QUALITY ASSURANCE IN HOMEOPATHIC MANUFACTURING PHARMACY PRACTICE

Quality Assurance

Manufacturers of homeopathic 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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