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How Belgium's New Local Distribution Rules Will Impact Companies Doing Business There

by Amanda Maxwell

With new legislation imminent in Belgium on distribution rules for medical devices, how much more open is the market going to become, and what must companies be aware of? Two experts discuss.

New legislation is likely to be published in Belgium by the end of the year that should make marketing many devices in the country easier. The law change responds to rulings made over recent decades by the European Court of Justice.

What do we know so far about how the changes will impact the industry and which devices will benefit? And how should companies prepare for the anticipated changes?

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Annabelle Bruyndonckx and Vladimir Murovec, lawyers with Simmons & Simmons, jointly responded to questions from *Medtech Insight* about what companies should expect. Bruyndonckx, a counsel with the firm, and Murovec, an associate, both work in Simmons & Simmons' Brussels office assisting clients in the device, and pharma, industry on regulatory, market access, compliance, distribution and other legal matters. Their insights on the pending Belgium law are

provided below.

Q ***Medtech Insight:*** **What is the current situation in Belgium when it comes to restrictions on distribution channels for medical devices and how does this fit into the current overall legislative framework?**

A In Belgium, the distribution of medical devices is regulated by law (the Medical Devices Act of 15 December 2013) and via three royal decrees, one for each European Directive (medical devices, active implantable medical devices [AIMDs] and *in vitro* diagnostic medical devices [IVDs]). The current royal decree implementing the Directive 93/42 relating to medical devices provides for a specific list of categories of medical devices (Annex XIII.1 of the royal decree of 18 March 1999, "the List") for which there are special distribution requirements for some products on that list.

The List of categories has two purposes. It delineates the jurisdiction of the competent authorities: some devices on the List are controlled by the Belgian Federal Agency for Medicines and Health Products (FAMHP), while others are controlled by the Belgian Federal Agency for Nuclear Control (FANC). Whether a category of medical devices falls in the List determines the distribution channel for all products covered by the category. In Belgium, some categories of medical devices must transit through a public pharmacy, a hospital pharmacy or a dental clinic before they can reach final users. This distribution restriction determining the outlet through which a product must pass currently concerns seven categories of products out of the 15 categories of the List (see below for a detail of the products concerned). It will be repealed by the new legislation.

Q **What will the impact of the repeal be?**

A The repeal is described as a "liberalisation" or "opening up" of the distribution circuit, in the sense that any medical devices company having a distribution activity will be able to rely on new sales platforms (whether physical or digital) and a wider range of intermediaries (supermarkets, global distribution chains, *para-pharmacies*) to reach end users. However, this also means that all new intermediaries and sales platforms

will be required to comply with the legislation on medical devices distribution (and the upcoming EU Medical Device Regulation), for their distribution activities to or from Belgium. The repeal will have limited impact on the distribution of IVDs and AIMDs. The two local decrees regulating these products do not include specific restrictions in terms of distribution channels.

Q **What is the likely time frame for the introduction of this system?**

A The new legislation is likely to be published between November 2018 and December 2018. Its entry into force is yet unknown.

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Q **Which products are due to benefit from this opening up of the distribution channels?**

A The liberalization or opening up of the distribution circuit will concern the following types of products:

- Sterile medical equipment entering in contact with the patient (e.g., dressings and compresses);
- Sterile injection equipment (e.g., insulin injection devices, lancing devices);
- Infusion equipment (e.g., syringes);
- Transfusion equipment and drainage equipment, probes and catheters, and any equipment for medical or obstetrical procedures presented as sterile (e.g., irrigation solutions and concentrates for hemodialysis);

- Implantable devices such as knee prosthesis, hip prosthesis and endoprosthesis;
- Devices used for contraception (e.g., intrauterine devices) and/or the prevention of the transmission of sexually transmitted diseases;
- Devices similar to a medicinal product and/or that have been previously registered as such (so-called “drug look-alikes," such as eye drops qualifying as medical devices);
- Devices used in dentistry, including custom-made devices (e.g., amalgam, crowns, prostheses; and
- Systems and kits consisting of the devices referred to above.

Q **Will there continue to be any other restrictions for distributing medical devices once the new legislation is in force?**

A While in theory users (patients) could be able to purchase their medical devices anywhere, some regulatory restrictions will, indirectly, influence the source of supply where products will be available. Firstly, health-care professionals working in hospital settings will still be required to acquire the products they use on patients (including, for example, implants and prostheses) directly from their hospital pharmacy. Secondly, the Belgian social security legislation will continue regulating and promoting the use of specific channels (including pharmacies, hearing aid dispensers and dentists) for the reimbursement of some medical devices. Thirdly, some local *lex specialis* will only allow certain medical devices to be used by specific types of health-care professionals. For example, a doctor or dentist having a depot of products at his/her practice must obtain his/her implantable medical devices from either a public pharmacy or a hospital pharmacy and may only deliver the devices in the context of a medical procedure.

The repeal will facilitate access, by the general public, to medical devices that used to be confined to pharmacies. It should be emphasized that the right to purchase a

device without barriers to supply does not entail the right to plan or perform treatment without the appropriate qualifications. The illegal practice of medicine, nursing, dentistry, care giving, etc remains a criminal offense when carried out by a person who diagnoses a patient or plans, performs or executes treatment without having the qualifications imposed by law.

Q **What does it mean for manufacturers and distributors – does it make a difference whether they are domestic, from the EU or from third countries?**

A The upcoming legislation makes no difference between domestic and foreign distributors/manufacturers. Since December 2017, the Belgian definition of a "distributor" has been aligned with the EU MDR/IVDR and reads as follows: "Any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the European Union market." The repeal does not have as a consequence that distributors will have to withdraw their products from pharmacies or dental practices from the date of entry into force of the new legislation.

A "free distribution circuit" means that (domestic and foreign) distributors and manufacturers will have the right to sell their medical devices across a wider spectrum of customers (i.e., not only pharmacists or dentists, but any other shop or platform that complies with the law). Manufacturers and distributors may equally decide to restrict the distribution of their medical devices to specific categories of customers, such as only pharmacies or para-pharmacies, in line with their commercial and branding strategy. This decision is specific to each company and the FAMHP has no prior involvement in it, as long as devices are distributed in line with the appropriate April 21, 2017, Good Distribution Practices (GDP) and the local legislation on medical devices. With new distributors entering the medical device sphere, this reform also has the potential to increase competition between existing distributors and new stakeholders such as global retailers and large para-pharmacy chains, which could potentially lead to decreased prices for patients.

Q **How should manufacturers and distributors prepare?**

A Existing manufacturers and distributors of medical devices should monitor the entry into force of the new legislation and assess which products in their portfolio are concerned by the opening of distribution channels. Whether they decide to add a new route to their distribution circuit or to withdraw products from pharmacies / dental clinics, they will have to ensure that the delivery and traceability standards of the FAMHP GDP (or similar requirements) are complied with when offering devices to their new customers. This includes verifying that their new customers' benefit from the required level of professional quality and performing customer inspections. Conversely, companies who become distributors/retailers of medical devices for the first time will have to carry out a gap assessment between their current distribution practices and those applicable to medical devices' distribution pursuant to Belgian law. All such distributors/retailers will have to be registered on the FAMHP Portal and comply with local vigilance procedures.

Q **How would these new distribution channels be supervised and by whom?**

A The FAMHP is the competent authority for the enforcement (control, inspection, sanction) of the medical devices legislation, including the upcoming legislation on the "liberalisation" of the distribution circuit. When FAMHP inspectors conduct investigations of economic operators registered on the FAMHP Portal, they use the FAMHP GDP as a benchmark and it is therefore recommended to ensure that these GDP are reflected in internal procedures, accounting for local specifics on device distribution.

Q **The new rules will presumably open the door to global trade too? Will this introduce challenges for the Belgian authorities?**

A Because this reform will open the distribution in Belgian of the categories of medical devices specified above, it will certainly facilitate the free movement of goods from and to other EU member states. From a competent authority (FAMHP) perspective, this may result in increased monitoring and investigation efforts, as any (domestic or foreign) company distributing medical devices on the Belgian market falls under the watch of the FAMHP. It should be noted that the FAMHP already carries out

inspections and investigates nonconformities suspected from foreign EU and non-EU companies, with the collaboration of other local health-care authorities when needed. Both in practice and in law, their enforcement powers are very broad (they can be compared to those of the judicial police) and their activity is not confined to the Belgian market.

Q **How does the upcoming Belgian situation differ to what is happening in other EU countries?**

A When the new legislation enters into force, the liberal approach of the Belgian system will resemble what has already been in place for years in other EU countries, such as the UK. Distributors should, however, be aware of the local specifics that may apply to them in Belgium as compared to other jurisdictions, for example, an obligation to register on the local FAMHP Portal, to implement local Good Distribution Practices, report incidents through appropriate channels, comply with local anti-gift provisions and report transfers of value on *www.betransparent.be* [Belgian Transparency Platform].

Q **How does this fit in with the upcoming MDR/IVDR rules?**

A With the MDR becoming applicable on May 26, 2020, those who have never distributed medical devices before the entry into force of the upcoming legislation will have to familiarize themselves with the strict obligations incumbent on economic operators – and specifically distributors – under the MDR. It is to be hoped that the significant burdens imposed by EU law will not discourage these new distributors, including retailers. At the Belgian level, a "light touch" regime has been put in place for distributors acting exclusively as retailers under the local GDP, which allows them for example to avoid performing customer inspections or guaranteeing the traceability of supply. As the MDR (in Article 30 [2]) allows member states to maintain or introduce national provisions on registration of distributors of devices which have been made available on their territory after May 26, 2020, it is expected that registration on the FAMHP Portal will remain compulsory for distributors (and importers) under the MDR.

Q **Has the European Court of Justice (CJEU) case law specific to medical devices been the catalyst for this new regulation? What has the impact of this case law been and why?**

A Yes indeed. The Belgian authorities considered the Judgments of the CJEU in C-369/88 (Jean-Marie Delattre, March 21, 1991) regarding pharmacists' monopoly of the right to sell certain products and C-108/09 (Ker-Optika, December 2, 2010) concerning the online sales of contact lenses and the Hungarian legislation authorizing the sales of contact lenses solely in medical supply shops. Considering the principles defined by the CJEU in these cases, the authorities retained four (cumulative) conditions that must be met to justify a restriction of the distribution circuits for medical devices:

1. Products concerned by the restriction should be clearly and precisely identified.
2. Only reasons relating to the protection of public health can justify such a restriction; the reasons should be identified together with the risk that a potential free movement of the products could cause to public health.
3. One should also be able to demonstrate why granting monopoly to a specific category of health-care professionals is a necessary means to reach the goal identified in (2).
4. It should be demonstrated that no other, less restrictive, measures could be adopted and lead to the same result as the envisaged restriction.

Only once all four of these conditions arising out of the CJEU case law have been met, will the authorities undertake to place restrictions on the distribution channels for medical devices via royal decree in the future.