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The European Pharmacopoeia: A Common European Initiative by the Council of Europe

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Abstract: The European Pharmacopoeia, founded in 1964, ensures the quality and safety of medicines by elaborating compulsory standards, by describing quality control methods, and by making it possible to detect counterfeit medicines. European Pharmacopoeia standards apply to all medicines regardless of their origin, their method of production or their type. The official standards published by the European Pharmacopoeia provide a legal and scientific basis for quality control during the development, production, and marketing of medicines. The establishment of the European Pharmacopoeia in Strasbourg represents an important strategic asset to the BioValley showing the trinational region as an importance life sciences cluster.

Keywords: BioValley · European Pharmacopoeia · European Union Directives · Public health · Quality of medicines · Trade

1. Introduction

Each year the BioValley Life Sciences week offers the opportunity to university students to discover several aspects of the life sciences. This year, the University Day was the occasion for the students of the Pharmacology University of Strasbourg to discover the European Pharmacopoeia which is based in Strasbourg. 2004 is the fortieth anniversary of the European Pharmacopoeia.

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2. 1964–2004: A Short History

A European Pharmacopoeia to guarantee the quality of medicines in Europe: this idea was the basis for the Convention (or international treaty) adopted by the Council of Europe in 1964. Four international organizations were involved, either simultaneously or successively, in work on a European Pharmacopoeia from 1951 to 1964: the Brussels Treaty Organization (1951–1952), the Western European Union (1953–1959), the European Economic Community (EEC) (early discussions to remove technical barriers to trade), and eventually the Council of Europe (with the agreement of the EEC), which finalized the Convention so that it could be opened for signature.

2.1. *Objectives of the European Pharmacopoeia*

- Description of the medicinal substances that are important for public health in Europe (not only originator medicines but also generics) and production methods and methods of analysis that ensure that these substances are of suitable quality.
- Rapid response to new risks to public health (*e.g.* mad cow disease, counterfeit medicines, *etc.*) by elaborating new methods of analysis and tests.
- Facilitation of the free movement and trade of medicines among as many countries as possible.

2.2. *Relationship between the European Pharmacopoeia and Medicines*

The official standards published by the European Pharmacopoeia provide a legal and scientific basis for quality control during the development, production, and marketing of medicines. Demonstrating compliance with these standards is a necessary part of the marketing authorization dossier for a medicine. The European Pharmacopoeia is also used by manufacturers and national and European health authorities to check the quality of medicines.

The European Pharmacopoeia plays a central role in the system of market surveillance (MS) of products. Its participation and administration of post-authorization MS programs aims at strengthening cooperation and scientific expertise both at a national and European level and creating a common quality assurance system.

2.3. *Importance of the European Pharmacopoeia to Consumers*

The European Pharmacopoeia ensures the quality and safety of medicines by elaborating compulsory standards, describing quality control methods, and making it possible to detect counterfeit medicines. This means a consumer can buy a medicine (such as aspirin tablets) in a pharmacy in any European country and obtain the same quality regardless of the

brand or type of medicine (original product or generic).

3. The European Pharmacopoeia at the Centre of the European Regulatory Framework for Medicines

3.1. *The European Pharmacopoeia and Medicines*

European Pharmacopoeia standards apply to all medicines regardless of their origin (chemical, biological, or herbal), their method of production (biotechnology-derived products or genetic engineering) or their type (homoeopathic medicines, originator or generic medicines, vaccines, *etc.*). A wide range of subjects is described: active substances, excipients, and even materials used in containers. It includes over 1800 monographs on preparations and substances, nearly 300 general methods of analysis and 2000 reagents.

The Certification procedure (CEP), set up by the European Pharmacopoeia in 1994, enables a manufacturer of a raw material for pharmaceutical use to demonstrate that the purity of their substance is suitably controlled by the monograph of the European Pharmacopoeia. This important activity is designed to help fulfil the needs of regulatory authorities and industry and develop a common understanding and interpretation of the pharmacopoeia standards.

The European Pharmacopoeia is used as a technical reference by the pharmaceutical, chemical, and biological industries in their commercial dealings with producers of raw materials and excipients.

3.2. *The European Pharmacopoeia: A Mandatory Reference for the Quality of Medicines in Europe (Marketing Authorization)*

The European Pharmacopoeia is at the heart of the quality dossier required by European legislation on medicines.

In 1964 its creation was the first step taken towards the construction of a common European regulatory framework for medicines, to protect public health, respond to new risks, and facilitate free movement of medicines to guarantee the same level of quality and safety for all. As an instrument of standardization it promotes exchanges and thus makes rapid access to new medicines possible by making it simpler to prepare and evaluate quality dossiers for marketing authorization.

In 1975, Directive 75/318/EEC on standards and protocols made the standards of the European Pharmacopoeia obligatory in marketing authorization dossiers in countries of the Community.

In 2004, the European Pharmacopoeia is more than ever an essential reference used in the evaluation of the quality of medicines in dossiers for national and European marketing authorization (MA) and it is still referred to in the revised Directives (Directives 2001/82/EC and 2004/28/EC on medicines for veterinary use and Directives 2001/83/EC, 2003/63/EC and 2004/27/EC for medicines for human use).

It is a scientific tool for standardization and the protection of public health; it has legally binding status enforced by the judiciary authorities.

Furthermore, the new European Union Directives make it obligatory to use all aspects of European Pharmacopoeia texts (nomenclature, test methods) related to various specific manufacturing processes or special types of medicines (vaccines for human or veterinary use, products derived from biotechnology, radiopharmaceutical preparations, plants or plant derivatives, *etc.*), substances used to prepare medicines (active substances, excipients, plants, *etc.*) or texts describing dosage forms (definition of the quality of a tablet, a syrup, *e.g.* by its disintegration and dissolution characteristics, microbiological properties, *etc.*).

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