EU Provisions: Health & Consumer Protection in terms of Intellectual Property Rights

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Abstract

The safety and health of European patients and consumers are subject to double protection: in national law, first and foremost in the EU European secondary legislation (regulations, directives and decisions), in a complementary or subsidiary manner, as appropriate. consumer protection is very broad to defend their economic interests, their physical security is the subject of a general directive and several specific directives, consumer protection policy took off at European level about twenty years ago. The main objective of the article is to investigate the legal provisions of comparative law on consumer protection as beneficiaries of medical services and to establish the direct link of the right to health with consumer protection and intellectual property law, respectively.

Keywords: health, protection, consumer, security, intellectual property

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1.Introduction

Protecting the health of consumers, especially European citizens, is a basic principle of European law, available in all sectors of activity and especially in the field of food security. Patient safety issues have first

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appeared in specific texts on drug safety (pharmacovigilance) and radiation protection. With the recent development of European competences in the field of public health, patient safety has become an important topic for cooperation between the European Commission (hereinafter the Commission), ministries of health and patient representative organizations and healthcare professionals. Thus, competences for health issues as well as legal issues for consumer rights were spread across many more areas and services of the Commission, most of which were brought together in 1999 in a new "Directorate-General for Health and Consumers DG SANCO" (Directorate-General for Health and Consumers), under the authority of a single European Commissioner: David Byrne, then Markos Kyprianou, since 2004. Following the further enlargement of the Union to 27 countries in 2007, the portfolio of consumer policies was entrusted to Bulgarian Commissioner Meglena Kuneva and the health for a Cypriot, Androulla Vassiliou.

2.EU health regulatory framework for consumer protection

Article 152 of the Treaty of Nice provides that a level of protection of human health is ensured in the definition and implementation of all policies and actions of the European Union. This applies in particular to food, transport, energy and all other products and services offered to consumers, as well as health products or services directly targeting patients. For the quality and safety of substances of human origin, this article specifies that measures taken by the EU cannot prevent a Member State from maintaining or establishing measures that are too strict.(Treaty of Nice, 2001)

Article 153 of the Treaty provides that the EU shall contribute to the protection of the health and safety of consumers when it adopts measures for the organization of the internal market or for supporting and supplementing national consumer protection policies. This article specifies that Member States may maintain or establish more stringent measures, compatible with the principles of the Treaty and notified to the Commission.

The Euratom Treaty created the European Atomic Energy Community in 1957 for cooperation in nuclear research and protection of the population. This treaty makes it possible to establish criteria for uniform safety and

radiation protection, in particular for patients and healthcare professionals exposed to ionizing radiation.(EU, 1957)

Council Directive 85/374 / EEC of 25 July 1985 harmonized the laws of the Member States relating to product liability in order to ensure a high level of consumer protection against damage caused by a defective product. The victim has three years to seek redress. This Directive establishes the principle of liability for the objective liability of the manufacturer or importer in the event of damage caused by a defect in his product. The defect is assessed in particular according to the date of presentation, use of the product or service. (EEC,1985/85/374)

The manufacturer's liability starts ten years from marketing. The manufacturer is exempted if he proves that the technical knowledge, at the time of placing the product on the market, proved to be insufficient to detect the defect. To this end, Member States are authorized to take derogating measures. In addition, the victim may rely on more favorable national provisions than the Directive. Directive 1999/34 / EC extended the liability for defective products to agricultural raw materials, such as milk and meat, by eliminating border problems with processed foods.

Directive 2001/95 / EC of the European Parliament and of the European Parliament Council of 3 December 20013 lays down general rules for the safety of consumer products. This Directive shall apply where there are no specific Community provisions governing safety or where Community sectoral legislation has shortcomings. A product is considered safe when it complies with the specific provisions of the Community governing its safety or in accordance with a European standard established in accordance with a procedure laid down in that Directive. (EC, 2001/95)

In the absence of EU provisions, these are national regulations or standards in the country from which they apply. Manufacturers and distributors must ensure that the product market fulfills the general safety obligation. In addition, they must:

- provide the consumer with useful information for assessing the risks of the product;
- monitor their placing on the market and ensure the traceability of their products;

- in case of danger, notify the competent authorities and cooperate with them;
- take appropriate measures in case of danger such as: withdrawal from the market, warning consumers, etc.

Member States shall ensure that producers and distributors fulfill their obligations through control and intervention structures as well as by imposing sanctions. The Commission mandates the European standardization bodies to establish the presumption of conformity with the general safety obligation. It manages the Rapid Alert System (RAPEX) and strengthens the system of appropriate response measures. (EC, 2004/418)

3.The Health Services within the EU action programs

The EU's multiannual consumer protection program was renewed in 2014, with a budget of almost EUR 188.83 million for the period 2014-2020. This program aims to ensure a high level of consumer protection and empower consumers through information and education. With increased power, consumers can better exercise their rights by organizing and thus play a more active role in the EU's single market.

The third EU action program in the field of health entered into force in 2014, while the first Community action program funded more than 300 trans-European projects from 2002 to 2007, and the second program had a budget of 321 .5 million for the period 2008-2013. The general objective of the third program is to complement, support and add value to the policies of the Member States, to improve the health of the citizens of the Union and to reduce health inequalities by promoting health, encouraging health innovation, enhancing the sustainability of health systems and protecting Union citizens from serious cross-border health threats. (EU, Consumer Programme, 2013)

It should be noted that, in the framework of the renewal of European programs, the European Commission has proposed to the Council and Parliament an important global program for health and consumer protection, endowed with EUR 1.203 million, of which EUR 969 million for health. The European Parliament preferred to split this ambitious major program again into two separate programs, while the Council significantly reduced the

appropriations allocated, considering the difficult financial prospects for the general budget of the European Union until 2013. Three scientific committees have been set up on the basis of Commission Decision 2004/210 / EC, as amended by Commission Decision 2007/263 / EC:

- Scientific Committee on Consumer Products
- Scientific Committee on Health and Environmental Risks
- Scientific Committee for Emerging and New Health Risks

The requirements for the quality, safety and efficacy of medicinal products placed on the market in Europe have been considerably strengthened since the first directive in 1965. These complex provisions, fully codified in 2001, relate to market access, drug information, surveillance measures. and control from research, manufacturing, marketing to hazardous or defective product withdrawal procedures. All rules and guidance notes for the application of regulations are updated electronically in a series of several thematic volumes (EUDRALEX). (EC, 2007/263)

The extension of the European Agency's powers in 2004 was accompanied by a considerable strengthening of pharmacovigilance measures, in particular the extension of obligations and notifications of adverse reactions and the creation of a European Medicines Database (EUDRAPHARM). Detailed requirements for European pharmacovigilance are published in Volume 9 of EUDRALEX. The European Medicines Agency frequently publishes information on pharmacovigilance through national agencies and the media. Community pharmaceutical regulations, including pharmacovigilance, have been extended to advanced therapies, such as genetic, somatic and tissue therapies, by Regulation (EC) No 882/2004. 1394/2007 which enters into force at the end of 2008.

Following a reflection process on patient mobility, including health ministers, professionals and patients, the Commission set up a High-Level Group on Health Services and Healthcare in 2004, composed of representatives appointed by the Ministers of Health. This group has been tasked with several major areas:

- providing cross-border healthcare;
- information on the quality, safety and continuity of care;

- patients' rights and responsibilities; - continuous professional training to guarantee the quality of services;
- reference centers for rare diseases or other specialized care assessing health technology and creating a viable European network;
- online information and health;
- the impact of the EU on health and health systems;
- exchanges of experience and expertise on patient safety.

In parallel with these activities, the projects were funded by the European Public Health Program on antibiotic resistance, nosocomial diseases and in 2005, two major European conferences of the Presidencies in Luxembourg and the United Kingdom. The Commission renewed its consumer protection strategy in 2007 and later in 2014. The subsidiary nature of consumer protection by the "Minimum Harmonization" Directives maintains significant differences in the level of protection and rights depending on the country. Following the research, the author found that there is a broad consultation within the EU based on a comparative report on national policies and legal systems for consumer protection.

European consumer protection measures aim to protect the health, safety and economic and legal interests of European consumers, regardless of where they live, travel or shop in the EU. EU provisions govern both physical transactions and electronic commerce and contain rules of general application accompanied by provisions targeting specific products, including medicines, genetically modified organisms, tobacco products, cosmetics, toys and explosives.

The Treaty of Lisbon emphasized the importance of health policy, stipulating that "a high level of protection of human health shall be ensured in the definition and implementation of all Community policies and actions". This objective is to be achieved with the Union's support to the Member States and by encouraging cooperation. The main responsibility for the protection of health, and in particular health systems, remains with the Member States. However, the EU has an important role to play in improving public health, preventing and managing disease, mitigating sources of danger to human health and harmonizing health strategies between Member States. The EU has

successfully implemented a comprehensive policy through the Health Strategy for Health for Growth and its action program for 2014-2020, as well as a body of secondary legislation. The current institutional structure to support implementation includes the Commission's Directorate-General for Health and Food Safety (DG HEALTH) and the specialized agencies, in particular the European Center for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA). (EU, Treaty of Lisbon,2007)

4.The impact of intellectual property infringements on the life and health of consumers

4.1. At the economic level

A 2016 study by the European Union Intellectual Property Office (EUIPO) and the Organization for Economic Co-operation and Development (OECD) estimated that international trade in counterfeit and pirated goods was worth about $ 461 billion. However, this estimate does not include products made and consumed in the internal market or intangible digital products. If these types of products were included, the EUIPO and OECD study estimates that international trade in counterfeit and pirated products would have exceeded $ 461 billion by several hundred billion dollars. In the EU, these products account for up to 5% of total EU imports, amounting to up to € 85 billion.

The EUIPO and OECD synthesis report brings together the findings of research over the last five years on the scale, scope and economic consequences of infringements of intellectual property rights in the EU. Research shows that annual direct losses amount to 60 billion euros due to counterfeiting in 13 economic sectors. The 13 sectors studied are: cosmetics and personal care; clothing, footwear and accessories; sporting goods; toys and games; jewelry and watches; bags and luggage, recorded music; spirits and wine; pharmaceutical products; pesticides; Smartphones; batteries and tires.

Counterfeit and pirated products come from several economies, with emerging economies playing an important role in this phenomenon, either as

counterfeiters (China being the largest producer market) or as transit zones. It is also noted that trade in counterfeit goods is being catalyzed by the increased use of small shipments by counterfeiters, due to the increase in e-commerce and also the reduction of risks and financial consequences of detection. The EUIPO and OECD study highlights the extent of funding that Governments and legitimate businesses lose due to trade in counterfeit and pirated products, which can be used to increase the level of development of society (e.g. to build schools, hospitals and others) or to create jobs. (EUIPO, 2019)

4.2.At the level of Health and Safety

The study by EUIPO and the OECD also showed that counterfeiting is not limited to luxury items such as watches and clothing signed by designers, but has also spread to pharmaceuticals, food, beverages, medical equipment, personal care items, toys, and safety items.

Interpol mentions “Trademark trafficking and copyright piracy are serious intellectual property crimes that defame consumers, threaten their health and safety, cost billions of dollars in lost government revenue, foreign investment or profits from and infringes the rights of trademark and copyright owners. Imitation products pose a significant threat to consumer safety around the world. Customers who do not ask questions in this regard risk their health and even their lives every time they use counterfeit products, alcoholic beverages and counterfeit food or travel in cars and planes maintained with counterfeit parts made below standard." (EUIPO, 2019)

On the other hand, the World Health Organization (WHO) states that "counterfeit medicines and other health products can have harmful effects on patients' health, and can even cause death in the worst cases." (Blackstone, 2014)

We would like to mention that by the Government Decision of the Republic of Moldova no. 880 of 22.11.12, the National Strategy on Intellectual Property was approved, covering the period between 2012 and 2020, the main objective being to increase the capacity of government institutions to apply intellectual property law. (HG RM nr.880 from 22.11.2012)

In the Republic of Moldova, the effective fight against counterfeiting and piracy requires a coordinated effort on the part of several institutions, including: State Agency for Intellectual Property, Customs Service, Agency for Consumer Protection and Market Surveillance, General Inspectorate of Police and General Prosecutor's Office. Similarly, a body dedicated to facilitating cooperation between institutions responsible for intellectual property, including having a role in the fight against counterfeiting and piracy, called the National Commission for Intellectual Property, has been established in the Republic of Moldova. There is also an Observatory against Counterfeiting and Piracy, made up of representatives of the State Agency for Intellectual Property, the Agency for Consumer Protection and Market Surveillance, the Customs Service, the General Inspectorate of Police and the General Prosecutor's Office. At the international level, it is relevant to note that there are international organizations that contribute to capacity building and cross-border investigations in the field of intellectual property, namely: EUIPO Observatory, Europol, Interpol, World Customs Organization (WMO), World Property Organization Intellectual Property (WIPO). With regard to infringements of intellectual property rights in the online environment, we would like to mention that there is a growing tendency to advertise, distribute and / or sell goods that infringe intellectual property rights on the Internet. In this context, several problematic aspects are outlined, namely: non-confirmation of the protection of intellectual property rights in the Republic of Moldova and non-compliance with the notification procedure of the rights holder.

5.Conclusion

Based on the above, we can conclude that from a historical point of view, EU health policy has its origins in health and safety provisions, later developing as a result of the free movement of persons and goods in the internal market, which made it necessary to coordinate public health in terms of consumption. In harmonizing the measures for the creation of the internal market, the basis of the proposals in the field of health and safety was a high level of protection. Various factors, including the crisis caused by bovine

spongiform encephalopathy at the end of the last century, have made health and consumer protection important issues on the political agenda. Likewise, with the consolidation of the sales market, we must recognize that counterfeiting has grown not only for expensive products but also in the domestic environment, which inevitably established a direct correlation between the doctor, the consumer and the consumer. In conclusion, we can say that consumer protection could, by itself and distinctly from the users' perspective, add a new dimension to the analysis of intellectual property. Considering that users of creative works as consumers of tangible goods may prove useful when faced with conflicts between intellectual property owners and beneficiaries of works, intellectual creations, however, raise other concerns that should not be taken lightly. simple to be suppressed by a standard contract. Not only are they commodities that can be judged by their usefulness and price, but also by information works that can affect consumer autonomy and freedom of expression.

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