The tricky business of drug/device classification in the EU

Ellen Gielen and *Bart Essink* discuss the implications of the long-awaited court ruling on borderline products.

On 3 October, the Court of Justice of the EU published its long-awaited ruling in the Laboratories Lyocentre case in relation to the classification of medical products[1,2]. The CJEU ruled that a product can be classified as a medicinal product in one EU member state and as a medical device in another. The case is significant for manufacturers of medical devices and medicinal products although it does not provide further guidance on those products belonging to the "grey area" between medical devices and medicinal products. It confirms previous rulings of the CJEU that products can be classified differently in different member states.

The judgment of the CJEU goes against efforts to harmonize regulation of the EU market. Based upon prior judgments with respect to the classification of products, the decision was not a big surprise. Nonetheless, it shows that the EU harmonization procedure is far from finished. In fact, EU regulation of the free circulation of goods has emerged from and been strengthened by the judgments of the CJEU[3]. However, the process of creating common standards across the EU market with respect to the classification of medical products should now be a priority. In the current legislative climate, the CJEU is not able to play a critical role on this front, and politicians should step in with further regulation from Brussels.

The facts

The CJEU judgment concerned the classification of a product manufactured by Laboratories Lyocentre, a commercial laboratory based in France. The product in question is a capsule-based oral treatment used to correct bacterial imbalances in the female reproductive organs. The product's composition consists of a particular bacterium of the *lactobacillus* genus, and includes other ingredients such as lactose and magnesium stearate. Until 2006, the product was marketed in Finland as a natural medicine under the brand name *Gynophilus*. The same product has been marketed in Finland since 2006 under the name Gynocaps and was packaged as a medical device with a CE marking. It is now sold and marketed in the same manner in Austria, Spain, Italy and France.

In 2008, the Finnish Medicines Authority ruled that Gynocaps did not satisfy the definition of a "medical device or accessory" under the Finnish law implementing EU Directive 93/42/EEC on medical devices. The FMA rather viewed Gynocaps as a preparation suitable for use as a "medicinal product" within the meaning of the Finnish law implementing EU Directive 2001/83/EC on medicinal products. As a result, Laboratories Lyocentre required a marketing authorization for the product. The FMA took this decision because a rival company had also wished to sell a lactic acid bacterial preparation which was similar to Gynocaps, and the other product had been defined as a medicinal product rather than a medical device.

After successive appeals through the Finnish court system, the matter ended up at the Finnish Supreme Administrative Court. The supreme court recognized that under the ruling in *Hecht Pharma* (C-140/07), one member state's definition of a product as a medicinal product does not preclude another member state's refusal to define it in the same way. Yet, to the Finnish court's knowledge, there was no case law about the power of a national authority to take a decision of its own volition that a product was not a medical device but a medicinal product – even though that product was CE-marked and sold in other countries as a medical device. Equally, there appeared to be no case law about which procedure such a body should follow when determining whether something was a medicinal product.

The Finnish court's main question was this: if one member state has defined a product as a medical device or accessory with a CE mark, can another member state classify it as a medicinal product? The referring court also asked whether two products with the same substance and mode of action (but not identical products) can be separately classed as a medicinal product and a medical device in the same member state.

The ruling

In May this year, the advocate general (AG) of the CJEU issued an opinion saying that it is usually clear whether a product falls under one or other of the directives. This is not always the case. We note that over the years the CJEU provided guidance to help manufacturers and national authorities decide how to classify products. The finer points of a manufacturer's decision as to how to market their products, and which classifications apply, can be a difficult one in the case of new products or when working with different national authorities. The grey areas between classifications can lead to the classification of a product as either a foodstuff, a medicinal product, a medical device, or a cosmetic to vary widely across different territories and to even appear arbitrary at times. In many cases, the most difficult products to effectively develop and market are those which can be considered "borderline products" due to the uncertainty as to the governing regulations across the single market.

The AG said that although the legislature has tried to define two types of product in a way that is, as far as possible, mutually exclusive, it has not managed to exclude the possibility that, in certain circumstances, different member states might classify a product differently (because, for example, they do not have the same information, or the available evidence is assessed differently). The AG added that within the area of overlap therefore, and in the absence of greater harmonization, the directives do not preclude member states from reaching different decisions. As a case in point we refer to Case C-88/07, *Commission v Spain*, from which it follows that one member state's definition of a product as a food supplement does not preclude another importing member state from defining it as a medicinal product, when the product displays those characteristics.

The AG noted that under EU law, a product that clearly falls within the definition of "medicinal product" must be regarded as such, even if it also falls within the definition of another type of product. At first sight, she said, this appears to exclude the possibility that different member states may classify the same product as a medicinal product and a medical device because, if there is any doubt, the pharmaceutical legislation applies. However, "there is no situation of doubt when two Member States each are clear in reaching their differing conclusions." This may appear to contradict the EU's normally strict rules on preserving the single EU market, but with the comments from the AG we have to conclude that there is not yet full harmonization in this area.

The AG stated in her opinion that, as long as there is no complete harmonization with respect to these types of product, it is possible for one member state to conclude with confidence that a given product is a medical device whereas another takes the position that the same product is a medicinal product. She additionally declared that if two products are identical, they cannot be classified differently in the same member state; however, if they are "similar" (sharing the same substance and mode of action), they can be.

The CJEU in its 3 October judgment generally concurred with the AG's opinion. The CJEU noted that the European Medicines Agency has not specifically adopted a position on the classification of vaginal preparations, like Gynocaps, that contain live *lactobacilli* cultures. However, it said the agency has "taken the view that on the basis of its intended use and effects, a gynaecological tampon containing live lactobacilli satisfied the conditions for classification as a 'medicinal product for human use', within the meaning of EU Directive 2001/83." The CJEU pointed out that under the legislation, the decision as to whether a product is defined as a medicinal product must be taken by the national authorities on a case-by-case basis, acting under the supervision of the courts, taking account of all the characteristics of the product, in particular its composition and its pharmacological, immunological or metabolic properties. It noted that only a product that does not achieve its principal intended action via pharmacological, immunological or metabolic properties may be classified as a medical device.

However, until harmonization of the measures necessary to ensure the protection of health is more complete, it will be difficult to avoid the existence of differences in the classification of products between member states. It seems that the main point of the CJEU decision, to justify differences in the classification, lies with the protection of health. Of course, the risk that the use of a product may entail for a person's health is a separate factor that must be taken into consideration by the competent national authorities when classifying a product. But it is actually surprising and somehow unsatisfactory that the assessments of risks to human health and the desired level of protection is not fully harmonized across the member states (or at least assessed differently). It is difficult to accept that that the assessments of risks to human health lead to different conclusions in the different, member states. The consequences of differing assessments of the risk to human health posed by a product across different jurisdictions requires greater attention from the European Commission and a focused effort to bring the markets into harmony in this respect.

Nonetheless, the AG stated in her opinion that asymmetries in scientific information, new scientific developments and differing assessments of risks to human health and the desired level of protection can explain why different decisions are taken by the competent authorities of two member states as regards the classification of a product. In addition, the AG stated that the fact that a product is classified as a medical device in accordance with Directive 93/42/EEC in one member state does not prevent it being classified, in another member state, as a medicinal product in accordance with Directive 2001/83/EC if it displays the characteristics of such a product. The CJEU differed slightly from the AG on the question of whether two similar products could be marketed in the same country, one as a medicine, the other as a device. Where the AG had said yes for similar products (same substance and mode of action) but no for identical products, the court said that a product which, while not identical to another product classed as a medicine, has the same substance and mode of action cannot "in principle" be marketed as a medical device in the same member state unless, as a result of another characteristic that is specific to that product, it has to be classified and marketed as a medical device. That the same substance in a product classed as a medicine cannot "in principle" be marketed as a medical device is a logical outcome if the substance's function is restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or making a medical diagnosis; it falls within the definition of a medicinal product under EU Directive 2001/83/EC.

Be this as it may, the CJEU does not set out criteria which will enable manufacturers to distinguish between medical devices and medicinal products. It just confirms that there is "harmonization work" to be done. There is a need for clear distinctions between medical devices and medicinal products, or more precisely, there is a need for one classification for a product within the EU market. It becomes an unworkable situation if products are classified differently within one market.

Without greater harmonization, existing differences between member states in the classification of products may hinder trade in the internal market. When a product is deemed to be a medicine, marketing authorization is required before it can be put on the market. Without this authorization, member states can prohibit the product from being sold within their national market. However, if the product is a medical device, no such authorization will be required and the product can be freely marketed, provided it complies with the relevant EU and national legislation. Other problems occur as well. For example, manufacturers have to comply with the rules governing the marketing of medical devices in one country and in other countries – in the same European market – face more stringent requirements of medicinal products.

In this context, the judgment shows that, despite the legal definition of a medicinal product and a medical device provided by Directive 2001/83/EC and Directive 93/42/EEC, respectively, legal certainty and clarity is still required by manufacturers and the competent national authorities in relation to borderline products. In order to contribute to a pragmatic solution that will be acceptable to all stakeholders, the margin of discretion to classify products should be narrowed. Other mechanisms could be used to achieve greater harmonization across the single market, such as assessing products in conjunction with Article 31 of Directive 2001/83/EC if member states have adopted divergent decisions concerning a medical product, or by providing the EMA with greater influence in matters of classifications.

Concluding remarks

The importance of greater clarity across the single market as to the rules governing the classification of products is obvious, especially in relation to the decision of manufacturers in the development, marketing and potential liability of new products.

The CJEU's decision confirms that member states must make classification decisions on a case-by-case basis. It recognizes that there is incomplete harmonization in the EU and, as such, there is a risk that member states may adopt different views leading to inconsistent positions in each jurisdiction.

It is clear that the directives in place cannot provide a satisfying solution, and it is increasingly likely that further legislation will be needed to achieve market harmonization for medical products across the EU.

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References

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