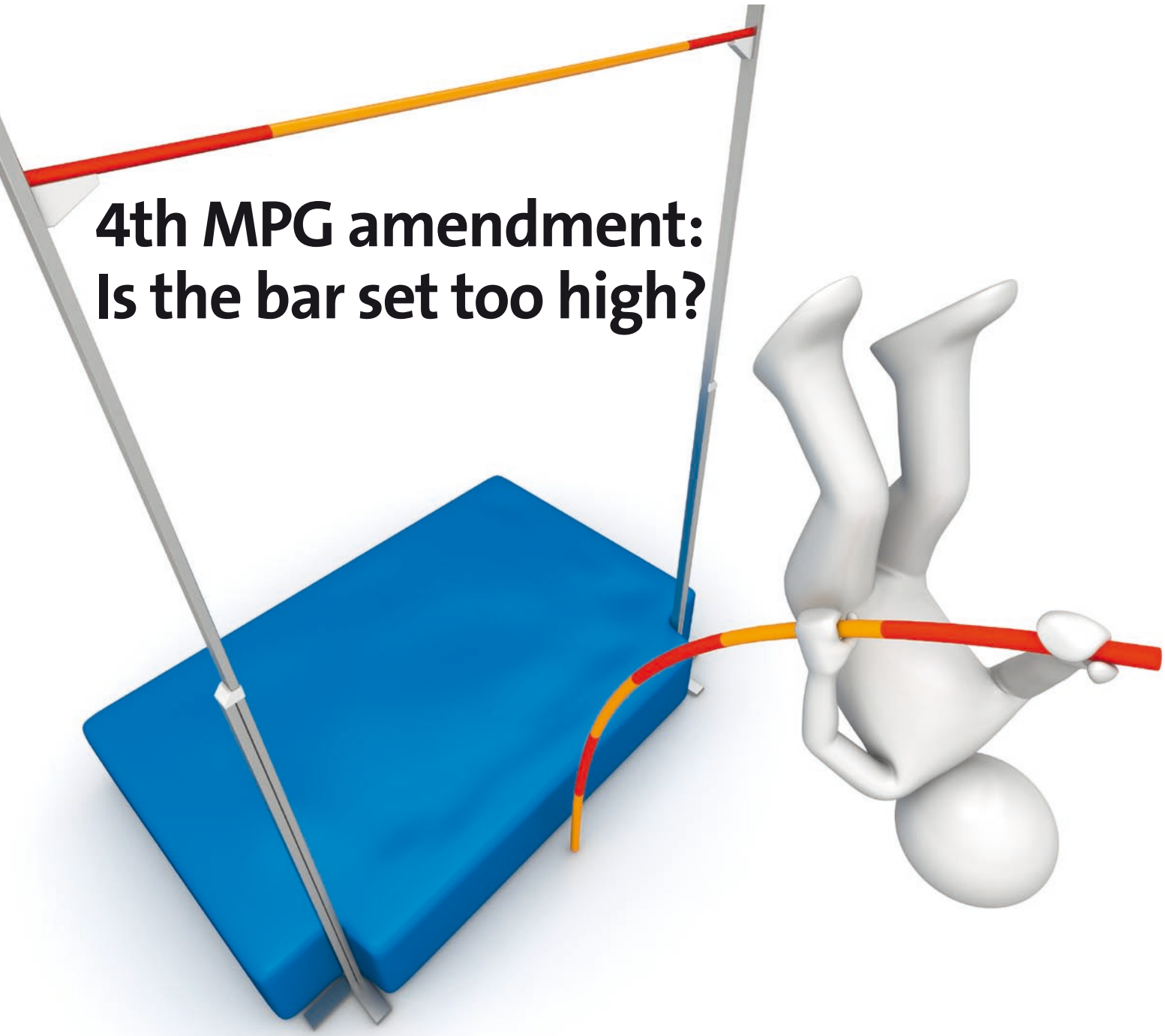
4th MPG amendment: Is the bar set too high?



Since the 4th MPG (German Medical Devices Act) amendment took effect, stricter requirements apply to clinical evaluation and investigation: A clinical evaluation is required for each medical device. In addition, a clinical trial is also fundamentally required for medical devices in risk class III and for implantable medical devices.

Further regulations for conducting a clinical investigation have been implemented in the Verordnung über klinische Prüfungen von Medizinprodukten (MPKPV - Ordinance on Clinical Trials with Medical Devices). The German Bundesrat reached this agreement on 7 May and, on the one hand, finally, consequently filled in the regulatory vacuum that had existed since March. On the other hand, now an ordinance has been cast that Spectaris had already called "excessively bureaucratic" in a statement issued at the beginning of the year. "One point that we were pushing was a notification procedure for the low-risk products described in the Medical Device Directive. The authorization procedures that have now been approved do not provide any additional patient benefits whatsoever, while nevertheless causing considerable organizational effort and extra costs for the industry," reports Dr. Tobias Weiler, assistant managing director and head of the medical technology trade association at Spectaris. "We expect to see the clinical trials relocated to other countries in Europe, which will mean a loss of jobs." BVMed spokesperson Manfred Beeres had similar comments. "In practice, the new ordinance will cause a considerable increase in the bureaucratic effort for a

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clinical trial without doing anything to reinforce patient safety. This is problematic, particularly for the small and medium-sized companies that greatly shape medical technology. Additional bureaucratic obstacles that result here lead to completely unnecessary difficulties."

The previous notification procedure for clinical trials of medical devices involving the Länder authorities has been replaced by an authorization procedure involving the Bund authorities, the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM - Federal Institute for Drugs and Medical Devices). Before the 4th MPG amendment took effect, the obligation of the medical device manufacturers was limited to reporting their clinical trials to one of the more than 70 ethics commissions. There are no reliable data on how many clinical trials were rejected by the ethics commissions in the past. There is, however, agreement that the quality of these decisions varied considerably - also due to the fact that the ethics commissions had to gain a picture of technical details although their composition was not selected with this purpose in mind. In the future, they will be responsible exclusively for legal-ethical aspects, and the BfArM will have the job of assessing the scientific-technical aspects.

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Some data must be entered twice

Clinical trials of devices with a high safety risk must be authorized by the BfArM and obtain a positive evaluation by the responsible ethics commission. The BfArM's authorization is assumed unless the BfArM has, within 30 days, stated reasons for denying its consent to a clinical trial. A consenting evaluation from the ethics commission must also be provided, which has 60 days to process the application. The manufacturer must consequently allow for this time period in its plans. The reports to both bodies are made electronically via the Deutsche Institut für medizinische Dokumentation und Information (DIMDI - German Institute of Medical Documentation and Information). The first reports from the field indicate difficulties with formalities, for example, when inputting data. In some cases, data already contained in the test plan, such as the inclusion/exclusion criteria, must be entered twice here.

Although these are most likely teething troubles that will be worked out eventually, the compulsory notifications of serious adverse events (SAEs) are also causing resentment in the long run. Because it is necessary to report not only all incidents that are directly related to the test product or the clinical trial, but also all events that result from the test persons' personal living conditions, and the reports must also be made separately by the party conducting the trial and the sponsor. "Somewhat overstated, this means that a report must be made if a patient who took part in a device's clinical trial is run over by a streetcar on the way home from the hospital," explains Dr. Martin Abel, head of Medical and Regulatory Affairs at Lohmann & Rauscher GmbH & Co. KG. "It is hard to understand how such an accident could have an impact on the further course of a clinical trial. This example illustrates which forms the notification requirement can take in extreme cases." Duplicated reports of SAEs are also possible, for example in the case of clinical trials with CE-certified devices and invasive or stressful examinations. Here, SAEs have to be reported both through the "normal" vigilance system and through the SAE system for clinical trials. The manufacturers are consequently encountering duplicated effort at various points. Consequently, the minimum requirement for the future is to avoid these duplications.

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Commentary: "Overshooting the mark"

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"There are two positive points in the MPKPV: First, it provides those involved with a certain degree of legal security, even if is substantially overdue. Second, some of the superfluous bureaucratic bite contained in the first ministerial draft has been eliminated. Now, for example, non-invasive, Class IIa medical devices can be exempted from the obligation to obtain authorization. Nevertheless, the regulators have possibly overshot the mark on some points. For example, there is the question of whether or not the numerous sponsor obligations are still covered by the power to issue statutory instruments. The MPKPV also leaves something to be desired in other areas. For example, it would have been expedient to provide even better delimitation of the scope of duties of the authorizing agencies and the ethics commission with regard to the examination of safety issues. It furthermore must be made clear that not all important fundamental issues are covered in the ordinance text. Some requirements have actually been toned down in the ordinance's explanatory statement. For example, it is only necessary to attach a plan for further treatment and medical care of the test persons to the application for authorization if it is not dispensable due to the special circumstances of the particular trial. The ordinance's explanatory statement also illustrates that the trial details still result from DIN EN ISO 14155-1-2 and DIN EN ISO 13612. Also the – not mentioned there – MEDDEV 2.7.1 Rev.3, Clinical Evaluation: A Guide for Manufacturers and Notified Bodies from December 2009 must be observed."