

Medical Device Authorisation: Clear or Cloudy?

According to a comparison study conducted by the Boston Consulting Group, the market authorisation of medical innovations proceeds at a more rapid pace in the EU than in the US. In spite of this, the comparison did not show an increase in recalls. Summary: The faster market access did not come at the cost of patient safety. Does this mean that all is well in the world of medical device authorisations in the EU? meditec writer Ramona Riesterer portrays the thoroughly mixed opinions in the medical technology industry.

Sabine Lieglein, Quality & Regulatory Manager at Philips Healthcare Deutschland, regards the fact that the Notified Bodies (NB), which are organised as profit-oriented companies under private law in the EU, carry out the certification of medical devices or the QM system as being entirely viable given the role of the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG). “In Germany, the ZLG designates the NBs. As a rule, such a designation is valid for five years, and the NB is subject to routine examinations during that time.” Dr. Peter Gebhardt, Director Regulatory

Affairs at Drägerwerk in Lübeck, shares this opinion. “Although the NBs are companies organised under private law, they are themselves subject to accreditation and routine monitoring by the competent authorities, the ZLG. As a result, it is in their own interest to pass the routine monitoring audits without major complaints.” He goes even further and sees merits in the system beyond just faster market access in the EU. “The current procedure in Europe has the advantage that the manufacturer is more strongly aware that it alone bears the responsibility for the products that it places on the market, and also makes itself legally liable for problems with

German Summary

Gemäß einer Vergleichsstudie der Boston Consulting Group läuft die Marktzulassung von medizintechnischen Innovationen in der EU schneller als in den USA. Trotzdem kam es im Vergleich nicht zu einem Mehr an Rückrufen. Fazit: Der schnellere Marktzugang läuft nicht auf Kosten der Patientensicherheit. Ist die Welt der Medizinprodukte-Zulassung in der EU also in Ordnung? meditec-Autorin Ramona Riesterer zeichnet ein durchaus gemischtes Meinungsbild aus der Medizintechnik-Industrie. Ausführlicher deutschsprachiger Beitrag sowie die Langfassungen der Statements unter: www.meditec.mi-verlag.de/medi0211zul

these products in the field." Michael Bothe, Director Medical Technology Products/Processes/Systems at VDE Prüf- und Zertifizierungsinstitut GmbH, sees these concerns solved by the legal form of his NB. "Not all NBs in Europe are profit-oriented. As a NB, the VDE Testing and Certification Institute is recognized as a non-profit GmbH (private limited company) in Germany. This legal form uniquely combines the independence and impartiality required by the accrediting bodies with a non-profit company's freedom, so that it is possible to offer particularly smaller and medium-sized companies testing and certification services with an acceptable financial cost." Dr. Rainer Boenigk, owner of Boenigk Interim & Consulting, on the other hand, is critical in his assessment. In his opinion, the supplier relationship between the manufacturer and the NB results in inadequate audits. "This is very clearly seen in the NB audit reports, which predominantly comprise minor nonconformities and comments. This occasionally leads to manufacturers being surprised when they are inspected by the FDA." Boenigk demonstrates this statement with a com-

parison. "How many manufacturers have had the CE certificate withdrawn? On the other hand, the list of companies that have received warning letters from the FDA or even been subject to an import ban is noteworthy." Does this mean that the NBs, which manufacturers are free to choose, are afraid that they will lose their customers if their audits criticize too much? Sabine Lieg-

Are Notified Bodies afraid that they will lose their customers if their audits criticize too much?

lein sees it this way. "A manufacturer could consider changing suppliers if there are disagreements. The consequence would be that all attached labels and manuals would have to be revised. A change is therefore only worthwhile under certain conditions."

According to MEDDEV 2.10/2, NBs are not permitted to offer or provide consultancy or advice. May a manufacturer nevertheless expect to be given

pointers for improvement or information regarding events on the market? Peter Gebhardt makes it clear. "The NBs actually only conduct product tests to a limited extent, in the form of type examinations; as a rule, the monitoring activities are restricted to auditing the QM system and inspecting and evaluating the so-called technical file in the framework of product design tests or audits. An NB is not permitted to carry out concrete, company-specific consultation if it is possible that the NB may later inspect this company." He adds, "As far as events on the market, a manufacturer should be better informed with regard

to its own products than its NB is. Because an NB is furthermore obligated to confidentiality, it is naturally not allowed to divulge any information concerning competitors or their products." It is not always possible to draw a clear line between consultation and certification in everyday practice, according to Sabine Lieglein, who explains, "In the framework of a certification or conformity assessment, the NB

Heightened monitoring is overdue

The meditec interview with Martin Rümke from the VDI Medical Technology Working Group (www.meditec.mi-verlag.de/medi0111rum) proved polarising. The question arises as to whether or not the profit-oriented organisation of the notified bodies (NBs) is problematic. Unfortunately, none of the bodies that we asked for a further analysis wanted to provide an official answer, except for the VDE Testing and Certification Institute, which, according to its own statements, is a non-profit organisation.

Although it is easy to conceive that the rules might be bent sometimes in a client-contractor relationship, the NBs' organisation under private law may not really be the crucial problem. Behind closed doors, it was discovered that a portion of the auditors cannot even tell whether or not a certain medical device fits into a certain risk class. They tend to simply accept the manufacturer's suggestion. That the manufacturer only hurts itself in this case is clear, because the manufacturer is the one who is ultimately responsible. But: Is it really asking too much to expect an audi-

tor to know whether the categorization in a risk class is correct?

It is reasonable that NBs are not allowed to offer consultation. But it is questionable whether or not a five years pause for the NB personnel must be accepted as the "guideline for the unobjectionability of earlier consultation activities" (requirement of the EK-Med, experience exchange group of the NBs for medical devices). Consider the fact that the loss of consultants that this causes considerably reduces the group of people with the necessary competence for assessing what is being shown. Particularly given the great wealth of complex and complicated medical devices, which, since March 2010, also includes stand-alone software. Which NB can really reflect this variety with its experts? According to the results of a comparison study conducted by the Boston Consulting Group, the market authorisation of medical innovations proceeds at a faster pace in the EU than in the US. In spite of this, the comparison did not show an increase in recalls. Summary: The faster market access did not come at the cost of patient



meditec writer Ramona Riesterer holds a diploma in medical radiology and in communication science.

safety. Does this mean that all is well in the world of medical device authorisations in the EU? Is this all just an academic discussion with no practical relevance?

Most likely not. Because it is an open secret that the quality of the bodies is anything but homogenous, although there are harmonized criteria that must be met by the NBs throughout the EU. Experts expect that the next reform of the European guideline will therefore call for the intensification of NB monitoring activities.

Ramona Riesterer

Your opinion is important to us. Send us an e-mail: meditec.redaktion@mi-verlag.de

		<p>1) Sabine Lieglein, Quality & Regulatory Manager at Philips Healthcare Deutschland: "In Germany, the ZLG designates the Notified Bodies. As a rule, such a designation is valid for five years, and the NB is subject to routine examinations during that time."</p>	<p>"Not all NBs in Europe are profit-oriented. As a NB, the VDE Testing and Certification Institute is recognized as a non-profit GmbH (private limited company) in Germany. This legal form uniquely combines the independence and impartiality required by the accrediting bodies with a non-profit company's freedom, so that it is possible to offer particularly smaller and medium-sized companies testing and certification services with an acceptable financial cost."</p>
		<p>2) Peter Gebhardt, Director Regulatory Affairs at Drägerwerk in Lübeck: "Although the NBs are companies organised under private law, they are themselves subject to accreditation and routine monitoring by the competent authorities, the ZLG. As a result, it is in their own interest to pass the routine monitoring audits without major complaints."</p>	<p>4) Dr. Rainer Boenigk, owner of Boenigk Interim & Consulting: "How many manufacturers have had the CE certificate withdrawn? On the other hand, the list of companies that have received warning letters from the FDA or even been subject to an import ban is noteworthy."</p>
<p>3) Michael Bothe, Director Medical Technology Products/Processes/Systems at VDE Prüf- und Zertifizierungsinstitut GmbH:</p>			

clearly evaluates which criteria are not satisfied. The expectations are explained in greater detail for further clarification. This talk can take on an advisory character, but essentially serves only to explain the nonconformities and consequently to point out the improvements. The NB is not permitted to give concrete measures regarding the nonconformities nor information regarding events on the market."

Michael Bothe points out that the separation of consultation and certification can also be solved organizationally. "In order to guarantee the independence and impartiality required by the accrediting bodies, there must be a clear dividing line between consultation and certification. The manufacturer can only expect general assistance in the interpretation and implementation of requirements resulting from regula-

tions and standards. In order nevertheless to provide certain consulting services, various NBs have founded legally independent consulting companies with separate staff."

With a look to the automotive industry and the question as to whether it has anything to teach in the QM area, Lieglein and Gebhardt point out that the comparison is inappropriate because the lot sizes take on a completely different magnitude. Boenigk considers the comparatively small lot sizes for medical devices to be the reason that supplier management and process step outsourcing have not been introduced in medical technology with the same consistency as in the automotive industry. "Problems in the supply chain have already been recognized by the FDA and the NBs, and have led to an intensified focus during the inspection or

monitoring audits." Nevertheless, it is his opinion that there is something to be learned from the consistently applied, integrated QM systems.

As to whether or not the high value of medical devices is sufficiently reflected by the CE label, Gebhardt states, "Attaching further test symbols in addition to the CE label is only possible to a limited degree. And such additional test symbols only serve to make the products more expensive without increasing the product safety and quality." Sabine Lieglein adds, "For medical devices in risk class I with measurement function, IIa, IIb and III, the CE label is used with the Notified Body's identification number, such as CE0123. This provides customers with complete transparency, enabling them to directly identify the parties involved."

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