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Mariosa Vella Cardona

Safer medicines for the consumer

Consumers can rest assured that all necessary efforts are being undertaken at EU level in order to guarantee the quality and safety of the medicinal products which they purchase. With the recent adoption of new legislation aimed at protecting patients against the ever increasing phenomena of falsified medicines, the pharmaceutical industry needs to gear itself to be in a position to offer the requisite guarantees to European citizens.

The primary objective of this new law is to ensure that falsified medicines do not enter the legal supply chain in the first place. Falsified medicines are fake medicines which are passed off as real, authorised medicines. They often contain ingredients, including active ingredients, which are of low quality or in the wrong dosage, either too high or too low. Obviously, since they would not have passed through the requisite legal evaluation of quality, safety and efficacy, they constitute a major health threat to consumers.

The new law introduces harmonised safety and control measures which will apply across Europe and which will ensure easier identification of falsified medicines, besides improving verifications and controls at EU borders and within the EU. It has now become obligatory for medicines to carry an authenticity feature on their outer packaging. This feature, the characteristics of which still need to be determined by the European Commission, will serve as a unique identifier which allows verification of the authenticity of the medicinal product.

The application of this authenticity feature to the outer packaging applies to all prescription medicines. However, if a risk assessment shows that certain products are not at risk of falsification, they could be exempted. This obligation does not, as a general rule, apply to over the counter medicines since these products are usually not the target of falsifiers. The re-packaging of medicinal products remains possible but the safety features must be replaced by equivalent safety features.

The directive also addresses the sale of falsified medicines over the internet. It introduces a common logo or trust mark for legally operating online pharmacies. A click on the 'trust mark' links the user to an official national register with a list of all legally-operating pharmacies. If the user clicks again on the register, he is linked back to the website of the registered online pharmacy.

The new directive imposes more stringent requirements for the control and inspection of plants manufacturing active pharmaceutical ingredients (APIs). Importers, manufacturers and distributors of active substances must be registered with the competent authority as brokers of medicinal products. Furthermore, the manufacturers of medicinal products must verify that the manufacturer and the distributor of the respective active substances comply with good manufacturing practice and good distribution practices. They must also ensure that the ingredients used are suitable for use in medicinal products. Wholesale distributors must verify that their supplying wholesale distributors are in turn authorised.

Indeed, since such ingredients are often produced outside the EU, the law ensures that there is strong international collaboration between the European Commission and the major regulatory players on the market including authorities in third countries. This is intended to ensure regular inspections of API manufacturing plants both inside and outside the EU.

Manufacturers and distributors are now legally bound to report any suspicion of falsified medicines to the competent authorities.

In turn, member states are obliged to have systems in place that make it possible to recall falsified or otherwise dangerous medicinal products as well as to impose effective penalties for the manufacturing, distribution, import and export of falsified medicinal products.

The directive must now be transposed by member states within 18 months and will begin to apply as from this date. However, some measures, such as those related to the safety feature, have a longer implementation deadline – five to six years – in order to allow for the necessary technical adaptations.

The production and trade of falsified medicines is on the increase. Statistics prove that the number of falsified medicines seized at the outer border of the EU has tripled between 2006 and 2009. Moreover, whereas this problem used to be related mainly to 'life-style' medicines, innovative and life-saving medicines such as medicines against cardiovascular diseases are also increasingly becoming the target of falsifiers.

Obviously, the infiltration of such products into the legal supply chain poses a serious threat to human health and also erodes the trust that consumers have in the pharmaceutical sector. Industry has therefore been left with little or no choice. Compliance with the new regulatory measures, as burdensome as they might be, is indispensable if the sector wants to compete effectively against such illegalities.

mariosa@vellacardona.com

Dr Vella Cardona is a practising lawyer and a freelance consultant in EU, intellectual property, consumer protection and competition law. She is also a member of the National Commission for the Promotion of Equality.