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Amendment to Austrian Act on Pharmaceuticals in view of EU Clinical Trials Regulation

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Introduction

The EU Clinical Trials Regulation[(1)] is set to replace the EU Clinical Trials Directive.[(2)] Although the regulation entered into force on 16 June 2014, the timing of its application depended on the development of a fully functional EU clinical trials portal and database. Due to technical difficulties with the development of the IT systems, the portal's go-live date had to be postponed several times.

However, on 21 April 2021, the European Medicines Agency's management board confirmed to the European Commission that the EU portal and database are fully functional. The Commission subsequently published a notice on 31 July 2021, fixing the date of applicability of the EU Clinical Trials Regulation as 31 January 2022.

To bring the Austrian Act on Pharmaceuticals in line with the new regulation (and to implement some further amendments), the government submitted a draft bill to Parliament on 15 December 2021. The bill was adopted by the National Council on 20 January 2022 and the Federal Council on 3 February 2022. It was published in the *Federal Law Gazette* on 14 February 2022.[(3)]

Information leaflets

To implement the amended article 63(3) of the EU Human Medicines Directive,[(4)] the Agency for Safety in Healthcare (BASG) is authorised to abstain from requirements regarding labelling and package information leaflets for medicines not directly dispensed to patients, such as hospital products. Article 69 of the EU Clinical Trials Regulation allows member states to decide in which language the labelling shall be made. Although Austria requires labelling to be made in German, the use of other languages is permitted, provided the different language versions are identical in content.

Evaluation of clinical trials

The share of tasks between the BASG and the ethics committee in respect of the evaluation of clinical trials broadly corresponds to the already existing legal framework. For flexibility reasons, details shall be established by ordinance. The process of approval of a clinical trial is regulated in chapter II of the EU Clinical Trials Regulation. A clinical trial may commence only after approval by the BASG in accordance with article 8 of the EU Clinical Trials Regulation.

Although the official language of Austria is German, section 31(2) of the Act on Pharmaceuticals provides that the dossier of a multinational clinical trial is to be submitted (only) in English. In national clinical trials, it can be submitted in German or English. The submission of the dossier in English shall facilitate the functioning of the evaluation of a multinational application. The English language requirement, of course, does not apply to documents handed over to trial subjects.

In its approval, the BASG shall refer to the English evaluation reports. In cases where Austria is the reporting member state, the report for the other member states shall also be in English. A translation into German is not required.

Section 32 of the Act on Pharmaceuticals sets out which ethics committee shall be involved in the evaluation. Prior to the amendment, so-called "lead ethics committees" (ie, ethics committees active in multi-centre clinical trials) had to fulfil specific criteria established by ordinance of the Ministry of Health. These leading ethics committees were published in the official journal of the *Wiener Zeitung*. For reasons of quality, only these leading ethics committees may apply for future participation in the evaluation process. The principle of instruction freedom applies to both the committees and their members. The committees must have a sufficient staffing such that they can provide timely comments to comply with the timing provided by the EU Clinical Trials Regulation.

According to section 34 of the Act on Pharmaceuticals, the ethics committees shall establish a platform to coordinate a uniform practice. The platform shall establish common rules of operation and a common plan for the assignment of business. The rules of operation must provide for details on ways of working. The platform must immediately notify the Ministry of Health if an ethics committee fails to fulfil the legal requirements.

It must be clear from an ethics committee's opinion whether it approves the conduct of a clinical trial. The opinion shall be made in a way that allows the BASG to directly incorporate it into its own evaluation report (section 36). The members of the committee shall meet once a month; however, it is also possible to deliberate and vote by technical means (section 36).

During the review process, some interested parties criticised the Act on Pharmaceuticals for its lack of provisions on the protection of vulnerable groups (eg, minors or persons unable to consent). Such provisions are now contained in the EU Clinical Trials Regulation, but the regulation does allow member states leeway to provide for specifics. The Act on Pharmaceuticals makes use of this leeway by allowing the inclusion of trial subjects unable to consent, provided that there is no indication that the subject denied inclusion prior to the loss of ability to consent.

Minors as trial subjects must give their consent in addition to the necessary consent of their custodians. Although the EU Clinical Trials

Regulation allows the inclusion of persons in (mandatory) military service as trial subjects, the Act on Pharmaceuticals excludes them from being included as such.

"Cluster-trials" permitted under article 30 of the EU Clinical Trials Regulation are not implemented in Austria.

To implement article 94 of the EU Clinical Trials Regulation, which provides that penalties must be effective, proportionate and dissuasive, in addition to administrative fines, section 48 of the Act on Pharmaceuticals provides that data obtained through a trial without approval must not be passed on to third parties or used in an authorisation process. If publications have been made already, they must be supplemented by the indication that the data has been collected illegally.

Emergencies

In light of the covid-19 pandemic, section 94d of the Act on Pharmaceuticals prolongates the maximum term of emergency ordinances in case of a pandemic or other significant event from six months to one year.

Comment

The amendments to the Act on Pharmaceuticals carefully brings it in line with the new EU Clinical Trials Regulation (including some minor additional updates not provided for in the EU Clinical Trials Regulation). One of the most striking changes is the possibility to submit documents not in German but in English only, and that the BASG shall report in English if Austria is the reporting member state. This could signal the beginning of a more open approach to the use of English in other administrative and court proceedings as well.

For further information on this topic please contact Rainer Herzig at Preslmayr Attorneys at Law by telephone (+43 1 533 16 95) or email (herzig@preslmayr.at). The Preslmayr Attorneys at Law website can be accessed at www.preslmayr.at.

Endnotes

(1) Regulation (EU) 536/2014.

(2) Directive 2001/20/EC.

(3) BGBl I 8/2022.

(4) Directive 2001/83/EC.