Exclusive-Interview with Dr. Wolfgang Lauer, BfArM

"It's not about bringing accusations, it's about the devices"

The breast implant scandal has once again triggered a debate on legislation regarding medical devices. meditec spoke to Dr. Wolfgang Lauer, Head of Medical Devices Division, Federal Institute for Drugs and Medical Devices (BfArM), about how the cornerstones of patient safety can be further expanded.

Pictuer: BfArM

Dr. Lauer, you have been Head of Medical Devices Division, Federal Institute for Drugs and Medical Devices (BfArM) since October 2011. How often have you heard people say: the BfArM has an engineer at last!
I have heard that on various occasions, but in fact it's not true - my predecessor was a medical specialist and an engineer, for example. Medical devices are always about medicine and products, so it's important for us to reflect that. We do so by examining issues in our coordination processes from a scientific and engineering point of view, as well as from a medical perspective.

After what happened with the PIP breast implants, will the BfArM be looking more closely at medical devices from now on?
I would not say that we have not looked closely at medical devices in the past. Numerically speaking, and in terms of assignments of course, our department only accounts for a rather small part of the BfArM as a whole. The work in the pharmaceuticals area is broader and more varied in scope than for medical devices, since we do not have to deal with approval aspects.

On the specific matter of the PIP implants: are there errors in the system that encouraged or at least failed to prevent this fraud?
As I see it, the debate on the legal system for medical devices currently in progress could be very helpful in terms of further developing the system. The advantage in the EU is that the system is regarded as being more open to innovation than that of the US, for example. The underlying principle is that the manufacturer has direct responsibility, backed up by regulatory oversight and market supervision. Direct responsibility means a margin of freedom for the manufacturer - both in a positive and a negative sense. And this is precisely the issue: anyone who deliberately wants to

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cheat will find loopholes. Unfortunately, it is not possible to close these loopholes completely. It's as if you were to put a policeman at every set of traffic lights to make sure everyone stops at a red light. Nonetheless, the PIP case does show that we will have to think about enhancing supervision. State approval would not have prevented the fraud, either. Everything was properly submitted and assessed as part of the conformity assessment procedure. The question is: what happened then? And that's where we get to the issue of supervision.

What form should this supervision take?
We have to ask ourselves whether we can make it more difficult to cheat - for example, by means of systematic, unannounced check-ups. These check-ups could be supplemented by product tests - in other words actually going in and saying: "I'd like to take a look at the third one on the left from this batch, please". And then it is inspected. But there are still a lot of unanswered questions: who would be able to do this? How thorough would the inspection be? Based on which guidelines? But the aim is clear: to create an atmosphere of uncertainty that makes the risk of being caught too high for fraudsters.

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Let's talk about the vigilance system: did it fail in the case of PIP?
In terms of the PIP case, we received relatively few reports of implant defects. Later on, we heard of more through the media than had been reported to us. Our spontaneous registration system depends on people's willingness to report back to us. Users are obliged to notify the authorities. But they themselves have to decide whether or not an incident has to be reported, based on the legal definition. So our assessment can only be as good as the number and quality of reports we receive. I am particularly interested in encouraging users to report incidents in detail. It's not about bringing accusations, it's about the products. For us it's important to get feedback from the field and expose problems with medical devices that affect patient safety.

What aspects come under the heading of patient safety, as far as you are concerned?
What we are looking at here is the classic triangle: patient - technology – organisation, all in relation to the individual undergoing treatment. Patient safety derives from many factors: training, the degree of intensity of use, the level of motivation among personnel. How it is all organised - processes interfaces, etc.: Are there conflicts that impact on the outcome? And then there are of course the tools - and that brings us to the medical devices themselves. The safety and performance quality of these products are fundamental, and usability is a key factor here.

I am aware of the problem from my own experience at university in Aachen, where I was involved in many ergonomics projects with manufacturers. In those days, usability was something where people said: "We'll make it round and colourful in the end". People were not aware of how usability relates to patient safety and its importance early on in product development. As I see it, there have been definite changes here: the inclusion of ergonomics in legislation and the establishment of the relevant norms have forced manufacturers to address the issue. They have to come up with user-friendly solutions and they have to illustrate and document these as part of the conformity assessment process. A rethinking process has definitely started here. Of course there are still some who have not entered into the spirit of this and just want to get through the document inspection.

The reporting system is geared towards the product as the cause of an adverse event. Does that properly cover the issue of usability?
Poor usability is a functional deficit, a product error - so incidents have to be reported in this connection, too. Just to say: "Someone was too stupid to use the device", is too short-sighted - and there's scientific evidence to prove this. The result might give this impression, but generally speaking the real reason is that the product promotes error. This is why we generally talk about 'errors of use' and not 'user errors', since the probability of such an error occurring increases with the product's complexity, among other things. In case of doubt, we advise people to report these as incidents.

What do you think of the term "acceptable risk" in this connection?
Every time I board a plan I take a risk that I clearly deem to be acceptable. The manufacturer is required to show this balance between the benefit and the risk of a medical product in terms of its acceptability. It has to be documented as part of the manufacturer's risk management system. This must contain details of what residual risk remains, how high this risk is, what damage it can cause, what measures have been taken to reduce the risk, etc.
Such risks must be quantified. In the case of an electronic component, it is fairly simple to calculate this statistically. In the case of risks relating to the use of a device, it is much more difficult, because a whole range of factors are involved: the user, the situation in which the device is being used, the complexity of the product etc. Risks relating to the use of a product can be significantly reduced by optimised usability and by providing risk-related training for users.

Interview conducted by Ramona Riesterer ←

German Summary

Nicht zuletzt der Betrugs-Skandal mit Brustimplantaten hat die Diskussion über das Medizinprodukte-Rechtssystem neu entfacht. meditec INTERNATIONAL sprach mit Dr. Wolfgang Lauer, Leiter der Abteilung Medizinprodukte, Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), über Möglichkeiten, die Eckpfeiler der Patientsicherheit weiter auszubauen. Der deutschsprachige Beitrag ist nachzulesen auf www.meditec-international.com/medi0212lau