The EU regulatory challenges and liability risks associated with 3-D printed medical devices

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In this hoganlovells.com Q&A, Hogan Lovells counsel Fabien Roy addresses EU regulations that apply to medical devices that are produced using 3-D printing technologies.

In 2015, the UK Intellectual Property Office (IPO) defined 3-D printing as a range of digital manufacturing technologies that produce component parts, layer by layer, through the additional use of materials. But when this process is used for medical devices, unique regulatory challenges and liability issues may arise. Roy discusses who is responsible for ensuring that the final product meets regulatory requirements: is it the manufacturer of the 3-D printer, or the healthcare professional who uses the printer to create the device?

What are some examples of medical devices that are made by 3-D printers, and what are the regulatory requirements in Europe regarding 3-D printing of these devices?

Roy: In the past 10 to 12 years, 3-D printing techniques have been applied for assistive surgical prosthetic devices, surgical implants, and scaffolds for tissue engineering. For example, in 2014, a Dutch patient received a completely new skull that was printed using 3-D printing technology.

EU regulation of these technologies includes requirements applicable to materials, manufacturing facilities, software, 3-D printers, and final products. In the EU, 3-D printing is considered an innovative technology and is not specifically regulated by the current Medical Device Directive or by the new Medical Devices Regulation, which would be applicable from May 2020. However, some requirements of the medical device framework are directly applicable to 3-D printing technologies.

Are custom-made medical devices created with 3-D printing technology subject to similar regulations as medical devices custom-made with other technologies?

Roy: Yes, custom-made medical devices are defined in the Medical Device Directive as having two basic criteria. The first criterion is that the device must be made in accordance with a specific written prescription from a healthcare professional and be intended for the sole use of that particular patient; in short, one prescription for one specific patient. The second criterion is that it

cannot be a mass-produced device that has been adapted to meet specific requirements. If the criteria for custom-made medical devices are not met, then all the requirements applicable to medical devices will apply.

The definition of custom-made devices was intended for circumstances in which a patient would need a specific device. So a healthcare professional would contact a manufacturer to create that specific device. It had not been sought for the development of 3-D printing technologies that could be used, for example, for several specific patients in hospital.

That's important to know because custom-made devices are not regulated as normal medical devices in the sense that custom-made medical devices do not require the involvement of a notified body in the conformity assessment procedure and no specific quality management system requirements apply to these products. In addition, no CE mark is affixed to these medical devices. So the regime is currently based on lighter rules than for general medical devices.

So who is legally responsible for the final product: the manufacturer of the 3-D printer or the medical professional who uses the printer to create the device?

Roy: The question of the liability is a complex one. For example, you have a 3-D printer in a hospital that is used by healthcare professionals. You have on one side the printer manufacturer and on the other side the healthcare professionals using the printer, and the question is, who is the legal manufacturer of the finished product? Meaning, who is taking responsibility for the safety and performance of the final product that will be used for the patient? Is it the manufacturer of the 3-D printer, who has no idea how the 3-D printer will be used? Or is it the healthcare professional, who has full control of the 3-D printer and has the ability to check the safety and performance of the final device? There are some uncertainties here.

Does Hogan Lovells help clients navigate the medical device regulations, and help manufacturers figure out how to make a 3-D printer that's regulation compliant?

Roy: Yes. A client may have a 3-D printer project and they will ask us, how will their product be regulated under the current medical device framework in the EU or the future Medical Devices Regulation? We will then assess whether it's a medical device, a custom-made medical device, a general medical device, or simply manufacturing equipment.

Depending on the classification of the product, we determine what requirements must be applied by the manufacturer of the product to ensure compliance with all applicable rules. We can also assist the client in determining how the new Medical Devices Regulation will affect the regulation of these 3-D printing technologies.

About Fabien Roy

As counsel in our Life Sciences practice, Fabien Roy focuses his practice at Hogan Lovells on advising clients on EU and national regulatory matters applicable to medical devices, medicinal products, and combination products throughout their entire life cycle. With a practice entirely focusing on complex regulatory issues faced by life sciences clients, he can quickly address and anticipate complex challenges and propose innovative solutions, enabling clients to focus on their businesses.

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