Centre for Integrative Medical Training
In Association with London Integrated Medical Health Education

# Pre-membership Course in Medical Homeopathy

A Blended Course in Homeopathic Medicine for Healthcare Professionals

## Unit 51-56

PHARMACY STUDIES

**Units 51 - 56**

# *Quality Assurance*

Manufacturers of homoeopathic remedies are obliged to operate under the same guidelines of GMP as do the allopathic pharmaceutical industry.

This brief overview covers the aspects of QA including QC, QP, and principles of GMP in regard to homoeopathy. Quality Assurance is a combination of Quality Management and Quality Control. The Orange Guide is used as a manual as per the rest of the pharmaceutical industry. Homoeopathic manufacturers are obliged to employ QPs to oversee and release batches. Quality Assurance is overseen by the MCA whose inspectors rigorously inspect the manufacturers many of whom hold both Specials and Full manufacturing licences as well as numerous Homoeopathic Registrations and archaic PLRs

**Introduction to the EC Homoeopathics Directive 93/73EEC**

A special system of licensing exists for homoeopathic medicines. This section covers the basics of the directive, from draft proposal to SI. The licensing of remedies as homoeopathic medicinal products is conducted through a Registration process. The latter will be discussed in some detail

**History**

In 1986, the Council asked the Commission to develop a Directive, widening the scope of Directive 65/65/EEC and 75/319. The purpose was to fulfil the aim of the Treaty of Rome and to complete the Directives 65/65/EEC and 75/319/EEC for all medicinal products in Europe. The final draft was submitted to the European Parliament. At its plenary session on 13th June 1991, the latter adopted 28 amendments, accepting only a few less important ones. A year later further amendments were accepted. All these came through dialogue with interested parties, nominally the homoeopathic manufacturers. Although a common position was arrived at by September 1992 it was several years more before the directive was finalized. The delays in reaching harmonization meant that a deadline of 31st December 1995 was posted as the very latest date by which all amendments could be accepted and the Commission shall report on how the Directive shall operate.

The Directive was finally published in 1993 and implemented in the UK as five Statutory Instruments in December 1994. The review of the Directive normally occurs one year after implementation. However the implementation across Member States was so erratic that the review was delayed a year. Even then very few States had implemented and those that had done so had achieved variable levels of completion..

By the end of 1994 four countries had implemented in different ways. This was largely due to the diversity of products and confusion as to the local interpretation of Article 7. The latter being the most basic system of registration for products that do not make claims and bear no indications by means of name of product. Article 9.2 is a more ambitious (some say ghost part) of the Directive which allows for the registration of indicated products. So far only Austria has attempted to implement this part of the Directive.

Article 6 deals with the acceptance of registered products across Europe. Insofar as a Member State shall decide whether or not to implement the Directive and inform the Commission of their decision, they must accept the products of those Member States who have agreed to implement and establish a registration system.

The details of Articles 7 and 9.2 will be discussed together with the impact of implementation by various Member States.

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Notes:

**REPORT**
Round Table Discussion on Non-conventional health care products and the internal market
European Parliament
Brussels, 7 February 2001, 15.00-17.00 hrs.

**Background**
The Working Group on Complementary and Natural Medicine organised a Round Table Discussion on Non-conventional health care products and the internal market.
This working group, a part of the Health Intergroup, is a group of members of the European Parliament from different political parties that advocates a more prominent status of complementary medicine. President of this Working Group is Ms Nuala Ahern (Ireland, Greens), Vice-Presidents are Mr Giles Chichester (UK, European People's Party), Ms Laura Gonzales-Alvarez (Spain, European United Left), Mr Renzo Imbeni (Italy, European Socialists) and Mr Paul Lannoye (Belgium, Greens).

Ms Nuala Ahern chaired the meeting. Mr Paul Lannoye was the other member of the Working Group that attended the meeting.

Special guest was European Commissioner for Enterprise and the Information Society, Mr Erkki Antero Liikanen (from Finland), whose attendance indicated that the European Commission takes this subject seriously. The Commissioner was accompanied by Mr Paul Weissenberg, Head of the Directorate F (Single market, regulatory environment, industries under vertical legislation) and two other officials. (Unit F/4 Pharmaceuticals and cosmetics is a subdivision of Directorate F).

About forty delegates from different interested parties (industry, practitioners, patients, etc.) attended the meeting. On behalf of the ECH Dr Ton Nicolai was there.

**Policy of the European Commission**
The two main objectives of the Commission in this field are
1. high level of safety, efficacy and quality
2. free access of every European citizen to all different sorts of medicinal products.
The harmonisation of market authorisations as far as conventional medicinal products are concerned is quite good, both the centralised registration (at the EMEA) and the national registration (including Mutual Recognition Procedure, MRP). In the field of non-conventional medicinal products the MRP involves lots of difficulties because of the highly different traditions in the Member States. This hampers the harmonisation of the market authorizations of the non-conventional medicinal products.

The European Commission, in their unceasing efforts to harmonise the market of non-conventional medicinal products, has been obliged to approach the issue step-by step. The Directives 92/73/EEC and 92/74/EEC on homeopathic medicinal products have been followed by Commission Directive 1999/83/EC on medicinal products of well-established use. The latter makes it possible to replace results of pharmacological and toxicological tests or clinical trials by detailed references to published scientific literature if it can be demonstrated that the constituent(s) of a medicinal product have a well-established medicinal use, with recognised efficacy and an acceptable level of safety; the period

of time required for establishing a 'well established medicinal use' of a constituent of a medicinal product must not be less than one decade from the first systematic and documented use of that substance as a medicinal product in the EU.
A new directive is on its way, a directive on traditional medicinal products that are longer than 30 years on the market. These two Directives do not apply to homeopathic medicinal products but show that the Commission is making a real effort to achieve its objectives.
As far as homeopathy is concerned, the Commission is constantly clashing with the Member States that are reluctant to harmonise the regulation of homeopathic medicinal products.

**Committee for Non-Conventional Medicinal Products at EMEA**
Currently, the EMEA (European Agency for the Evaluation of Medicinal Products) in London comprises two scientific committees, responsible for preparing the Agency's opinion on any question relating to the evaluation of human or veterinary medicinal products, the CPMP (Committee for Proprietary Medicinal Products) and the CVMP (Committee for Veterinary Medicinal Products) respectively.
At the moment there is an Ad Hoc Working Group on Herbal Medicinal Products without an official status and subordinate to the CPMP (the CPMP comprises mainstream experts only!). Mr Paul Weissenberg confirmed that the European Commission is considering the possibility of establishing a Committee for Non-Conventional Medicinal Products. This will imply a change of Council Regulation 2309/93, which stipulates the existence of only the CPMP and CVMP.

If this Committee for Non-Conventional Medicinal Products will be established, their members are to be appointed by the governments of the Member States. The Commission "assumes that the Member States will appoint people with expertise in that particular field".

**Homeopathic medicines in the new pharmaceutical legislation**
The new pharmaceutical legislation will include homeopathic medicinal products. For more details the reader is referred to the report on the Workshop on the review of the pharmaceutical legislation (European Commission - Enterprise Directorate-General, Brussels, 26 January 2001)

Brussels, 7 February 2001
Report by Dr Ton Nicolai
ECH, President

**REPORT**
**Workshop on the review of the pharmaceutical legislation**
**European Commission - Enterprise Directorate-General**
**Brussels, 26 January 2001, 09.30-13.00 hrs.**

***Background***
The European Commission is working on a proposal to review the pharmaceutical legislation in order to rationalise and, if possible, simplify the system and to meet the challenges of EU enlargement. DG Enterprise would like to have a direct dialogue with all interested party associations, which are directly or indirectly concerned by the pharmaceutical EU legislation, and give these associations the opportunity to directly express their main concerns and opinions.

At the workshop of 26 January there was a discussion about several areas of interest including herbal and homeopathic medicines. Dr Philippe Brunet (Head of Unit F/4 Pharmaceuticals and cosmetics) chaired the meeting and was flanked by several officials. One of these officials, Mr N. Behrndt, gave information on herbal and homeopathic medicines. About forty delegates from about twenty different interested parties (industry, practitioners, patients, etc.) attended the meeting. On behalf of the ECH Dr Ton Nicolai was there.

**General aspects of the new legislation**
The new Directive envisages maintaining the current two procedures for authorising the products to be placed on the market, namely the centralised procedure and the mutual recognition procedure (MRP). The centralised procedure (through the EMEA) is currently mandatory for all medicinal products resulting from biotechnology and optional for all new products. The MRP implies the automatic recognition of a national authorisation by another Member State, but in actual practice Member States re-evaluate cases and apply their own criteria, which leads to rather inconsistent situations. The European Commission proposes some specific regulations to improve this situation.
This is also important for homeopathic medicines because they are only registered at the national level and fall within the MRP. Homeopathic medicines, however, have additional problems with the MRP (see below).

There will be a parallel Directive for veterinary medicinal products. In this case there is another problem to deal with, i.e. the maximum residue limits (MRLs) as far as food producing animals are concerned. These MRLs have to be fixed for every individual medicinal product and every individual species. Decisions on market authorisation and MRLs are taken independently.

**Homeopathic medicines in the new legislation**
Homeopathic and herbal medicines will be included in the new legislation but for these products specific regulations will be applied. Basically, the current EU directives 92/73 and 92/74 on homeopathic medicinal products (for human use and for veterinary use respectively) will be integrated into the new legislative system. The suggestions that were made by the European Commission as a result of the inconsistent application of the Directives 92/73 and 92/74 in their "Report to the European Parliament and Council on the Application of Directives 92/73 and 92/74", - COM (97) 362 final -, will

be incorporated in the new system.

Unlike mainstream medicinal products that have to fulfil requirements of safety, quality and efficacy, homeopathic medicinal products need only fulfil the requirements of quality and safety, not of efficacy. This principle will be maintained.

The MRP is causing problems as it is, but in case of homeopathic medicines this procedure creates even more problems. The fact is that the wording of article 6, paragraph 1 of the Directives 92/73 and 92/74 "Each Member State shall take due account of registrations and authorizations previously granted by another Member State" leaves too much room for interpretation. The new Directives will exactly define under which specific conditions existing national registrations should be mutually recognised or endorsed by other Member States.

Other routes of administration of homeopathic medicines than oral and external will be included in the new Directives, such as injections, suppositories and eye drops.
The current degree of dilution to guarantee the safety of homeopathic medicines that are subject to the simplified procedure, - one part per 10.000 of the mother tincture -, will be adapted depending on the toxicity of the substance involved.

The current Directive 92/74 excludes the special, simplified registration procedure for homeopathic intended to be administered to food producing animals. This leads to the odd situation that veterinary homeopathy is extremely hampered in case of food producing animals, whereas it is much safer than allopathic medicines as far as residues are concerned. This situation will be adapted in the new Directive.

The current rather coloured information on the labelling "homeopathic medicinal product without approved therapeutic indication" will be changed; a revision of the warning to consult a doctor will be made more consumer friendly.
The current situation where the national authorities can set their own requirements for the normal registration procedure (for those homeopathic medicines that are not eligible for the simplified procedure) will be harmonised.

**Conclusion**
By and large, the European Commission as well as ECHAMP (European homeopathic industry) and the ECH are in full agreement on the above-mentioned points. The Commission will take due account of the opinions of the attending organisations and will finalise their proposal for a new Directive in April 2001. The proposal will be submitted to the European Parliament and Council of Ministers in May or June 2001, which, of course, may imply some amendments. Obviously, all interested parties are to make sure that the Commission's proposal reaches the finishing line in one piece.

Brussels, 26 January 2001
Report by Dr Ton Nicolai
ECH, President

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**⌂ Home Study**

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