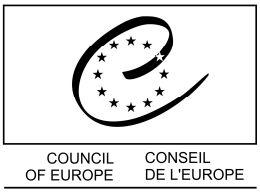
http://www.coe.int/pharmacrime



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COMPARATIVE ANALYSIS OF EUROPEAN REGULATION OF MEDICAL DEVICES AND MEDICINAL PRODUCTS

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I have been asked by the Council of Europe to assess whether there are similarities or otherwise differences in the regulatory regimes respectively applied to medical devices and medicinal products. This paper complements the slide presentation I gave to the Council of European legal affairs committee established to prepare the penal code to combat counterfeit medical products.

There are certain differences in the approach to regulation of medical devices as compared with medicinal products. These differences are principally borne out of how these two industries are structured, and the types of products manufactured. Medical technologies and devices industry is based on mechanical, electrical and materials engineering. Therefore, the focus to ensure safety and effectiveness of a medical device is placed on the characterisation of the material in terms of its quality, safety and functionality, and how these parameters will affect the performance and engineering of the finished medical device. For example, material may be used to provide an optimal environment to promote wound healing in the injured tissue. Drug development, however, is based upon an iterative approach focussing on characterisation on the biology of the drug molecule and how the underlying biology alters the disease state of the patient.

The traditional thinking is that a medicinal product exerts its primary mode of action through a pharmacological means, and a medical device exerts its clinical effect by mechanical and/or electrical (i.e. physical) action. Some commentators have said that medical devices are “pharmacologically inactive”. However, use of emerging technologies may render this demarcation between medical devices and medicinal products obsolete or otherwise increasingly challenging. In fact, there is an increasing number of products based upon convergent technology platform. That is to say that a medicinal product can be used in combination with a medical device by exploiting the synergistic effects of these components for a medical purpose. A medical purpose is defined in European Community law to include treatment, prevention and diagnosis of a disease and condition.

Whilst the pharmaceutical industry largely consists of multinational companies, the medical technology and devices industry is made up of a few large companies and a large number of very small companies. But one also sees, in the recent years, emergence of new start-ups and “one-product” companies in the pharmaceutical sector. There is also increasing collaboration between the larger multi-national companies and smaller companies primarily to fill the depleted product pipelines in the larger companies as the smaller companies have been shown to be more innovative in research and larger companies have

the infra-structure to undertake large scale product development and marketing. One also sees certain multi-national pharmaceutical companies buying up medical devices companies. Therefore the above generalisation of pharmaceutical industry that is pre-dominated by multi-national companies may not be completely reflective of the current dynamics of these two healthcare industries.

In the European Union, medical devices are regulated under the “New Approach” regulatory regime. Consistent with the broader Community law governing medicinal products, the “New Approach” directives governing medical devices focuses upon protection of public health and patient safety. New Approach directives are based upon the following principles:

- Harmonisation is limited to essential requirements
- Only products fulfilling the essential requirements may be placed on the market and put into service
- Harmonised standards, the reference numbers of which have been published in the Official Journal and which have been transposed into national standards, are presumed to conform to the corresponding essential requirements
- Application of harmonised standards or other technical specifications remains voluntary, and manufacturers are free to choose any technical solution that provides compliance with the essential requirements
- Manufacturers may choose between different conformity assessment procedures provided for in the applicable directive.

Regulation of medical devices (including conventional medical devices, active implantable medical devices and in vitro diagnostic medical devices) requires medical devices to meet the “essential requirements” before they can be placed on the market or put into service through a process of conformity assessment. The conformity assessment procedure is related to classification of the device based upon an assessment of certain risk factors. For conventional medical devices, these risk factors include duration of use, and invasiveness of the medical device.

Annex I describes the basic framework for essential requirements. Similar to regulation of medicinal products, the underlying principle for evaluating whether a

medical device meets the essential requirements is firmly based upon an assessment of benefit/risk. Annex I states, amongst other things, the following:

> "The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety."

The benefit/risk balance for medicinal products is assessed by weighing the size of pharmacological effects (treatment effects) against the risks. In the case of assessing benefit/risk balance for medical devices, the focus in placed on characteristics and performances of the medical devices which should not be adversely affected to such a degree that the clinical conditions and safety of the patients are compromised. Quality of a medicinal product is guaranteed by compliance with good manufacturing practice underpinned by a system of quality management system. This ensures the finished medicinal product is fit for the intended purpose. The regulatory regime for medical devices similarly contemplates a quality system to be put in place and in operation to assure acceptable performance and characteristics.

Common to both regulatory regimes, after a relevant product has been placed on the market, it must be subject to post-market surveillance to monitor the ongoing benefit/risk balance. Manufacturers for devices or medicines are required to have a system to collect, collate, report and manage post-marketing safety issues. The common theme is to manage the risks that may arise from using healthcare products, irrespective of whether they are medicines or devices.

In conclusion, whilst there are certain differences in the approach to benefit/risk assessment, the regulatory regimes for medical devices and medicines essentially share the same over-arching aim to protect public health and patient safety.