INTERNATIONAL ORGANIZATIONS FOR MANAGEMENTS, ASSURANCE AND CONTROL OF QUALITY OF MEDICAL PRODUCTS

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Since one of criteria of quality of medical product is correspondence with official specification of quality of final product and all other official requirements is applied to this product and production, some national and international organization have been established to control the quality of medical products. For example there is Food and Drug Administration (FDA) in USA, European Agency for the Evaluation of Medical Products (EMEA) in European Union, International Organization for Quality of Medical products, the World Health Assembly (WHA), World Health Organization (WHO), International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

Quality Assurance within the pharmaceutical industry is a broad concept embracing research and development through manufacturing, quality control, storage and distribution, to the information provided to the prescriber and the patient.

All elements of Quality Assurance are equally critical to the whole; a weakness or breakdown in any part of the system or procedures could give rise to the release on the market of a defective product that could have serious or even fatal consequences.

Good Manufacturing Practice (GMP) is the most fundamental element of Quality Assurance and internationally recognised, basic standards of GMP have been published by WHO. In view of their special nature, the manufacture of medicinal products should only be permitted under strictly controlled and monitored conditions, in accordance with GMP.

Reputable multinational companies abide by self-imposed standards of GMP wherever they manufacture products, world-wide. National regulations and requirements must always take precedence, but internal company guidelines and self-auditing procedures are often more stringent than those applied externally.

If a government allows local manufacturers which do not meet GMP standards to operate within its territory, the responsibility for such a decision must be taken on a national basis. To permit or sanction the export of products which have not been manufactured under GMP conditions, and thus allow such products to circulate in international commerce, is unacceptable.

Quality standards for pharmaceuticals have been built up over the years by experts from industry, pharmacopoeial authorities, regulatory agencies and academia and are based on experience and the need to safeguard the safety and efficacy of the product, for the sake of the patients' health. There can be no "double standards" in the quality assurance of pharmaceutical products.

Quality Assurance has cost implications and a preoccupation with procuring products at the lowest possible price must, inevitably, favour sources that put cost before quality, with consequent risks for the patient and public health.

The WHO definition of GMP emphasises the point that quality must be built into the production process: Good manufacturing practice is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

GMP rules are directed primarily to diminishing the risks, inherent in any pharmaceutical production, which cannot be prevented completely through the testing of final products. Multinational companies normally work to the more demanding standards of GMP imposed by regulatory agencies in the European Union and the US FDA, as well as their own internal guidelines.