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Contraffazione di farmaci per uso umano: questioni aperte in tema di salute pubblica, proprietà intellettuale e criminalità organizzata.

Abstract

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ABSTRACT

Counterfeiting of medicines is a global phenomenon which can be examined and defined from a dual perspective: the protection of public health and the protection of intellectual property rights. From the first point of view, the falsification of a medicine is the deliberate and intentional adulteration of the identity, composition or source of a medicine and can cause serious damage to the health of those who take it. From the second point of view, counterfeiting means violation of intellectual property rights, such as trademarks and patents, relating to a medicine, and is mainly relevant for the legal consequences of such violation.

Being a globally relevant phenomenon, it is necessary establish a multilevel protection. In fact, the Convention on the counterfeiting of medicinal products and similar offenses of the Council of Europe (so-called Medicrime Convention) of 2011 and the Directive 2011/62/EU on falsified medicines are dedicated to the falsification of medicines.

The MEDICRIME Convention imposes on the States Parties the obligation to criminalize the conducts of production and distribution of falsified medicines, as well as “similar crimes”, instrumental conducts which are also dangerous to public health.

The European Directive imposes, with the integration of Implementing Regulations, a traceability system for medicines, by means of the provision of a unique identification code and compliance with good manufacturing practices of the active substances. To complete the system outlined by the Directive, the provisions regarding online pharmacies are fundamental, which are increasingly

replacing physical ones. The provision of a common logo, which through a series of hypertext links refers to the subjects who have authorized the remote selling and to the list of pharmacies to which the same authorization has been granted, also allows the last link in the chain, the consumers, to be able to distinguish the subjects legally engaged in the online sale of medicines, from the so-called rogue and fake e-pharmacies. The control of the distribution chain is also accompanied by the provision of sanctions, thus placing itself in parallel with the Medicrime Convention.

Rules on counterfeiting of pharmaceutical products are then found in the TRIPs Agreement annexed to the Treaty establishing the WTO.

The TRIPs Agreement provides for minimum rules on counterfeiting, trademarks and patents, emphasizing the necessary coordination between companies, customs and judicial authorities.

Public and private law profiles, therefore, are juxtaposed until they almost intersect in the name of a general collective interest: guaranteeing the achievement of the highest possible standard of health through the expansion of the audience of subjects who have access to genuine, safe, effective and quality medicines.