European Commission - Fact Sheet

50 years of Pharmaceutical Legislation in Europe – making a difference in the well-being of patients across Europe

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This year marks the 50th anniversary of the introduction of the first EU legislation on human medicines. Council Directive 65/65 introduced clear rules on the authorisation and distribution of medicinal products and some founding principles that are valid until today. Since then we have come a long way in a number of areas:

Safety

Once a medicinal product has been authorised in the Union and placed on the market, its safety is monitored during its entire lifespan to ensure that in case of adverse reactions the appropriate action is taken swiftly, including additional warnings, restrictions of use or even withdrawal of the product from the market.

The process by which this is done is called Pharmacovigilance. Through pharmacovigilance rules we monitor the safety of medicines and take action to reduce the risks and increase the benefits of medicines. Pharmaceutical legislation has strengthened time after time pharmacovigilance activities. These include collecting and managing data on the safety of medicines and trying to detect any new or changing safety issues as well as communicating with and informing stakeholders and the public.

Additional monitoring of medicines

EU legislation introduced a new symbol in the form of a black inverted triangle to identify medicines for which additional monitoring is considered necessary. As of September 2013, the new symbol is printed on the package leaflet and the summary of product characteristics of the medicines concerned, along with information on how to report suspected side effects. This is particularly important as patients now have the right to report suspected side effects directly to their national authorities.

Protection against falsified medicines

To protect patients from the risks associated with unauthorised ' fake' or 'falsified' medicines, the EU has introduced strict rules which became applicable at the beginning of 2013. These include rules for imports of active substances from third countries, controls and inspections, rules for record-keeping by wholesale distributors as well as an obligation for manufacturers and distributors to report any suspicion of falsified medicines.

Ensuring on-line purchasing is safe

The sale of falsified medicines over the Internet is also addressed by the EU's pharmaceutical legislation. On 24 June 2014 the European Commission adopted a new common logo. Member States have one year from this date to ensure that the provisions on the common logo are applied. Therefore, by mid this year, all online pharmacies or retailers legally operating in the EU should display the logo. The logo helps identify the websites which are operating legally. Buying from a legally operating pharmacy or retailer guarantees the safety of the products.

Orphan Medicinal Products

Orphan medicinal products are intended for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affect no more than 5 in 10,000 people in the European Union. To date, the European Commission has already authorised 111 orphan medicines for the benefit of patients suffering from rare diseases. The sponsors responsible for these medicines benefit from incentives such as fee waivers for the regulatory procedures or a 10 year market exclusivity.

Since only a very small number of the population is affected by these diseases, the pharmaceutical industry has been reluctant in the past to invest in the research and development of medicinal products to treat them. In response to this situation and in order to stimulate the research and development of orphan medicines, in 2000 the EU introduced new legislation with the aim of providing incentives for the development of orphan and other medicinal products for rare disorders.

Medicines for Children

Studies carried out before EU legislation was adopted showed that over 50 % of the medicines used for

children might not have been tested for use in this specific age group. The lack of age-appropriate medicinal products to treat conditions in children can be explained by the fact that pharmaceutical companies frequently did not carry out the necessary research and development to adapt medicinal products to the needs of the paediatric population. This left healthcare professionals with no alternative but to use products 'off label' with the associated risks of inefficacy or adverse reactions.

New legislation governing the development and authorisation of medicines for paediatric use entered into force in the European Union on 26 January 2007. The Regulation sets up a system of requirements, rewards and incentives together with horizontal measures to ensure that medicines are researched, developed and authorised to meet the therapeutic needs of children.

The key objectives of the Regulation are to ensure high-quality research into the development of medicines for children and that the majority of medicines used by children are specifically authorised for such use.

Clinical trials

Clinical trials are investigations in humans intended to discover or verify the effects of one or more medicinal products The Clinical Trials Regulation aims to create an environment that is favourable for conducting clinical trials, with the highest standards of patient safety, for all EU Member States. Intrinsic to this is the simplification of current rules by having a streamlined application procedure and a single authorisation procedure for all clinical trials, allowing a faster and thorough assessment of an application by all Member States concerned, and ensuring one single assessment outcome and authorisation per Member State The Regulation entered into force on 16 June 2014 and will enter into application in 2016.

Advanced Therapies

Advanced therapy medicinal products are medical products the manufacture of which involves gene transfer, manipulations of cells, or tissue engineering. These medicinal products offer hope for life-threatening disease and other unmet medical needs such as cancer or neurodegenerative disorders and for conditions related to the ageing population.

The lack of an EU-wide regulatory framework in the past led to divergent national approaches which hindered patients' access to products, hampered the growth of this emerging industry and ultimately affected EU competitiveness in a key biotechnology area. In 2007 the EU agreed on a Regulation on advanced therapies that is designed to ensure a high level of public health protection and the free movement of these products in the EU.

One of the main elements of this Regulation is a centralised marketing authorisation procedure, so as to benefit from the pooling of expertise at European level and direct access to the EU market as well as special incentives for small and medium-sized enterprises.

Read Commissioner Andriukaitis' statement

For more info: http://ec.europa.eu/health/human-use/50years/index_en.htm

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