply with all relevant regulations made pursuant to section 85(1) Medicines Act and, where appropriate with other provisions of that Act and pursuant regulations regarding the inclusions of *appropriate quantitative particulars* and, in any event, with EC Directive (92/27 EC).

Quality Defects & Adverse Reactions
6 Any member who suspects a herbal remedy exempt from licensing of being defective, either as a result of it's qualitative standards or as a result of an adverse reaction suffered by a patient/customer, shall report full details of the defect to the BHMA who may, at their discretion pass the report to the Defect Medicines Reporting Centre or the Adverse Reaction/Pharmacovigilance Group in the MCA.

7 All members shall respond promptly and responsibly to any warnings issued by either the BHMA or the MCA concerning the quality or safety of any herbal remedy exempt from licensing products.

Enforcement
8 The regulation of this Code of Good Practice shall be the responsibility of the BHMA who will work with the support and co-operation of the MCA.

CODE OF GOOD PRACTICE (HERBAL REMEDIES EXEMPT FROM LICENSING)

Schedule I
Publications

The European Pharmacopoeia

The British Pharmacopoeia/Compendia

The British Herbal Pharmacopoeia

The Chinese Pharmacopoeia

The Japanese Pharmacopoeia

Schedule II
Prohibited Substances

Heavy metals or their chemical derivatives

Synthetic medicinal substances

Substances derived from species currently scheduled in the Convention on International Trade in Endangered Species (CITES)

EU Definitions

Traditional Medicines Directive

Labelling

- Herbal Medicinal product for traditional use in a specified indication.

- efficacy has not been clinically proven but relies exclusively on long-term use and experience.

- user should consult a doctor or a *qualified practitioner* if the symptoms persist.

- The nature of the tradition may be required to be stated.

Adequately address standards of safety

- No toxicity tests required.

- Bibliographic evidence
  - ESCOP monographs
  - WHO monographs
  - articles in scientific journals
  - relevant reference texts

- Expert report could validate traditional knowledge and experience.

Appropriate Medicinal Claims

- Wording proposed by applicant
- Justified by expert
- No clinical trials needed
- Justified by bibliographic evidence
  - ESCOP monographs
  - WHO monographs
  - Commission E monographs

Avis aux Fabricants

Australian CMEC

French. Avis Aux Fabricants

Indication Claims

- Traditionally used in the treatment of minor circulatory disorders.

- Traditionally used in travel sickness.

- Traditionally used in the symptomatic treatment of neurotonic conditions of adults and children notably in cases of mild disorders of sleep.

- Traditionally used in subjective signs of venous insufficiency such as heavy legs (Topical).

Australian TGA
Indication claims

- May help increase joint mobility associated with arthritis.

- For the symptomatic relief of premenstrual tension syndrome.

- Helps relieve nervous tension, stress and mild anxiety.

- To help maintain blood circulation to the peripheral areas of the body such as the legs, hands and feet.

- Formula to support the liver.

Public Health

Be Adequately Protected

- Products not meeting minimum quality standards.

- Products which are unsafe under normal conditions of use.

- Products whose labels or advertising is untruthful.

Implications of National Licensing Scheme

- Derogation from "normal" regulatory process.
- Reduced burden on manufacturers.
- No expensive Pharmacotoxicological tests.
- Expert Report to collate Bibliographic and Empirical Evidence of Safety.
- No expensive clinical trials
  - Expert Report to incorporate evidence from herbal practitioners.
- Applicant to propose and justify wording of indication claim.

Advantages of National Licensing Scheme

1. Products with defined Regulatory Status.

2. Enhanced consumer protection.

3. Independent audit of Quality and Safety.

4. Accuracy check on information to the consumer.

5. Prevention of safety problems through improved Quality Assurance.

MAURICE MESSÉGUÉ

MAKE USE OF MY BELOVED PLANTS....
BUT MAKE SURE THAT YOU GO AND SEE YOUR DOCTOR WHENEVER IT BECOMES NECESSARY.

TO TRUST IN NATURE DOES NOT MEAN THAT YOU MUST DEPRIVE YOURSELF OF THE DISCOVERIES OF SCIENCE.

I have been studying medicinal plants since I became a Pharmacy student in 1962. Professionally I am a Pharmacognosist – a specialist in medicinal plants and as such a member of staff of the only University Department of Pharmacognosy in the British Isles. I, along with my colleagues, have a vested interest in seeing more people use more plant based medicines.

We have an interest in exploiting plants as sources of medicines e.g. the use of Taxol® from Yew trees to treat cancer. We have an interest in using phytochemicals as lead molecules for new synthetic drugs. But above all I have an interest, chiefly through my work as Chairperson of the ESCOP Scientific Committee over the past eleven years, in the use of plants directly as medicines. That is where the plant itself or an unprocessed extract is administered directly to the patient.

A key and welcome milestone in the increasing use of traditional medicinal products is the draft Directive 2002/008(COD) which will amend Directive 2001/83/EC as regards traditional herbal medicinal products. The approach adopted by this draft Directive heavily influenced the National approach adopted in Ireland and the work of the *ad hoc* Scientific Committee on Herbal Medicinal Products (SCHMP) which I was privileged to chair. This SCHMP was established to advise the Irish Medicines Board (IMB) on the interim National Scheme which would ensure consumer access, on a secure regulatory basis, to high quality traditional medicinal products pending the enactment and implementation of the EU Directive.

It was indeed a privilege for me to be invited to establish and chair a talented multidisciplinary Committee comprised of Medical Herbalists, Aromatherapists, Pharmacognosists, Phytochemists, Pharmacists, Medical Practitioners as well as Complementary Medicine and TCM Specialists who worked constructively and effectively with specialist staff from the IMB to fulfil, in a timely manner, the terms of reference, from the Minister of Health and Children to the IMB. These terms were as follows:-

To advise the Minister in relation to an interim National Licensing Scheme pending introduction of EU Directive 2002/0008 (COD).

That the Scheme to be brought in by Regulation not Primary Legislation.

That it should adequately define the medicinal products to which it relates.

That it should adequately address standards of quality and safety.

And where standard proof of efficacy has not been met that,

- the product should be identifiable
- the medicinal claims made be appropriate and
- the interests of public health be adequately protected.

It is important to consider these Terms of Reference carefully to establish exactly what we were asked to do and equally and more importantly what we were not asked to do.

What was not included.

1. We were not asked to advise the Minister for Health on Statutory Self Regulation (SSR) for herbal practitioners. We did draw the Minister's attention to the fact that the Scheme we were proposing could not function if highly trained medical herbalists were required to hold a manufacturers license and to have individual product authorisations for each and every extemporaneous prescription they compounded for dispensing to patients under their care. The need for an interim exemption pending SSR and appropriate wording for such was incorporated into the final report to the Minister.

2. We were not asked to review the list of plants which are on the prescription only list in Ireland. There is a recognition that there are well established procedures for deregulating a prescription only product to an over the counter product.

3. We were not asked to devise a new regulatory agency or system for traditional medicinal products. It was and indeed still is open to a Minister for Health and the Government of the day to establish an Expert Committee to advise on such a new

regulatory agency and structure. The present Minister for Health and Children chose not to do that, but chose instead to ask the Irish Medicines Board to advise on an interim scheme which could be introduced by Regulations and which would not require primary legislation. That, therefore, further implied that the SCHMP was expected to work within the concepts of Directive 65/65/EEC as interpreted by the European Court of Justice. I would also point out to those vehemently opposed to the definition of a medicine as set out in 65/65/EEC that the Member States did have an opportunity last year, during the review of Pharmaceutical legislation which led to the Codified Human Medicines Directive 2001/83/EC, to revise the definition of a medicinal product and they chose not to do so.

Accomplishments.

On the positive side what has been accomplished?

Institutional Framework.

The SCHMP has recommended the establishment of a permanent, adequately resourced and staffed Traditional Medicines Unit (TMU) within the IMB. The staffing will include herbal assessors i.e. those with formal education and training in herbal medicine and its practice, who will work alongside pharmaceutical and medical assessors. The former are essential for the evaluation of those Expert Reports on Safety and those justifying the indication claims which will draw together empirical evidence and crucially the experience of practitioners as well as the available bibliographic information.

That TMU will be supported by a multidisciplinary Subcommittee on Traditional Medicinal Products (STMP). The multidisciplinary nature of that STMP is vital. Experience of working within its predecessor has shown all of us involved, the value of having a range of disciplines, knowledge and expertise available. The possibility of having this subcommittee established as a full Statutory Committee was discussed but since that would have required an amendment of the Irish Medicines Board Act i.e. primary legislation, it could not fall within the Terms of Reference. The SCHMP was of one mind over the question of the multidisciplinary membership, believing that strength is built on diversity. The scientific and professional independence of those appointed to the STMP is another advantage which would be in jeopardy if

representatives of the industry were appointed to the STMP as some have suggested. Given the commercial sensitivity of the information which would be discussed by the STMP, conflicts of interest would be frequent, inevitable and unacceptable.

Implications for the CHMP.

The lessons learned by my colleagues and I about the need for, and value of multidisciplinary working could usefully be applied to certain aspects of the new EU Directive on Traditional Herbal Medicinal Products. In particular, the proposal to establish a Committee on Herbal Medicinal Products (CHMP) within the EMEA in London. As presently worded this Committee will consist of one member from each EU country chosen because of their role and experience in the evaluation of HMP's who will represent their competent authorities. This Committee will establish Community herbal monographs under both the "well-established use" regime and the "Traditional" scheme. With all due respect to those regulators experienced in the evaluation of HMP's, such a task is too important to be left to the regulators alone. I have proposed that the European Parliament should be given the right to nominate as full voting members of the CHMP, two scientists particularly qualified in the field of medicinal plants and two practitioners particularly qualified in the field of herbal medicine. This proposal is based on the precedent which allows Parliament to appoint *"two scientists particularly qualified in the field of drugs, designated by the European Parliament on the basis of their particular qualifications in that field"* to the Board of the European Monitoring Centre for Drugs and Drug Addiction under Council Regulation (EEC) No. 302/93.

To avoid any misunderstanding I have in mind the appointment of independent scientists such as Professor Arnold Vlietinck of Belgium, Professor Franco Vincieri of Italy or Professor Gerhard Franz of Germany who attend meetings of the HMP Working Party of the EMEA at present. The value of practitioners on such a committee should be self-evident. Certainly my experience of working with herbal practitioners on the Irish Committee has convinced me that the European CHMP needs their input. How else can data on the traditional use of the medicinal product be assessed for sufficiency? How else can the requirement that the efficacy is plausible on the basis of long-term use and **experience** (my emphasis) be adequately assessed?

Adequately define the medicinal products to which it relates.

This aspect of our work has attracted much criticism. It has also been the most difficult aspect because at all times my colleagues and I had to bear in mind that we were advising on an interim scheme. Therefore, we needed to work up a scheme that would allow a seamless transition from the National into the Transnational systems. We found ourselves stuck with a faulty so-called definition.- the 30 year rule from the Directive. That 30 year rule is not an adequate definition of "tradition" or of "traditional use". I recognize the compromise it represents but it is wrong. In my personal opinion it is merely an extension of the timeframe of "well-established use" as set out in Article 10.1.a.(ii) of the Human Medicines Directive (2001/83/EC).

(a) The applicant shall not be required to provide the results of toxicological and pharmacological tests or the results of clinical trials if he can demonstrate:

(ii) that the constituent or constituents of the medicinal product have a well established medicinal use, with recognized efficacy and an acceptable level of safety, by means of a detailed scientific bibliography.

There are several factors to be taken into account in assessing the validity of "well-established use", including that the product must have been in documented use in the EC for not less than 10 years. To all intents and purposes therefore the present flawed definition for Traditional Herbal Products is merely an extension from 10 to 30 years. It suffers from the fact that it does not address the concepts of traditional use within its different paradigms and cultures. It also discriminates against ethnic medicines from non-European traditions, many of which are unlikely to have been on the market within the EU for even the 15 years required as part of a further compromise. I do not believe this is acceptable on ethnic grounds because these medicines and the systems of medicine which give rise to them must be valued culturally and accorded the respect they deserve. Equally consumer protection will not be provided for. This is ironic because many of the safety problems encountered have involved ethnic medicines especially those of the Chinese tradition. These range from the Fang Ji Case to the contamination with Phenylbutazone of Chuifong Toukawan Rheumatism Pills. It might have been thought that such occurrences were a thing of the past but the spate of reports in the first 3 months of this year show the need to include these medicines within the Scheme in order to protect consumer safety and also to ensure consumer access to the valuable pharmacopoeias of those ethnic traditions.

Alternative Definitions.

The SCHMP and the IMB have made known our misgivings at European level without success, so far. The difficulty we faced was in formulating an alternative definition. We did consider the wording from the Complementary Medicines Evaluation Committee of the Australian TGA which states that *"Traditional use refers to documentary evidence that a substance has been used over three or more generations of recorded use for a specific health related or medicinal use"*. There was some debate over how many years constituted a generation and the consensus was 20, so we would have been requiring evidence of use over 60 years. This was considered to be more problematic than the EU's 30 years. We were also surprised that originally the Canadian Committee had not defined traditional use and that a definition had only recently emerged which still does not define traditional use but lists some examples. One helpful definition was submitted by the Irish Association of Health Stores which refers to *"use in an established tradition of practice"*. Unfortunately this begs the question of "established by who and for how long?" and we still have no clear idea of what is an established tradition of practice and how it could be described and set down in the legally binding language of a Regulation. Because of time constraints and the difficulty of formulating an acceptable alternative definition/description the Committee reluctantly accepted the need to work within the parameters of the Directive while seeking to have the Directive improved. Implicit in that, is a need to put forward an alternative definition which captures and acknowledges the cultural concepts and paradigms of traditional systems of medicine. The definition I put forward for discussion attempts to do that by borrowing from some of the phrases used in the Cochrane Collaboration's Definition of Complementary and Alternative Medicine. This reflects a personal suggestion and does not represent the thinking of the SCHMP.

Possible Definition of "Traditional Medicinal Products"

A traditional medicinal product is a medicinal product used in a system of medicine (other than that intrinsic to the politically dominant health system of a particular society, or culture in a given historical period) which is self-defined by its practitioners or by its users as preventing or treating illness or promoting health and well being".

Scope of the National Scheme.

The scope of the proposed National Scheme is broader than the Directive, firstly because the early drafts of the Directive were more inclusive than the final version published in January, secondly because there was a desire to facilitate the continued availability of products other than Herbal Products by also giving them a clear and unambiguous regulatory status. Some would view the inclusion of materials such as Fish Oils and Royal Jelly in products making medicinal claims, as a punitive measure, when the actual intent is to accommodate such products which are potentially "homeless" in regulatory terms and give them an assured and definite regulatory status. Other "homeless" products such as Anthroposophic remedies could be included if the review of the Homoeopathic Directives did not result in their inclusion within that framework. It has also been stated that Combination Products of herbal substances and vitamins would be included and that the levels of vitamins allowable will be in line with EU legislation in force at the time. Thus, if the new Food Supplements Directive permits levels of vitamins up to the Upper Safe Limit (USL) as opposed to the RDA's currently in force, then those USL's would also apply to Combination Products within the National Scheme. There is also a clear commitment to develop Guidelines in conjunction with the industry that would help clarify these matters. Our response to the submissions made concerning the draft final report highlights the organic nature of any such Guidelines and the fact that they will be continually modified in the light of practical experience with the intention of making these classifications as useful and as transparent as possible.

Adequately Address Standards of Quality.

It is my contention that the implementation of various guidelines on Quality and GMP for HMP's as set out by the EMEA or globally by the World Health Organisation would do much to eliminate many of the adverse reactions reported to have been caused by HMP's. Far too many of the serious toxicity problems reported with HMP's have, after investigation, turned out not to involve the herbal substances themselves, but some other toxic plant, an undeclared synthetic drug or an environmental contaminant such as a heavy metal. In other words, I remain convinced that many so-called safety problems are easily preventable by proper implementation of Quality Control and Quality Assurance Schemes. These must be based on recognised

protocols which have been specifically adapted to the special circumstances arising from the use of plant materials in particular. There has been criticism that these requirements are too onerous but when one looks at the purpose of the Quality Guidelines for HMP under the following headings one can reasonably ask which aspect could be safely omitted.

The Purpose of Quality Control.

1. Proof of identity.
2. Proof of quantity present.
3. Proof of phytochemicals present.
4. Proof of purity
   - absence of other plants
   - absence of pesticides
   - absence of heavy metals
   - absence of bacteria and fungi
   - absence of mycotoxins
   - absence of rodent/insect filth
   - absence of fumigants
   - absence of synthetic drugs

It is surely also in the interests of the consumer that procedures used to ensure quality should be amenable to an external audit conducted on their behalf by an independent authority. Compliance with these requirements should not need extensive basic research, because many quality monographs are well-documented in the European Pharmacopoeia, in National Pharmacopoeias (French, German, Swiss) and in unofficial pharmacopoeias such as British Herbal Pharmacopoeia, the United States Herbal Pharmacopoeia and the Homoeopathic Pharmacopoeias. What I find reassuring is the involvement of the industry in the elaboration of these Notes for Guidance (N.f.G) and that the Points to Consider (PTC) document on Good Agricultural and Collection Practice actually arose from Guidelines developed by the European Herb Growers Association themselves. It is equally important to acknowledge the proactive positive attitude of industry associations, such as the BHMA which I had the privilege to witness at first hand as chair of their Code of Good Practice for Herbal Remedies Exempt from Licensing Committee. My experience is that there is a willingness within the Industry to maintain the already high standards of Quality and where necessary to make improvements. It is vital that the efforts of those committed to Quality Control and Assurance should be recognized

and rewarded while those who ignore the Guidelines should pay the price of their neglect of consumer safety.

Adequately Address Standards of Safety.

The Scheme, in line with the Directive, reduces the burden on manufacturers by not requiring that new expensive toxicity tests be performed. Instead bibliographic evidence can be presented along with an Expert Report. The idea is that the company's chosen expert would draw together the traditional knowledge of the safety of a herbal substance and refer to the long experience of safe use of it, validate that information and integrate it with published data on the substance. It would be desirable if some form of generic Substance Approval Procedure, as suggested by the Irish Health Trade Association, could be developed. This could provide an invaluable link to the Centralised Monograph Procedure already referred to in the context of the Directive.

Identifiable Products.

The labelling requirements are similar to those of the Directive and require a statement that "the product is a Traditional Medicine Product for use in a specified indication and that the product has not been clinically proven but relies exclusively on long-term use and experience". In such cases the medicinal claims made must be appropriate. They can be proposed by the applicant and justified on the basis of accuracy and truthfulness by the applicant's Expert. Here again the expense and burden of clinical trials is lifted from the applicant whose Expert can refer to Bibliographic evidence from ESCOP, WHO or Commission E Monographs, standard texts and compilations such as Mills and Bone. The wordings to be agreed between the applicant and the assessors could be similar to those published in the French Avis aux Fabricants. The Committee was also impressed with the range of indication claims developed and approved by the Australian CMEC and recognized the value of many of them.

Protection of Public Health.

Despite inaccurate and wildly misleading claims that the Scheme would result in all Traditional Medicinal Products being banned, the only products which could be threatened by this Scheme are those which do not meet minimum Quality Standards

or which are unsafe under normal conditions of use or where the label or advertising is untruthful. It is our view that the vast majority of the products currently available will continue to be available. Further, we expect that because there will be a definite and assured regulatory situation, this will encourage new players to place new products on the market. This would further enhance the choice available to Irish consumers.

Conclusion.

There are a number of implications arising from the proposed National Licensing Scheme and by extension from the Directive.

Implications of The National Licensing Scheme.

It involves a derogation from the 'normal' regulatory process.

There is a massively reduced burden on manufacturers.

No expensive Pharmacotoxicological tests are required.

The applicants chosen Expert in their Report will collate Bibliographic and Empirical Evidence of Safety.

No expensive clinical trials need be conducted.

The Expert Report will incorporate evidence from herbal practitioners.

The applicant themselves will be able to propose and justify the wording of the indication claim.

Arising from these there will in my view be a number of real advantages for all involved.

For once the perceived regulatory threat hanging over these products will be removed and we will have products on the market within an assured regulatory framework and with a definite regulatory status. This will provide a secure background for the industry to plan investment and production.

Consumer protection will be enhanced through independent audits of Quality and Safety and through checks on the accuracy of the information being made available. Many of the safety problems will be prevented through improved adherence to Quality Control. All of these are worthwhile and achievable. However, their

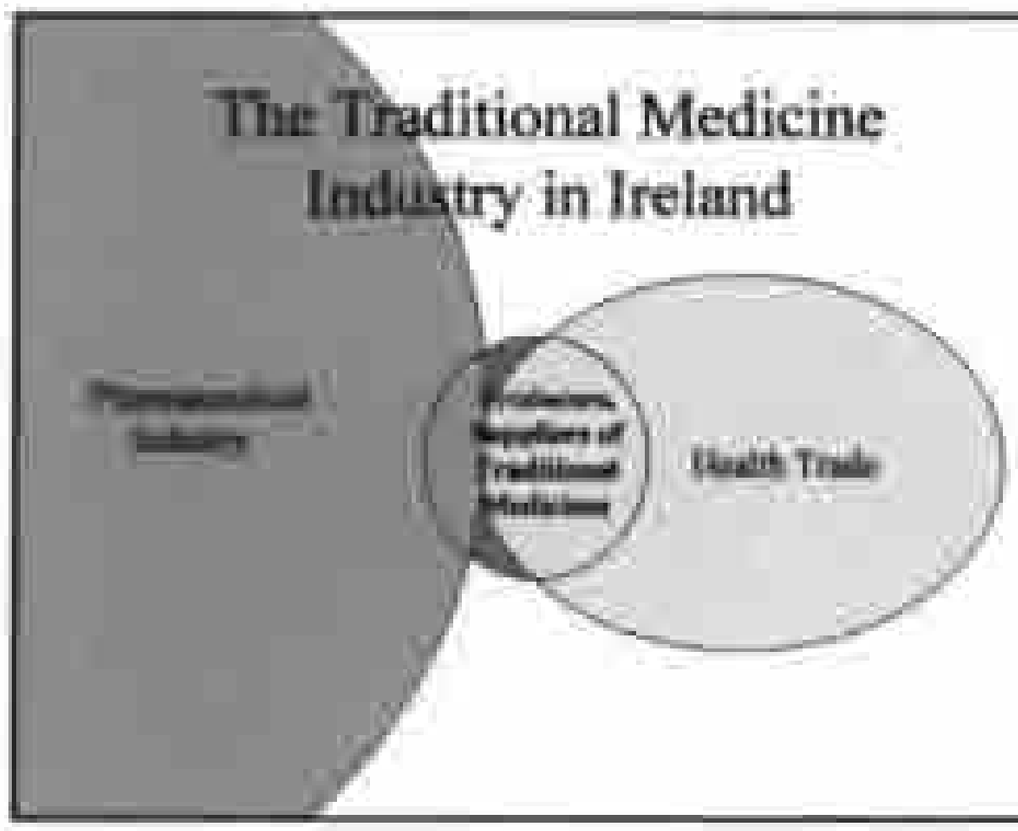
achievement will require commitments from all concerned. My approach has been heavily influenced by the commonsense attitude expressed by the famous and indeed infamously prosecuted French Herbalist, Maurice Messegué, who wrote many years ago, *"Make use of my beloved plants above all in benign conditions. But make sure that you go and see your Doctor whenever it becomes necessary. To trust in Nature does not mean that you must deprive yourself of the discoveries of Science".*

What that second sentence says to me is that attempts to reach the goal of *"responsibly providing Phytotherapy for the purpose of achieving definite outcomes that improve a patient's quality of life"* will require cooperation between Producers, Practitioners, Patients and Regulators. We need to create a partnership which incorporates learning that emanates from the laboratory and learning that does not emanate from the laboratory. We need to do this for the benefit of all of us who find ourselves in a totally changed regulatory environment. We don't have all the signposts or a complete route map. The challenge we face both at National and at European level is the creation of the partnership which will help us all navigate our way through that landscape. Who will join us in that partnership?

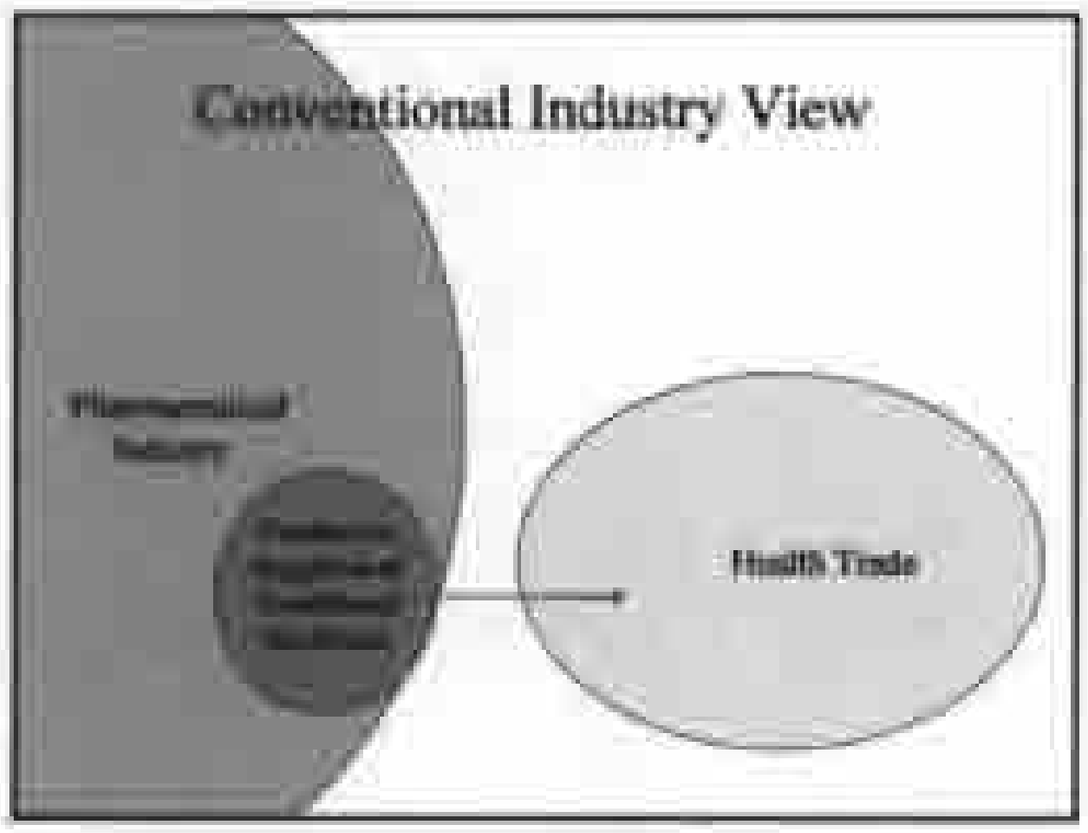
Implications for Industry

Jonathan Griffith

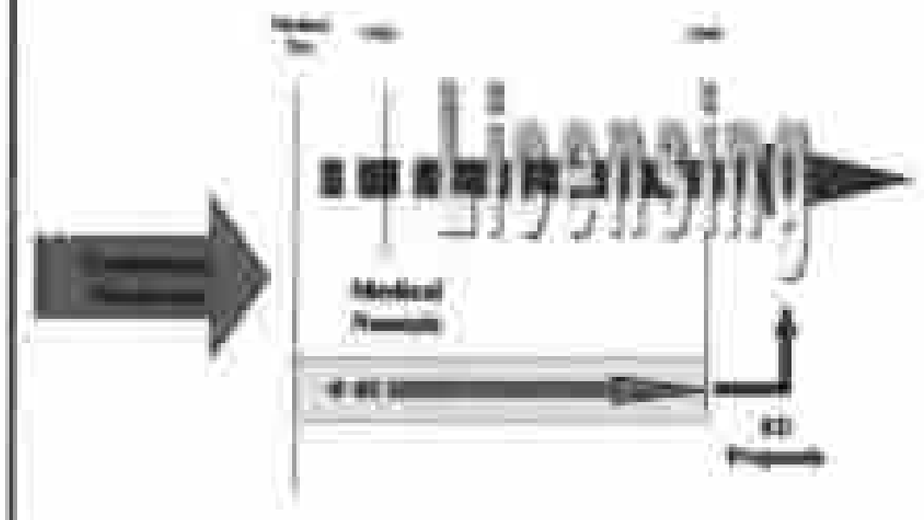
The Traditional Medicine Industry in Ireland



Conventional Industry View



The Trading Environment



Assessing the Implications

How well does the scope of the regulations reflect the market place?

How will the quality requirements affect the way we do business?

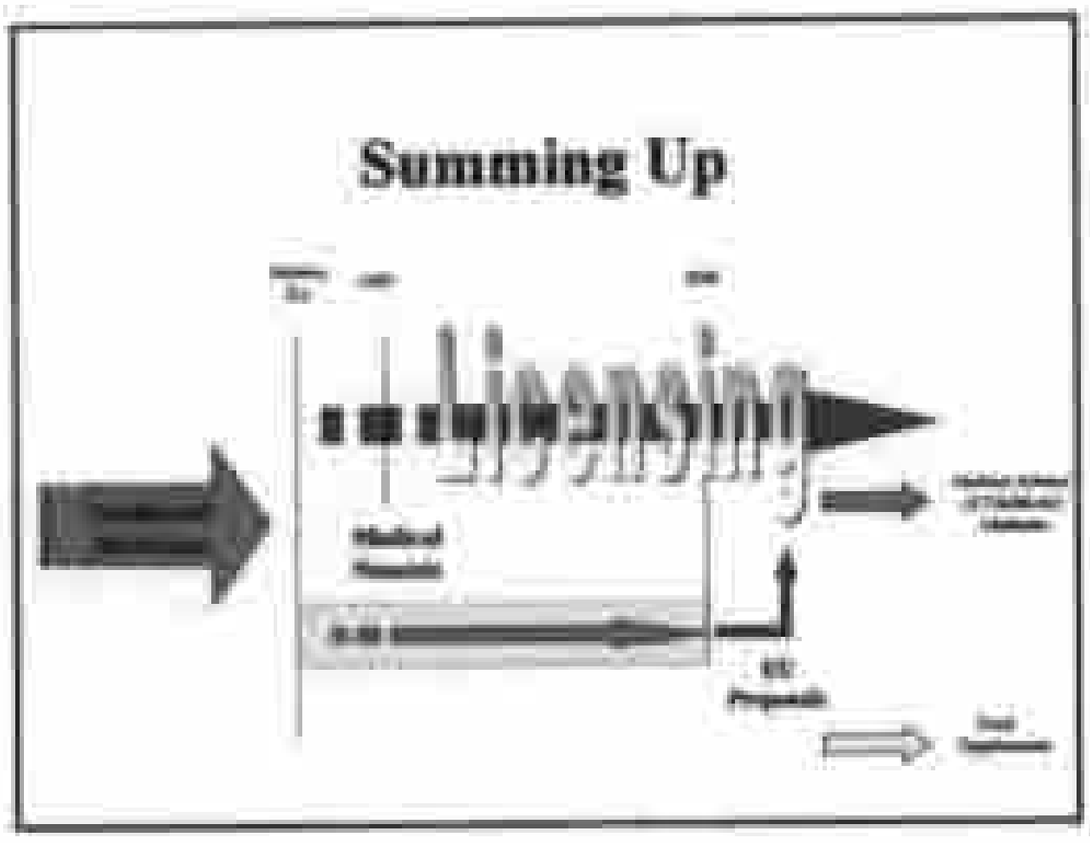
Are we going to lose products because of safety considerations?

How will traditional usage claims affect the way I market products?

Cost / Benefit Analysis

Immediate Implications for Industry

Scope		(-)	+
Quality		-	+
Safety		-	=
Efficacy		?	+ +
Cost/Benefit		+ +	- -


Summing Up

WHOLESALE AND MANUFACTURE

GETTING LICENSED

OVERVIEW

General approach to Pre-packaged Food Orders

Definitions

Definitions *(cont'd.)*

Manufacturing includes

APPLICABILITY OF LICENSING REQUIREMENTS

General Applications

BENEFITS OF LICENSING SYSTEM AND ADHERENCE TO GOOD PRACTICE

- [illegible]
- [illegible]
- [illegible]
- [illegible]
- [illegible]

WHOLESALE (1)

- Wholesalers must comply with European guidelines on Good Distribution Practice of Medicinal Products for Human Use

WHOLESALE (2)

[illegible]

- Personnel
- Documentation
- Premises and Equipment
- Deliveries to customers
- Returns
- Emergency Plan & Recalls
- Self inspections

MANUFACTURE (1)

- Manufacturers must comply with European Guide "Good Manufacturing Practice for Medicinal Products in the European Community"
- Guide has 9 basic chapters and 14 specialised Annexes

MANUFACTURE (2)

The basic Chapters of GMP Guide cover:
- Quality Management
- Personnel
- Premises and Equipment
- Documentation
- Production
- Quality Control
- Contract Manufacture and Analysis
- Complaints and Product Recall
- Self Inspection

MANUFACTURE (3)

- Requirements of Annexes are additional to those of the nine basic chapters
- Most relevant Annex is No.7 "Manufacture of Herbal Medicinal Products"
- Annex emphasises importance [illegible] specifications [illegible] for [illegible] processing instructions, sampling and quality control
- Revision of Annex 7 under consideration

INSPECTIONS (1)

INSPECTIONS (2)

EVIDENCE

RELATED ACTIVITIES

SUMMARY

Product Registration – What is involved?

[illegible] MB, PhD, FRCPI
Senior Medical Officer
Irish Medicines Board

Introduction

- Products eligible for registration
- Application
- Regulatory requirements elsewhere
- Value of Product Registration
- Future

Summary of Criteria

Traditional and Herbal

<u>or</u>

Traditional and Non-Herbal

<u>or</u>

Traditional and Combination

Application

- Administrative details
- Product Information
  - Summary of Product Characteristics (SPC)
  - Package leaflet and Label
- Manufacturer's or Wholesaler's Licence
- Quality Dossier
- Safety Data
- Evidence of traditional use claim
- [illegible]

Administrative Details

- Product name
- Composition
- Manufacturer
- Existing authorisations/registrations
- Refusals, suspensions or revocations

Application form will be developed

Summary of Product Characteristics (SPC)

- Summary of Information
  - Administrative details
  - Clinical particulars
  - Pharmaceutical particulars
- Legal Document

Justify any omission of data

SPC – Clinical Particulars I

- Traditional Indications (Claims)
  - [illegible]
- Dose and method of administration
  - [illegible]

SPC – Clinical Particulars II

- Contraindications
- Special warnings/precautions
- Interactions
- Pregnancy and breast-feeding
- Effects on ability to drive / use machines
- Side effects
- Overdose

SPC – Pharmaceutical Particulars

- Pharmaceutical form
- List of excipients
- Shelf life
- Special precautions for storage
- Nature and contents of container
- Instruction for use/handling, disposal

Package Insert and Label

- In accordance with the agreed SPC
- Traditional Use Claim:
  - Name of tradition
  - Consult doctor or qualified practitioner if symptoms persist
- True, valid and not misleading
- Readable

Justify any omission of data

Quality Dossier

- What is required?
  - [illegible]
- What does that mean?
  - [illegible]
  - [illegible]
- Why?
  - [illegible]

Safety Data

- What is required?
  - [illegible]
- What does that mean?
  - [illegible]

Positive and Negative Data!

Evidence of Traditional Use

- Bibliographic evidence of [illegible] use of product or a corresponding product for [illegible] years
- [illegible]
- E.g.
  - Published articles
  - Pharmaceutical monographs [illegible]
  - [illegible]

Simplified registration

Traditional Indication Claim

- Three references from conventional or traditional medical literature

and

- EU recognised pharmaceutical monograph(s) or other monographs recognised by competent authority

Bibliographic data replaces clinical trial data

Expert Report

- Report written and signed by an "Expert" [illegible] qualified and experienced person [illegible] the applicant
- Critical evaluation of all aspects of the dossier
- Bibliographic data should be [illegible]
- Justify basis for traditional indication claim
- Emphasis on Risk/Benefit

Assessment

- Multidisciplinary Team
  - Pharmaceutical
  - Herbalist
  - Medical
- Correspondence/dialogue with applicant during assessment
- Result: an agreed SPC, Package Insert, Label

Requirements in Other Regulatory Systems

Canada - Applicants for licensing must provide information supporting the efficacy and safety of the natural health products when used under the recommended conditions of use

Australia - Sponsors must hold evidence to support all claims they make about a product

GMP requirements apply in both Canada and Australia

Value of Product Registration

- **For Industry**
  - Recognition of [illegible] traditional medicines
  - Distinction between registered products and [illegible] products
  - ↑ Consumer Confidence ↑ Sales
  - [illegible]
- **For Consumer**
  - Quality and Choice

The Future

- Introduction of Legislation
- To be developed
  - Application Form
  - Guidelines

This system recognises the value of TMPs

PHARMACOVIGILANCE
&
TRADITIONAL MEDICINAL PRODUCTS

[illegible]
[illegible]

PRESENTATION TOPICS

- Defining Pharmacovigilance
- Legislative Framework
  - EU
  - National
- Pharmacovigilance in the IMB
- System Requirements
- Pharmacovigilance Guidance Documents

PHARMACOVIGILANCE

"The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or of any other drug-related problems"

LEGISLATIVE BACKGROUND

- EU
  - Directives → 65/65 ; 75/319 as amended (2000/38 & 2001/83)
  - Regulations → 2309/93 ; 540/95
- National
  - IMB Act
  - Clinical Trials Act

EU LEGISLATION

Obligations of Competent Authorities

[illegible]

- Encourage reporting of suspected ADRs & retention of reporting requirements
- In collaboration, develop guidance on collection, verification & presentation of adverse reaction reports
- [illegible]

IMB ACT – Pharmacovigilance Obligations (1)

- To exercise the powers conferred on the supervisory authority by Council Regulation (EEC 2309/93)
- To exercise the power specified in the Control of Clinical Trials Act (1987 & 1990)
- To establish and maintain a service for obtaining and assessing information in regard to the safety, quality and efficacy of medicinal products

IMB ACT – Pharmacovigilance Obligations (2)

- To establish and administer a service for obtaining and assessing reports on any adverse effects of medicinal products in use in the State.
- To advise the Minister and others concerned as to the precautions or restrictions, if any, subject to which medicinal products may be marketed or continued in use in the state.

Collaboration & the IMB

- Commitment to EU systems for regulation of medicines
- Established partnership in WHO programme
  - WHO database
  - 87 participating countries
  - classification project
- SCHMP

History of Pharmacovigilance

- [illegible] – Establishment of voluntary ADR reporting (Doctors & Dentists)
- [illegible] – Introduction of Pharmacists to ADR reporting
- [illegible] – Introduction of Nurses to ADR reporting
- [illegible] – Introduction of veterinary pharmacovigilance system

Pharmaceutical companies required to submit pharmacovigilance data as a condition of the marketing authorisation

General Conditions Applicable to Product Authorisations

"The authorisation holder shall keep a record of reports of adverse effects associated with the use of preparation to which the authorisation relates. The record shall be available for inspection by a person authorised by the Minister who may take copies thereof. The authorisation holder shall furnish to the Minister a copy of any such report of which he has a record or of which he is aware."

SYSTEM REQUIREMENTS

- Establish Pharmacovigilance System
  - Data collection, collation & evaluation
  - Ongoing reporting (individual & aggregated reports)
  - Ongoing pharmacovigilance evaluation (e.g. changes in benefit/risk assessment)
  - Action required for information
- NDPs
- Qualified Person

PHARMACOVIGILANCE GUIDANCE DOCUMENTS

- IMB Website (http://www.imb.ie/)
- IMB Newsletters
- Volume 9 – *Pharmacovigilance Medicinal Products for Human & Veterinary Use*

  (http://pharmacos.eudra.org/F2/eudralex/vol-9/pdf/volume9.pdf)
- ICH Guidelines

VALUE OF PHARMACOVIGILANCE SYSTEMS

- Important data source
- Signal/hypothesis generation
- Facilitates risk identification & evaluation
- Communicate surveillance over product lifetime
- Cost effective early warning system

CONCLUSION

- Pharmacovigilance systems essential for effective monitoring of product safety
- Requirements mentioned in National & EU legislation
- Detailed guidance & advice available
- Pharmacovigilance data add value by facilitating detection of new safety issues & confirming the expected safety profile of products

IRISH MEDICINES BOARD

Annex 2

Seminar Programme

Bord Leighreas na hÉireann
Earlsfort Centre, Earlsfort Terrace, Dublin 2. Tel: [illegible] Fax: [illegible]
Website: www.[illegible]

IRISH MEDICINES BOARD SEMINAR

Implications of the Proposed Regulatory System for Traditional Medicinal Products

Seminar Programme

Date: **2nd May 2002**

Venue: **Hilton Dublin Hotel, Charlemont Place, Dublin 2**

8.30 – 9.00	Registration
9.00 – 9.10	**Opening Address – Prof. Frank Hallinan, Chief Executive, Irish Medicines Board.**
Session 1	***Introduction to Regulation of Traditional Medicinal Products.*** ***Chairperson: Prof. Frank Hallinan, Chief Executive, Irish Medicines Board.***
9.10 – 9.30	'The Proposed Interim National Licensing Scheme – An Overview' Dr. Dairine Dempsey, Herbal Medicines Project Manager, Irish Medicines Board.
9.30 – 10.10	'The Traditional Medicines Directive' Mr. Richard Woodfield, Herbal Policy Manager, Medicines Control Agency, UK.
10.10 – 10.30	COFFEE
Session 2	***Direct to the Consumer*** ***Chairperson: Dr. Joan Gilvarry, Medical Director, Irish Medicines Board.***
10.30 – 10.50	'Implications for the Herbalist' Ms. Helen McCormack, Herbalist.
10.50 – 11.10	'Implications for the Consumer' Ms. Breda Dooley, Consumer Representative Member of the Irish Medicines Board.

11.10 – 11.30	'Implications for the Community Pharmacist' Ms. Geraldine Lavelle, Community Pharmacist.
11.30 – 11.50	'Retail Implications – Health Food Stores' Ms. Aideen Hurley, Irish Association of Health Stores.
11.50 – 12.30	KEYNOTE SPEAKER – Dr. Desmond Corrigan, Director of the School of Pharmacy, Trinity College Dublin.
12.30 – 13.00	Panel Discussion
13.00 – 14.20	LUNCH
Session 3	***Implications for the Industry*** ***Chairperson: Ms. Sue Rattigan, Chairperson, Irish Health Trade Association.***
14.20 – 14.40	'Implications for the Industry from an Industry Perspective' Mr. Jonathon Griffith, Irish Health Trade Association.
14.40 – 15.00	'Wholesale and Manufacture – Getting Licensed' Mr. John Lynch, Director of Inspection, Irish Medicines Board.
15.00 – 15.20	'Product Registration – What is involved?' Dr. Elaine Breslin, Senior Medical Officer, Irish Medicines Board.
15.20 – 15.40	'Pharmacovigilance – What is required?' Ms. Niamh Arthur, Pharmacovigilance Co-ordinator, Irish Medicines Board.
15.40 – 16.40	Panel Discussion.
16.40 – 16.50	Close of Meeting. Dr. Dairine Dempsey, Herbal Medicines Project Manager, Irish Medicines Board.
16.50 – 17.00	COFFEE