ALERT

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France Simplifies Local Medical Device Regulations and Sets Precedent for Other Member States

On April 26, 2018, the French administrative Supreme Court (*Conseil d'Etat*) issued a ruling that annulled Decree 2016-1716 of December 13, 2016 ("2016 Decree") related to the summary of characteristics for medical devices. The decree's provisions had taken effect as of July 1, 2017. It had required manufacturers, their authorized representatives, and distributors directly supplying medical devices to users to submit a summary of characteristics for implantable medical devices and Class III medical devices, other than custom-made devices, to the National Authority on Drugs and Health Products ("ANSM") when these medical devices entered the French market. Noncompliance was subject to a criminal fine of up to €150,000.

The 2016 Decree was adopted prior to Regulation 2017/745 of April 5, 2017, on medical devices ("MedDev Regulation"), which will enter into force in 2020 and was designed by the French government as a transition tool prior to the implementation of the new European regime.

However, following a claim filed by the French MedDev industry syndicate SNITEM, the *Conseil d'Etat* held that even though the summary of characteristics required by the 2016 Decree was similar to the "summary of safety and clinical performance" to be filed pursuant to the MedDev Regulation, neither Regulation 2017/745 nor currently applicable Directive 93/42 gave Member States authority to impose national obligations on provisions relating to such a wide scope of medical devices prior to the MedDev Regulation's entry into force in 2020.

In addition, the *Conseil d'Etat* was concerned that additional requirements would restrict the free movement of medical devices on the European market. Thus, it held that Member States should not impose requirements and sanctions related to placing medical devices on the market or putting them into service, in addition to the requirements related to CE marking (a medical device manufacturer's claim that a product meets the essential requirements of all relevant European Medical Device Directives).

As a result of this ruling, manufacturers, their authorized representatives, and distributors directly supplying medical devices to users that have already submitted the summary of characteristics in accordance with the 2016 Decree may be entitled to recovery of the costs associated with the submission requirements, as well as reimbursement of any fines.

The relevance of the decision expands beyond France, as the underlying reasoning is based on the current European Medical Device Directives, and thus in substance applies in all Member States. The local regulations regarding distribution of medical devices in local markets vary widely. In particular, Eastern European states in various instances impose rather comprehensive notification and submission requirements, which can be somewhat onerous in particular if product distribution is transferred from one distributor to another. Based on this landmark decision in France, manufacturers, their local representatives, or distributors may also be able to challenge other over-restrictive local regulations.

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