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CLIENT ALERT

New European Commission Medical Device Safety Initiatives Aimed at Notified Bodies Will Impact Device Manufacturers As Well

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On September 24, 2013, the European Commission adopted two measures to improve the safety of medical devices put on the market in the EU.[1] The measures are directed principally at the operation and control of so-called notified bodies. Notified bodies are independent public or private third-party organizations or companies designated by EU Member States to carry out control of manufacturers of medium and high risk medical devices put on the EU market. A control made in one Member State is valid throughout the EU.

The new measures, however, will have consequences for manufacturers of medical devices as well. They will face increased announced and, notably, unannounced audits that encompass their entire supply chain. As a result, it is essential that manufactures anticipate the impact of audits and controls in agreements with critical subcontractors and suppliers.

Origin of the measures

These new measures follow the 2010 scandal involving the French breast implant manufacturer Poly Implant Prothèse, S.A. (PIP). PIP used industrial gel in the production of its breast implants instead of medically approved gel. PIP had been controlled by the notified body TUEV Rheinland.

While TUEV Rheinland was conducting regular audits at PIP, it always announced when those audits would occur. Taking advantage of the notice, PIP would substitute the industrial gel with medically approved gel and thus TUEV Rheinland never discovered the manufacturer's malpractice.

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The PIP scandal exposed weaknesses in the EU medical product safety control system. To restore patient confidence, the European Commission adopted measures to tighten the auditing system.

Specifically the European Commission concluded that technical progress and increasingly complex assessment methods had led to significant variations in the level of competence of the notified bodies in the European Union and in varying degrees of stringency applied by them in the assessments they performed.

In order to harmonize the approach towards notified bodies, the European Commission, without creating new obligations or rights, fixed a common interpretation of the main elements of the criteria for the designation and extension of the

designation of the notified bodies within the EU, as well as set common minimum requirements for the surveillance and monitoring of the notified bodies by the designated monitoring authorities of the Member States.

Impact of the measures on manufactures

While notified bodies will feel the most direct impact from the new measures, they will have a clear impact on manufacturers of medical devices as well. The measures indeed aim to ensure that notified bodies carry out proper verifications of the fulfillment of the legal requirements by manufacturers. Accordingly, manufacturers can expect increased surveillance and monitoring measures from their notified bodies.

In light of the PIP scandal, it is no surprise that, in addition to recommendations concerning the product and quality system assessment and related "announced" surveillance and renewal audits, the measures (and in particular the Recommendation) stress the importance of "unannounced" audits.

In accordance with the Recommendation, notified bodies should carry out unannounced audits at least once every three years. This frequency will be increased (i) in case of high risk devices, (ii) if the devices of the type in question are frequently non-compliant or (iii) if specific information provides reasons to suspect non-conformities of the devices or their manufacturer. An unannounced audit should not take less than one day and should be executed by two auditors.

To increase efficient control, notified bodies are also directed to extend their unannounced audits to the premises of the manufacturer's critical subcontractors or crucial suppliers. Critical subcontractors are subcontractors in charge of processes which are essential for ensuring compliance with legal requirements and crucial suppliers are suppliers of crucial components of devices or of the entire devices.

In addition, the Recommendation gives clear direction of the measures that should be taken in the course of an unannounced audit, including effectively checking the ongoing manufacturing process and/or a device taken from the ongoing manufacturing process.

In view of the above, medical device manufacturers can expect an increased diligence in the controls performed by their notified bodies as well as an increase in unannounced audits.

Anticipation of impact of the measures

Manufactures should not only anticipate the consequences and impact of such unannounced controls and audits in their own internal organization but also in their agreements concluded with their critical subcontractors and/or crucial suppliers.

Contractual arrangements between the manufacturers and critical subcontractors and/or crucial suppliers should in this respect, at least, contain provisions:

- allowing unannounced audits by the notified bodies at any time at the premises of the critical subcontractors and/or crucial suppliers and setting the minimum requirements necessary for the notified bodies' representatives to be able

to (safely) perform their controls (e.g., access to the ongoing manufacturing process, the traceability system, the (appropriate) administrative documentation, etc.);

- providing sanctions and/or (urgent) remedies and/or indemnities in case the permanent unannounced access of the notified bodies to the premises of the critical subcontractor and/or crucial supplier is not assured/is hindered;
- anticipating the request of the notified body to provide a standing invitation to visit the critical subcontractors and/or crucial suppliers at any time (leaving the date of visit and date of signature open (to be filled-in by the notified body) in case such subcontractors or suppliers would be located in countries requiring a visa;
- obliging the critical subcontractors and/or crucial suppliers to continuously inform the manufacturer (who in turn will inform the notified bodies) on the period when devices falling under the notified bodies certificates will not be manufactured;
- determining the financial implications of unannounced audits (e.g., the cost of the device/components supplied for the assessment of the device/components, the cost of the security arrangements, etc.);
- determining the consequences of a negative result of unannounced audits; and
- imposing to subcontractors and suppliers to provide similar provisions in agreements concluded with own subcontractors and suppliers and this throughout the entire production/supply chain.

These principles are, of course, merely guidelines. Agreements are drafted according to the particular circumstances of each case and additional or other provisions might have to be considered in view of those circumstances.

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[1] Commission Implementing Regulation (EU) No 920/2013 of September 24, 2013 on the designation and the supervision of notified bodies under Council Directive 90/42/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (O.J. 25.9.2013, L 253/8); and Commission Recommendation of September 24, 2013 on the audits and assessments performed by notified bodies in the field of medical devices (2013/473/EU) (O.J. 25.9.2013, L 253/27).

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