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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

PHARM 643

PHARMACEUTICAL COMMITTEE
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Subject: **2015 – 50 years of EU pharmaceutical legislation**

Agenda item 2d

In 1965 the first European measure in the area of pharmaceutical law was adopted: Council Directive 65/65/EEC. In the wake of the Thalidomide disaster in the late 1950s and the early 1960s this Directive of 25 articles introduced one of the key principles of pharmaceutical law, the requirement that no medicinal product may be placed on the market unless a marketing authorisation has been issued by a competent authority.

A large body of legislation has developed around this principle. Nowadays, EU pharmaceutical legislation is a comprehensive, sometimes complex, body of regulatory provisions providing for harmonised rules covering the whole life-cycle of medicinal products, from research and development to authorisation and to the monitoring post-authorisation. It establishes a network of expertise bringing together national competent authorities, Member States, the European Medicines Agency and the European Commission.

The EU legal framework is definitely not an area in which the law stands still. Especially, the last decade has been marked by a peak of activity, leading to numerous new legal acts with the ambition to improve the functioning of the system, addressing shortcomings and reaching out to new areas, including a better involvement of healthcare professionals and patients.

In view of the 50th birthday of EU pharmaceutical legislation, the year 2015 will provide the opportunity to look back, take stock and consider the future, in order to remind all stakeholders of the achievements of the last decades and the continuous challenges in this area.

The Commission is currently considering different activities for 2015, including communication actions and a conference in Brussels to mark the 50th anniversary. It is however, also open to take into account additional ideas from Member States.

Action to be taken:

For information