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Comprehensive Amendments of German Drug Laws upcoming

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Recently, the ***German Federal Ministry of Health*** published a new draft law (*"Viertes AMG-Änderungsgesetz"*) which aims to amend several provisions of the German Drug Act (*Arzneimittelgesetz*) and other drug-related laws.

Most of the intended amendments result from an adjustment of German laws to the new European Clinical Trials Regulation (Regulation (EU) No. 536/2014). For instance, several provisions of the German Drug Act related to clinical trials (*e.g.*, definitions) will then refer to the Clinical Trials Regulation or are amended accordingly. The German Ordinance on Good Clinical Practice (*GCP-Verordnung*) will cease to be in force. Furthermore, some amendments, particularly those that refer to the informed consent of study subjects, will go beyond the scope of the Clinical Trials Regulation.

For example, it is foreseen that the trial-related information are given to the study subject by a medical doctor and not "only" by a member of the investigating team. Also, clinical trials on incapacitated subjects may only be conducted in Germany if there are scientific grounds for expecting that participation in the clinical trial will produce a *direct* benefit to the incapacitated subject outweighing the risks and burdens involved. In contrast to the Clinical Trials Regulation, under the new draft law it shall not be sufficient that such benefit exists for the population represented by the incapacitated subject concerned.

Besides, the new draft law includes transitional provisions for clinical trials. The current versions of the German Drug Act and the German Ordinance on Good Clinical Practice shall apply for another 3 years to clinical trials for which an authorization was requested within 6 months of the notification that the EU portal and the EU database have achieved full functionality. If such authorization is requested within 6-18 months of such functionality notification, the trial sponsor may choose whether the clinical trial shall be subject to the new or the old regulatory regime. In the latter case, the provisions of the German Drug Act and the German Ordinance on Good Clinical Practice shall apply for another 3 years.

In addition to these clinical trials-related amendments, the German Drug Act and other drug-related laws shall be changed. These amendments refer, *inter alia*, to pharmacovigilance and drug

advertising rules. The existing pharmacovigilance rules are going to be expanded to cover specific measures related to the product surveillance of biological drugs (especially biosimilars) and their tracing and tracking. Additional changes of the German Radiation Protection Ordinance (*Strahlenschutzverordnung*) and the German X-Ray Regulation (*Röntgenverordnung*) are also intended, but not yet specified.

As a next step, the new draft has to be agreed upon by the German government. Afterwards, it will be subject to further parliamentary deliberations. It may be adopted during the next year, but will only take into effect after the EU portal and the EU database have achieved full functionality.

Pharmaceutical companies should carefully monitor this process as it will directly impact their regulatory obligations related to clinical trials in Germany – but also obligations beyond clinical trials.

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