MEDICINES AND MEDICAL DEVICES

Medicines and medical devices are subject to the rules of the single market and have a direct impact on people’s health. A robust legal framework is in place to protect public health and guarantee the safety of these products. It covers the full cycle, from trials and testing, to authorisation for placement on the market, to surveillance and recall. Access to affordable medicines, the fight against antimicrobial resistance, the ethical conduct of clinical trials, and incentives to research and development are just some of the key issues the EU deals with in this field. In order to keep up with scientific and technological advancement and respond to emerging health threats, legislative and policy measures are subject to regular evaluation and follow-up.

LEGAL BASIS

Articles 168 and 114 of the Treaty on the Functioning of the European Union (TFEU).

Context

While the Member States are responsible for devising health policies and organising and delivering health services and medical care, the EU has a complementary competence. This allows it to support and coordinate actions and adopt binding legislation on certain clearly defined subjects, such as medicines and medical devices.

ACHIEVEMENTS AND CURRENT DEVELOPMENTS

A. General rules on medicines

A medicinal product (medicine) is a substance or combination of substances that is used 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 evaluation of medicines has been centralised through the European Medicines Agency (EMA) since its creation in 1993 and 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[1] and Regulation (EC) No 726/2004[2], which lay down the rules for establishing centralised and decentralised procedures.

This set of rules was updated in 2010 and 2012 in order to strengthen provisions on monitoring the safety of medicines (amending Directive 2010/84/EU[3], amending Regulation (EU) No 1235/2010[4] and amending Directive 2012/26/EU[5]). 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 legislation was amended again in 2011 to prevent falsified medicines from entering the legal supply chain. A raft of new provisions, covering such issues as obligations of importers, manufacturers and distributors, inspections and recall mechanisms, safety features and good manufacturing practices, is now included in the directive (amending Directive 2011/62/EU[6]).

In addition to the general rules on medicines, specific regulations are also in place for orphan medicinal products for the treatment of rare diseases (Regulation (EC) No 141/2000[7]), medicines for children (Regulation (EC) No 1901/2006[8]) and advanced therapies (Regulation (EC) No 1394/2007[9]). More information on this topic is set out in section D.

B. Clinical trials

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 medicine 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 latest revision of the EU legislation from 2014 established harmonised rules for the authorisation and conduct of clinical trials (Regulation (EU) No 536/2014[10]). Clinical trials must undergo a scientific and ethical review and must receive prior authorisation. Furthermore, they may only take place if the rights, safety, dignity and well-being of participants are protected and prevail over all other interests, and only if the trial is designed to generate reliable and robust data. The application of this new regulation has been postponed due to technical difficulties, and is now expected to take place in 2020.

C. Advanced-therapy medicinal products

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[11] and Directive 2009/120/EC[12]. Because

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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 this emerging field of biomedicine, which has enormous potential for patients and industry.

D. Orphan medicinal products and medicines for children

Paediatric medicinal products are also specifically regulated (Regulation (EC) No 1901/2006) to ensure that they have been researched and tested specially for children in an ethical way, that they meet the needs of children and that they have age-appropriate doses and formulations. Pharmaceutical companies carry out studies on children to obtain evidence about the safety and efficacy of new medicines before requesting marketing authorisation. The EMA's Paedriatric Committee assesses those studies and the data generated by them.

In the EU, rare diseases are those which affect no more than 5 in every 10 000 people. Orphan medicinal drugs are specifically designed 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 Medicines Initiative (IMI), have been established to encourage the pharmaceutical industry to develop orphan drugs. In 2017, the Commission began its evaluation of the legislation on medicines for children and rare diseases. This process is still ongoing.

E. Medical devices

New pieces of legislation concerning medical devices and in vitro diagnostic devices have been adopted recently. Medical devices cover a broad range of products, from simple bandages and glasses to special medical equipment used by doctors and hospitals. In vitro diagnostic devices are used for the external examination of samples taken from the human body, e.g. in a test tube (‘in vitro’ literally means ‘in the glass’).

Regulation (EU) 2017/745 and Regulation (EU) 2017/746 set the rules on placing medical and in vitro diagnostic devices on the market and on related clinical investigations. Devices are grouped according to their risk category, each of which has a specific set of rules. The new regulations are a significant step towards strengthening patient safety as they introduce more stringent procedures for conformity assessment and post-marketing surveillance, require manufacturers to produce clinical safety data, establish a unique device identification system for the traceability of devices, and provide for the setting up of a European database on medical devices.

F. Antimicrobial resistance

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 microorganisms that have developed resistance to such agents, thereby posing a threat to public health. EU-level action to tackle antimicrobial resistance dates back to the late 1990s. The latest policy initiative is the European One Health Action Plan against Antimicrobial Resistance (AMR)\[19\], adopted in 2017. Its main goal is to maintain the possibility of effective treatment of infections by reducing the emergence and spread of AMR and increasing the development and availability of new, effective antimicrobials. Parliament responded to this action plan in a recent resolution\[20\] and in 2019 the Council adopted conclusions on the next steps for making the EU a best practice region in combatting AMR\[21\]. In its resolution, Parliament emphasised its conviction that ‘diseases have to be tackled in both people and animals, while also taking into special consideration the food chain and the environment, which can be another source of resistant microorganisms’ and underlined ‘the important role of the Commission in coordinating and monitoring national action plans implemented by Member States and the importance of cross-administrative cooperation’.

ADDITIONAL CHALLENGES

The EU continuously strives to implement initiatives to foster research and innovation in the pharmaceutical sector. Research framework programmes have always supported health-related research. The current programme, Horizon 2020 (Regulation (EU) No 1291/2013\[22\]) aims to keep ‘older people active and independent for longer’, supports the development of new, safer and more effective interventions, and contributes to the sustainability of health and care systems. The next framework programme, Horizon Europe, will promote health-related research and respond to the current challenges by addressing topics such as lifelong health, environmental and social health determinants, non-communicable and rare diseases, infectious diseases, tools, technologies and digital solutions for health and care, and healthcare systems.

Other EU funding programmes such as the third EU health programme (Regulation (EU) No 282/2014\[23\]) and the European Social Fund Plus, which will run from 2021 to 2027, also play an important role. Furthermore, the EU has given considerable support to developing innovative drugs and urgently needed treatments, and accelerating patient access to new treatments via the IMI and its predecessors.

Access to essential medicines is part of the right to health, according to the World Health Organisation. 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 has been exacerbated by the economic

crisis. Parliament, concerned with this serious situation, has published several own-initiative reports on access to medicines. In 2016 the Council adopted conclusions on strengthening the balance in the EU’s pharmaceutical systems[24] and in 2017 Parliament adopted a resolution on options for improving access to medicines[25]. Access to affordable medicines will also remain a priority for the new Commission, as emphasised by Commissioner Kyriakides during her hearing before Parliament[26].

Given the increasing concerns about shortages of certain medicines, which may be further affected by Brexit, the supply side of medicines also requires attention. To this end, the EMA recently issued guidance on the detection and notification of shortages of medicinal products[27].

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. Recent pieces of legislation, adopted with the very active participation of Parliament as co-legislator, include regulations on clinical trials, medical devices and in vitro devices. Parliament has advocated for patient safety to be strengthened during the legislative process. Non-legislative resolutions and debates on current issues such as access to medicines or AMR highlight the attention that Parliament attaches to ongoing challenges and emerging threats. During the hearing of Commissioner Kyriakides, Parliament further emphasised the need to act on those challenges.

At present, the EU is still considering draft legislation on health technology assessment (HTA)[28]. The new regulation would define a support framework and procedures for cooperation on clinical assessment of health technologies at EU level, and common methodologies for the clinical assessment of health technologies. Among other things, it would help to accelerate access to new medicines. Amendments by Parliament aim to ensure that HTA is used to promote innovations that achieve the best results for patients and society in general, and enable medical staff, patients and medical institutions to determine whether a new health technology is an improvement on existing health technologies, in terms of its risks and benefits. Negotiations in the Council to establish the position of the Member States are ongoing.

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12/2019