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The supreme Land authority responsible for medical devices and the Federal Ministry of Health have come to an agreement on the procedure to be adopted by Notified Bodies according to the

Commission Recommendation of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices (2013/473/EU) (OJ L 253 p. 27 of 25.09.2015)

I. Starting point and preliminary remarks

In response to the PIP breast implant scandal, and as an emergency measure to supplement the Commission Implementing Regulation (EU) No. 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices of the same date, the European Commission published a **Recommendation on the audits and assessments performed by notified bodies in the field of medical devices (2013/473/EU) (hereinafter Recommendation 2013/473/EU)**. The recommendation comprises requirements and concrete details on product assessments, quality management system assessments and unannounced audits. Considerable confusion emerged among the stakeholders involved with respect to the unannounced audits described in the recommendation and their implementation in practice. However, since the recommendation was published, differences stemming from diverging interpretations of the requirements contained in the recommendation have been observed in the way in which the unannounced audits have been handled by the notified bodies.

In response to an invitation by the Federal Ministry of Health, representatives of the Central Authority of the Laender for Health Protection with Regard to Medicinal Products and Medical Devices (ZLG), of German notified bodies and of the German medical devices industry came together in the course of three meetings to discuss these problems and find, as far as possible, consensual solutions. There was general agreement on the need for **Recommendation 2013/473/EU to be handled in a uniform and practice-oriented manner and in a manner which should be in line with the future requirements under the new Medical Devices Ordinance.**

Furthermore, it was agreed that the **manner in which unannounced audits are conducted** must be seen as closely connected to the concrete causes of the PIP breast implant scandal.

Since no consensus could be reached between the representatives of the notified bodies and the manufacturers, with regard to key points, the Federal Ministry of Health, the Land authorities responsible for medical devices and the Central Authority (ZLG) decided to issue a publication on the authorities' position on this topic. This publication is meant to describe the procedure for unannounced audits in keeping with Recommendation 2013/473/EU. The aim is to have German notified bodies proceed uniformly in the future. In order to ensure a uniform, Europe-wide procedure by all notified bodies, the representatives of the German authorities will submit this publication to the competent European bodies.

Above all, as a means of avoiding any repetition of the PIP case, notified bodies should examine, based on random sampling conducted in the course of additional unannounced audits, whether the medical devices have been manufactured in compliance with the technical documentation. Notwithstanding the importance of unannounced audits without specific cause, it must be noted that the safety of the medical devices on the market is guaranteed especially in the conformity assessment procedure conducted by the manufacturer and the notified body, through Post Market Clinical Follow-Up Studies undertaken by the manufacturer, through the vigilance system, the surveillance activities of the competent authorities, through regular annual audits by the notified bodies and by means of unannounced audits with specific cause by notified bodies. Generally, this guarantees that medical devices are safe for both users and patients.

II. Procedure

1. Scope of application

Two forms of unannounced measures can be undertaken by the notified bodies:

1.1 Unannounced audits which, pursuant to the directives on medical devices[1], can be conducted in addition to the routine announced audits if there is a specific cause and

1.2 unannounced audits that are to be conducted by the notified body, with a specific regularity, pursuant to Recommendation 2013/473/EU, without specific cause and which, based on random sampling, are to provide evidence that the devices currently in production comply with the corresponding technical documentation.

[1] Directive 93/42/EEC, Directive 90/385/EEC, Directive 98/79/EC

The subject of this publication is to be the unannounced audits described under 1.2.

2. The target group for which this publication is intended

The target group for which this publication is intended comprises the notified bodies, the manufacturer and crucial supplier/critical subcontractor.

3. Explanatory Notes

3.1 Manufacturer[2]

'Manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the per-son who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient.

3.2 Critical subcontractors; crucial suppliers

The critical subcontractor is in charge of processes that are essential for ensuring compliance with legal requirements pursuant to Directives 90/385/EEC, 93/42/EEC and 98/79/EC. A crucial supplier is a supplier of essential device components or of the entire medical device. In connection with the effective implementation of Recommendation 2013/473/EU, for the purposes of this publication, the term 'critical subcontractor/crucial supplier' will be understood to mean the Original Equipment Manufacturer (OEM; definition under 3.3) who manufactures on behalf of a Private Label Manufacturer (PLM; definition under 3.4).

3.3 Original Equipment Manufacturer (OEM)

Enterprises that manufacture finished devices for a PLM and, in this case, do not appear as manufacturers within the meaning of medical device legislation.

3.4 Private Label Manufacturer (PLM)

Enterprises that appear as manufacturers within the meaning of medical device legislation but do not manufacture themselves (often referred to as 'quasi manufacturers'). The medical

[2] Definition pursuant to Article 1 (2) (i) of Directive 90/385/EEC, Article 1 (2) (f) of Directive 93/42/EEC and Article 1 (2) (f) of Directive 98/79/EC.

devices are modified either only minimally or not at all by the PLM; as a rule, they are only purchased, stored and distributed under the PLM's own name.[3]

3.5 Device type

'Device type' means a specific type of device that differs from others owing to shared characteristics. These shared characteristics include: technology, design, area of application, parts or modules with respect to safety, EMC, performance, functionality etc. A device type can therefore be defined by means of a maximum configuration and its list of components/modules, supplemented by a description of the way in which the models are manufactured based on the maximum configuration and the components of the modules.

4. Conduct of unannounced audits

4.1 Frequency of unannounced audits

4.1.1 Once every three years, the notified body shall conduct an unannounced audit on the premises of the manufacturers of active implantable medical devices pursuant to Directive 90/385/EEC as well as those of Class III medical devices and Class IIb implants pursuant to Article 9 in conjunction with Annex IX of Council Directive 93/42/EEC 14 June 1993 concerning medical devices.

4.1.2 In the case of manufacturers of Class IIb non-implantable medical devices and of Class IIa medical devices pursuant to Article 9 in conjunction with Annex IX of Directive 93/42/EEC as well as of in-vitro diagnostic medical devices pursuant to Directive 98/79/EC, the notified body shall conduct an unannounced audit once every five years.

If irregularities are observed in the course of one of these above-mentioned audits, the notified body is authorised to additionally conduct **unannounced audits <u>with specific cause</u>** on the premises of the manufacturer or of one of his/her subcontractors/suppliers. Non-conformities discovered during audits on the premises of a manufacturer's production site could also lead to **unannounced audits <u>with specific cause</u>** in one or several (other) production sites belonging to the same manufacturer, together with further random sample taking.

4.2 Extent of unannounced audits

In principle, an unannounced audit is intended to last one day and be conducted by two auditors. After taking into consideration the conformity assessment procedure selected by the manufacturer and the contractual provisions, the notified body is entitled to expand the extent of the unannounced audit.

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[3] EC-Med Document 3.9 B16 "Certification of OEM devices"

4.3 Content of unannounced audits

With a view to the proper functioning of the quality assurance system, the notified body shall examine, based on one randomly selected representative product (if there is sufficient time and, if required, then several), whether this product has been manufactured in compliance with the technical documentation. Alternatively, it can also have this (these) product(s) inspected by a qualified independent third party.

4.4 Notification of periods of non-production

The continuous notification of periods of non-production by the manufacturer is, in many cases, not possible and, additionally, entails a great deal of administrative time and effort. Instead, manufacturers are to inform the notified bodies, at the latest, by the end of the second calendar week of the current calendar year of site closures/company holidays that are scheduled to take place in the current calendar year. The notified body is to be informed without delay of changes in plans in the course of the year. In the case of manufacturers who are only Private Label Manufacturers pursuant to 3.4, this is to apply accordingly to subcontractors/suppliers pursuant to 3.2.

4.5 Authentication of auditors in the case of unannounced audits

Before commencing with the unannounced audit, the auditors must present the manufacturer with a letter of authentication from the notified body.

4.6 Dealing with a refusal on the part of the manufacturer

Refusals on the part of a manufacturer in the context of an unannounced audit can lead to the suspension of the corresponding certificates. A refusal on the part of a subcontractor/supplier pursuant to 3.2 can have corresponding effects on the manufacturer's relevant certificates even if the manufacturer is not responsible for or could not foresee the causes.

4.7 Dealing with findings made in the course of unannounced audits

The procedure for dealing with findings/non-conformities observed in the course of unannounced audits corresponds in principle to the procedure regarding routine audits. The manufacturer stipulates the measures and implements these, so as to remedy the findings/non-conformities recorded in the course of the unannounced audit. Findings/non-conformities, especially those that affect the safety of the medical device, justify the conduct of additional unannounced audits with specific cause.

4.8 Unannounced audits in foreign countries

The conduct of unannounced audits in foreign countries corresponds to the conduct of unannounced audits in Germany. Should the conduct of an unannounced audit in a foreign

country be objectively not possible, the notified body shall perform product testing on the device pursuant to Annex III number 4 of Recommendation 2013/473/EU.

4.9 Costs in respect of unannounced audits

The costs for unannounced audits are to be agreed upon, by contract, between the manufacturer and the notified body and/or included in the existing contracts. The costs include fees and expenses incurred by the notified body in connection with the conduct of unannounced audits.

5. Unannounced audits <u>without specific cause</u> on the premises of the OEM

If the manufacturer is purely a PLM pursuant to 3.4 the unannounced audits pursuant to 4 of the present publication are to be conducted at the OEM pursuant to 3.3. The OEM is entitled to transmit the audit reports resulting from these unannounced audits to its PLM or to its further PLMs. These may be submitted to the notified body by the PLM. Such audit reports are to be appropriately taken into account in the planning and conduct of unannounced audits.

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