MEDICINES AND MEDICAL DEVICES

Medicines and medical devices are products subject to the rules of the single market, and therefore the EU holds competency for their authorisation through evaluation and supervision. In order to protect public health, before being placed on the market new pharmaceuticals for human use must be authorised under a centralised procedure by the European Medicines Agency (EMA) and/or in a decentralised manner by national agencies. Medical devices require a detailed regulatory framework for market access through private-sector organisations called notified bodies; revisions are ongoing and a new legislative approach will come into force in 2017.

LEGAL BASIS

Article 168 of the Treaty on the Functioning of the European Union (TFEU).

OBJECTIVES

European health policy is based on the principle that the good health of the population is a condition for meeting the basic EU objectives of prosperity, solidarity and safety. Furthermore, the EU health strategy proposes three objectives: fostering good health in an ageing Europe; protecting citizens from health threats; and supporting dynamic health systems and new technologies. In economic terms, the pharmaceutical sector, being one of the most resilient industries, makes an important contribution to European wellbeing through the availability of medicines, economic growth and sustainable employment.

ACHIEVEMENTS AND CURRENT DEVELOPMENTS

A medicinal product or a medicine is any substance or combination of substances presented for the treatment or prevention of diseases in human beings. With the aim of safeguarding public health, the market authorisation, classification and labelling of medicines has been regulated in the EU since 1965. The great disparities between Member States' legislation have hindered the trade in medicines on the internal market. The European Medicines Agency (EMA) has been responsible for the evaluation of medicines since its creation in 1993. A centralised authorisation procedure was put in place in 1995 to guarantee the highest level of public health and to secure the availability of medicinal products. The main pieces of legislation in this area are Directive 2001/83/EC and Regulation (EC) No 726/2004, which lay down the rules for establishing the centralised and decentralised procedures. In 2008 the Commission proposed the 'Pharmaceutical Package', a renewed vision for the pharmaceutical sector focused on 'safe, innovative and accessible medicines', and three legislative proposals aimed at providing information to the public, monitoring safety and combating falsified medicines. Specific regulations have been adopted for orphan medicinal products (Regulation (EC) No 141/2000), medicines for children (Regulation (EC) No 1901/2006) and advanced therapies (Regulation (EC) No 1394/2007).

Once medicines are placed on the market, they are monitored throughout their entire lifespan by the EMA under the Pharmacovigilance System, which records any adverse drug effects in daily clinical practice. The first legal framework for pharmacovigilance entered into force with Directive 2001/83/EC and Regulation (EC) No 726/2004. In 2012 new requirements and procedures were laid down in the new Regulation 1027/2012 and Directive 2012/26/EU.

Clinical trials are systematic investigations of medicines in humans that are intended to study the efficacy and safety of a given medicine. In order for a product to be placed on the market, it must be accompanied by documents indicating the results of the tests that it has undergone. Standards have been developing progressively — both in the EU and internationally — since 1990 and are codified in EU legislation, a process that is mandatory for the pharmaceutical industry. The basis establishing acceptable conduct for clinical trials in humans is founded in the protection of human rights and the dignity of the human being, as reflected in the 1996 Helsinki Declaration. Directive 2001/20/EC (the Clinical Trials Directive) deals with the implementation of good clinical practice, which is reinforced in Directive 2005/28/EC. In 2012 the Commission sent Parliament a proposal for a regulation on the matter (COM(2012) 0369). A new, revised piece of legislation came into force in 2014, in the shape of Regulation (EU) No 536/2014 repealing Directive 2001/20/EC.

Advanced-therapy medicinal products are a relatively new kind of product or pharmaceutical based on advances in cellular and molecular biotechnology and novel treatments, including gene therapy, cell therapy and tissue engineering. These complex products, which involve pharmacological, immunological or metabolic actions, cannot be treated in the same way as conventional drugs, and they require specific legislation as laid down in Regulation (EC) 1394/2007 and Directive 2009/120/EC. Because of the risk of disease transmission that they pose, tissues and cells must be subject to strict safety and quality requirements. Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells is therefore of great relevance to these products. A committee for advanced therapies was created at the EMA with responsibility for assessing the quality, safety and efficacy of advanced-therapy medicinal products and following scientific developments in the field. In 2012 the Commission launched a public consultation to engage with interested parties (i.e. stakeholders, including small and medium-sized enterprises) in order to establish their views on advanced-therapy medicinal products. This emerging field in biomedicine has enormous potential for patients and industry.

Paediatric medicinal products have also been specifically regulated (under Regulation (EC) No 1902/2006 amending Regulation (EC) No 1901/2006) to ensure that medicinal products meet the needs of children, a legislative gap previously having existed in this field whereby children were treated with the same medicines and doses as adults. Following on from an earlier consultation, in 2013 the Commission sent Parliament a progress report on the paediatric regulation covering the first five years of its application.

In the EU, rare diseases are those which affect no more than 5 in every 10 000 people, and orphan medicinal drugs have been designed specifically to treat these illnesses. Regulation (EC) No 141/2000 lays down the centralised procedure for the designation of orphan drugs. To date, the EU has authorised few orphan medicines, and owing to the low number of people who are affected by rare diseases, research in this field has been neglected. With this in mind, different measures, such as the Innovative Medicine Initiative (IMI), have been established to encourage industry to develop orphan drugs.

The fight against antimicrobial resistance (AMR) is part of the ‘protection against health threats’ objective of the EU’s ‘Together for Health’ strategy. Antimicrobial agents are substances

that kill or inhibit microorganisms, including bacteria, viruses, fungi and parasites. The use (and misuse) of antimicrobial agents is linked to an increasing prevalence of micro-organisms that have developed resistance to such agents, thereby posing a threat to public health. The Antimicrobial Resistance Surveillance System was established under Decision 2119/98/EC, and in 2001 the Commission adopted a strategy against antimicrobial resistance (COM(2001) 0333). In response, the Council adopted a recommendation on the prudent use of antimicrobial agents in human medicine (2002/77/EC). Current objectives aim to prevent the spread of resistant strains and ensure that antibiotics are used only when needed. In 2011, the Commission launched an Action Plan against the rising threats from AMR, which has four main pillars: surveillance; research and product development; prevention; and international cooperation. On 11 December 2012 Parliament adopted a resolution on 'The Microbial Challenge — Rising threats from Antimicrobial Resistance'[1]. In 2015, it further adopted a resolution on 'Safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance'; among other things, the resolution called on Member States to set specific and ambitious quantitative targets for reducing the use of antibiotics.

A new directive on falsified medicines (Directive 2011/62/EU), addressing the alarming increase in that phenomenon in the EU, was issued in 2011 and transposed by the Member States in January 2013. Falsification can refer to identity, history or source, the presence of substandard, falsified or non-relevant ingredients, wrong dosage, etc. In an effort to combat falsified medicines, the Commission has taken steps to promote reflection on ways to improve market access and develop initiatives to boost pharmaceutical research in the EU, tackle counterfeiting and the illegal distribution of medicines, provide for access to high-quality information on prescription-only medicines, and improve patient protection by strengthening pharmacovigilance.

A body of EU legislation has been adopted to specify the essential requirements that medical devices must fulfil in order to be placed on the market, and the procedure for assessment of conformity, as well as conditions for clinical investigation and for packaging and labelling. In 2012 the Commission launched proposals for two new regulations: (a) on medical devices (COM(2012) 0542), amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009; and (b) on *in vitro* diagnostic medical devices (COM(2012) 0541). Parliament approved both these regulations in plenary in April 2014. On both regulations, there is political agreement in the Council on its first-reading position.

ADDITIONAL CHALLENGES

The Commission recognises the role played by pharmaceutical research and development, and is currently implementing initiatives to foster innovation. In 2006 the Seventh Research Framework Programme (FP7) and the Competitiveness and Innovation Programme (CIP) were adopted to support new technologies and the expedited commercialisation thereof. The Third Health Programme was provided for under Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health 2014-2020, and will support actions in the fields of communicable diseases and other health threats as well as human tissues and cells, blood, human organs, medical devices and medicinal products.

Creating incentives for the development of pharmaceuticals is a relevant measure for combating diseases, especially in the developing world. The EU has been losing ground in pharmaceutical innovation, with research and development investment gradually being relocated from Europe to

[1]OJ C 434, 23.12.2015, p. 49.

the USA and Asia. Furthermore, the sector is becoming more and more globalised, which, while bringing opportunities with access to new markets, also gives rise to a global division of labour. In this context, the IMI was created as a key measure for the strengthening of competitiveness in biopharmaceutical research and development.

Access to essential medicines is part of the right to health, according to the WHO. However, access to health treatment is becoming more and more heavily dependent on the availability of affordable medicines. Findings show striking differences in the sales and availability of innovative medicines between different Member States. The problem is exacerbated by the economic crisis. The European Parliament, concerned with this serious situation, has launched an own-initiative report on 'EU options for improving access to medicines'.

ROLE OF THE EUROPEAN PARLIAMENT

Parliament has consistently promoted the establishment of a coherent public health policy and a policy on pharmaceuticals that takes into account both the public health interest and industrial aspects. It has also actively sought to strengthen and promote health policy through opinions, questions to the Commission and own-initiative reports on issues including antimicrobial resistance, patient safety and protection against hospital infections, medicines, medical devices and alternative therapies.

At present the EU is still considering draft legislation on 'Medicinal products for human use: information on products subject to medical prescription' (2008/0255(COD)). Parliament considers that information on medicinal products that are subject to prescription must be made available to patients and the general public. Patients should be entitled to easy access to a summary of product characteristics and the package leaflet in electronic and printed form. The leaflet should include a short paragraph setting out the benefits and potential risks of a given medicinal product, as well as further information aimed at the safe and effective use of the medicinal product concerned. A clear distinction must be made between the interpretation of information and advertising, and the ban on advertising to the general public for prescription-only medicinal products should be maintained.

The European pharmacovigilance system was reinforced by Parliament's amendments to the latest proposals by the Commission at various technical levels.

On the issue of falsified medicines, Parliament, together with the Council, stipulates that a clear definition of 'falsified medicinal products' must be introduced into legislation, in order to clearly distinguish falsified medicinal products from other illegal products, as well as from infringements of intellectual property. Given that the distribution network for medicinal products is increasingly complex, the new legislation addresses all actors, including wholesale distributors and brokers who are involved in the sale or purchase of medicinal products without selling or purchasing those products themselves, and without owning and physically handling the medicinal products. Safety features should allow verification of the authenticity and identification of individual packs and provide evidence of tampering. The illegal sale of medicinal products to the public via the internet poses a significant threat to public health, as falsified medicinal products may reach the public through such a method of sale.

In summary, with respect to the various pieces of legislation related to medicines, Parliament has made significant improvements to the proposals presented by the Commission, contributing to the creation of a safer context for the use of pharmaceutical products for the health and wellbeing of EU citizens.

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