Regulatory Affairs – Rocket Science?

Regulatory Affairs is a term commonly used in any authority or industry for any measures taken in highly regulated areas: All these measures aim to arrange for market access and continuous compliance of the respective products with legal provisions, particularly in health care industry (medicinal products, medical devices, dietary supplements, cosmetics…).

Regulatory Affairs Managers come from various backgrounds, most often from the life sciences. They are biologists, biochemists, pharmacists and from all other fields that are dedicated to the research of medical, biological and chemical interactions, pathways and mechanisms.

This two day workshop provides an insight into the different legal categories of products, the legal provisions prior and subsequent to launch.

A comprehensive manual including all information dealt with, and the respective information sources will be supplied.

Participants are invited to join an interactive set of teaching and training sessions supported by practical examples from the market and accompanied by hands-on exercises to apply the theoretical knowledge gained. Coffee and lunch breaks give room for a vivid discussion of specific questions of individual participants.

Participants

This workshop addresses graduate students working in life sciences and future employees of the health care sector who are interested in a brief but comprehensive overview on Regulatory Affairs.
Graduate students looking for an introduction on where research might lead in the development of treatments and cures of human diseases will learn about the different stages of medicinal product development, with a strong focus on the final approval and marketing of drugs.

Contents of the workshop

Regulatory legal framework and sources of guidance

Who makes the rules for the authorisation of medicinal products? The laws, guidelines, regulations and other official documents regulating what is needed in order to commercialise a medicinal product in the European Community are introduced in this part of the workshop, along with the agencies and authorities that issue and maintain these sources of guidance.

What exactly defines medicinal products, medical devices, cosmetics and food supplements? In hands-on exercises, the participants are challenged to classify and discuss different products.

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Marketing Authorisations and their maintenance

In order to commercialise a medicinal product, a pharmaceutical company has to apply for Marketing Authorisation. There are different types of applications, depending on the target states and the type of medicinal product to be authorised. The intelligence behind the choice and contents of the Marketing Authorisation Application is a challenge Regulatory Affairs Managers are faced with frequently.

In this module, the participants learn about National, Mutual Recognition, Decentralized, and Centralized Procedures, as well as the different types of applications for medicinal products. Apart from a so called full application, a medicinal product may for example be authorised via a Mixed Application, as a Generic, or as a Biosimilar.

A change in the composition or manufacture of a medicinal product, even if it is very minor, has to be notified to and regulated by the authorities, making a variation procedure necessary. In a defined interval, a renewal of the Marketing Authorisation has to be applied for.

A comprehensive overview of all procedures concerning the application for and maintenance of a Marketing Authorisation of a medicinal product is introduced in this part of the workshop.

Specific medicinal products and special procedures

Especially in the rapidly growing field of biotechnology, stem cell therapy and other highly specialised fields of biomedical research, adapted procedures have to be followed to authorise medicinal products for special patient groups. To enable a treatment without sometimes very time-consuming procedures, the laws and regulations also allow special circumstances, for example for Advanced Therapy Medicinal Products and Biosimilars.

Accelerated procedures and procedures concerning exceptional circumstances as well as compassionate use are introduced in the course of the work shop, as well as the special rules for medicinal products for children, orphan medicines for rare diseases and the possibilities of scientific advice from the authorities.

Patent, data and market exclusivity

The biomedical world is increasingly governed by patents. This also holds true for the manufacture, intended use and combination of medicinal products. Single pharmaceutical companies may hold a patent for an important drug, thus gaining market exclusivity. The rules and laws governing this protection are something people in Regulatory Affairs have to know and work with.

National specifics in Germany

Although there is a tendency towards harmonisation within the EU and also world-wide, certain national specifics continue to exist. For example, in Germany, these are simplified procedures for Standard Marketing Authorisations, National Duplicate Marketing Authorisations ("Dublette") and parallel imported medicinal products (i.e. products which have previously been authorised in other member states of the EU or the European Economic Area (EEA) and are brought into the German market by a third company).

The dossier of a medicinal product

Before a medicinal product can be authorised and marketed, in many cases, quite some time has elapsed for research, development, establishment of manufacture, all quality control steps, packaging and preclinical and clinical testing. The electronic Common Technical Document (eCTD) is the format for the dossier which is submitted to the authorities, describing in detail all stages and characteristics as well as all available research and sampling data demonstrating that the product is safe for its users. This module of the workshop introduces the eCTD and explains its structure and contents.

Product information

Anyone who has ever taken a medicinal product is familiar with the fact that there is a leaflet accompanying this product. But who decides what must be stated in this leaflet? Who ensures that a layman understands how to take the medicinal product and what risk exists? Does a physician need additional information for the decision of a prescription or recommendation?

Unsurprisingly, these accompanying product information texts are also regulated in content, design and for some passages even in wording by the authorities. This part of the workshop describes the rules applying to product information texts. Participants will have the opportunity to create the texts for a virtual product.

Clinical trials and Non-interventional studies

As a basic requirement of any market access procedure, medicinal products need to demonstrate their efficacy and safety in humans. If the product is not a generic or a well-established product, this evidence is to be provided by clinical trials. This module introduces the comprehensive regulations governing design, execution and documentation of clinical trials. Furthermore, clinical trials will be distinguished from another type of investigations called non-interventional studies which are conducted with products which are already used in medical practice in accordance with their Marketing Authorisation.

Advertising and Information

Pharmaceutical companies are also marketing companies and have a legitimate interest in selling their products. So of course they advertise their products, to laymen as well as to health care professionals. Did you know that it is forbidden to advertise medicinal products to laymen that are subject to prescription? The advertisement field for medicinal products is a very interesting field with lots of legal and ethical restrictions. Find out which advertisements are allowed and which are considered to be misleading and why.

Pharmacovigilance

Although drugs are tested in preclinical and clinical trials before a Marketing Authorisation is issued, it is impossible to foresee in detail all effects the drug might have in a population of hundreds of thousands users, all with a variety of metabolisms, genetic background, concomitant diseases and the intake of other potentially interactive substances.

To offer the best protection for all users, a complex pharmacovigilance system exists in the EU and in the single countries. Any adverse effects are sought to be documented. Alert systems are in place to be able to react with speed to serious risks posed to public health, and warnings and text updates on risks are issued to protect the users, the latest example being the elevated thrombosis risk in users of combined hormonal contraceptives. The pharmacovigilance system is introduced and explained in this session.

Speaker

Dr. Johannes Kremer is pharmacist and CEO of DiaMed GmbH in Münster (est. 1992). The company employs 10 scientists of various backgrounds, including biology, pharmacy and chemistry, as well as 3 office management staff members.

DiaMed GmbH supports national and international clientele with regard to development, registration, manufacture and marketing of medicinal products and health care products.

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