The Rhineland-Palatinate
Officer for Data Protection
and Freedom of Information

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Statement on the Anonymisation Report (EMA Policy 0070) for Praxbind

Dear Mr. Ahland,
Dear Sir/Madam,

In connection with its responsibility as the regulatory authority for data protection according to § 38 (1) Federal Data Protection Act (BDSG) in conjunction with § 24 (1), sentence 2 *Land* Data Protection Act (LDSG), the Rhineland-Palatinate Officer for Data Protection and Freedom of Information (LfDI RLP) was asked to prepare a statement on the procedure for the anonymisation of clinical documents in connection with EMA Policy 0070, described in the Anonymisation Report for Praxbind issued by Boehringer Ingelheim International GmbH and intended for the European Medicines Agency (EMA).

The LfDI RLP has already commented on the topics of the transparency of study data from clinical trials and on the corresponding company procedure of Boehringer Ingelheim in its letters dated 13 February 2014 and 29 January 2015, respectively. In this context, we would refer you to these letters.

Preliminary remarks

The following statement issued by the LfDI RLP deals exclusively with questions of informational self-determination and data protection legislation. Furthermore, the disclosure of study data may, in some cases, adversely affect other legally protected interests or the legitimate interests of third parties, for example industrial and business secrets, or the legitimate interests and expectations of contract partners. However, the LfDI RLP cannot issue any statement on this matter from the official regulatory standpoint.

The following statement focuses on the question of the implications of the disclosure of study data with respect to the personal data of patients. While it is acknowledged that corresponding clinical trials also involve other types of personal data, for example relating to doctors/investigators, clinic employees, representatives of companies and authorities, such data will not be addressed below with a view to prioritisation.

Finally, it must be borne in mind that health data, which is primarily involved in this context, is particularly problematic from the standpoint of a regulatory authority for data protection. This applies not only because special types of personal data, as defined in § 3 (9) BDSG, are involved here, but also because, according to the basic legal interpretation of the legislation on informational self-determination, the data protection for health data normally ends with the death of the individual concerned. Since the death of patients taking part in clinical trials is not an unusual event, preserving the protection of health data is invariably associated with certain deficits, which are only partly addressed by the (post-mortem) General Right to Privacy in terms of civil law. Ultimately, as a result of advances in medical technology, particularly in the field of genetics, health data always also involves information that can potentially be related to an extended group of third parties (ancestors, descendants, other relatives). This also suggests that, from the standpoint of a regulatory authority, a particularly proactive approach is needed when dealing with this category of data.

Statement

The Anonymisation Report for Praxbind submitted by Boehringer Ingelheim fully satisfies the legal requirements from the standpoint of data protection legislation. On the basis of the company procedure for creating transparency in study data from clinical trials (already reviewed elsewhere), in the submitted report Boehringer Ingelheim draws the relevant conclusions arising from the legal requirements, particularly the Federal Data Protection Act (BDSG).

Based on the structured approach of Boehringer Ingelheim and the statements in the report, all of which are reasonable, the following aspects in particular will be considered from the standpoint of the data protection legislation:

The approach chosen by Boehringer Ingelheim on the question of the ability to link data to individuals (see § 3 (1) BDSG) is appropriate. The categorizations of Boehringer Ingelheim are based on the so-called "absolute approach" in respect of the ability to link data to individuals; this approach is shared by all regulatory authorities in Germany. Although alternative "relative" approaches can be found in isolated cases, particularly in the literature, these have not caught on and will soon become redundant, given the value judgements expressed in the European General Data Protection Regulation, which comes into effect in 2018. Recital 26 of Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EG (Data Protection Directive) states that in order "to determine whether a natural person is identifiable, account should be taken of all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly." In this regard, it is appropriate and proper to implement the standard applied here by Boehringer Ingelheim.

Also reasonable in every respect is the risk assessment undertaken by Boehringer Ingelheim (2.1.2 of the Anonymisation Report). The regulatory authority for data protection fully agrees here with the logically and convincingly developed criteria.
This applies, on the one hand, to the question concerning the specification of the minimum group of participants that are "critical from the standpoint of data protection legislation"; the number of 25 assumed here is appropriate. Moreover, this also applies to the risk-oriented classification of "single centre trials". The problem of de-anonymisation of participants in such studies from the standpoint of data protection legislation is convincing. Finally, the approach selected in the anonymisation concept for processing "full case narratives" is also appropriate. The regulatory authority agrees with the argument presented in the risk scenario that, particularly in view of the publication and potentially worldwide access to this data, the standard to be set should regularly rule out any further disclosure of full case narratives.

Accordingly, the presented anonymisation concept is considered to be compliant with the requirements of data protection legislation.

Finally, we would point out that this assessment was necessarily based on the current circumstances and the existing legal situation. As already mentioned in the preliminary remarks, it is not only the legal situation relating to clinical trial data that is constantly changing but also the state-of-the-art in science and technology in particular. This means that the LfDI RLP should be consulted again in the event of any future widening of the publication of study data.

Yours sincerely

On behalf of the LfDI RLP

[signed]
Dr. Stefan Brink