

H. Lundbeck A/S
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Denmark

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Caseworker
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Decision by the Danish Data Protection Agency approving Binding Corporate Rules of Lundbeck Group

**The Danish Data
Protection Agency**
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1. Having regard to Article 47(1) of the EU General Data Protection Regulation 2016/679 (GDPR), the Danish Data Protection Agency shall approve Binding Corporate Rules (BCRs) provided that they meet the requirements set out under this Article.

Whereas:

VAT No. 11883729

2. In accordance with the cooperation procedure as set out in the Working Document WP263 rev01, the Controller BCRs application of Lundbeck Group were reviewed by the Danish Data Protection Agency as the competent supervisory authority (SA) for the BCRs (BCR Lead) and by the Dutch Supervisory Authority and the Norwegian Supervisory Authority acting as co-reviewers. The application was also reviewed by the concerned SAs, to which the BCRs were communicated as part of the cooperation procedure.
3. The review concluded that the Controller BCRs of Lundbeck Group comply with the requirements set out by Article 47(1) of the GDPR as well as the Working Document WP256.rev.01 and in particular that the aforementioned BCRs:
 - i. Are legally binding and contain a clear duty for each participating member of the Group including their employees to respect the BCRs by;

requiring all members of the Lundbeck Group to enter into signed contracts with H. Lundbeck A/S, which is the headquarter of the Lundbeck Group (See Annex 4 for a list of the participating entities and Annex 3 for the BCR-contract for the obligation to comply with the BCRs); and

requiring that the BCRs are incorporated in Lundbeck's Code of Conduct, and that all employees are informed of the BCRs and possible disciplinary sanctions in case of violation of the BCRs (see section 4 of the BCR Application Form and part 1 section C of the BCR Policy)
 - ii. Expressly confer enforceable third party beneficiary rights to data subjects with regard to the processing of their personal data as part of the BCRs (see part 1, section C and part 2, rule 10 of the BCR Policy and part 2, section 4 of the Application Form);

- iii. Fulfil the requirements laid down in Article 47(2) (see the BCR Application Form and the BCR Policy).
4. The EDPB provided its opinion 05/2022 in accordance with Article 64(1)(f). The Danish Data Protection Agency took utmost account of this opinion.

DECIDES AS FOLLOWING:

5. The Controller BCRs of Lundbeck Group provide appropriate safeguards for the transfer of personal data in accordance with Article 46(1) and 2(b) Article 47(1) and (2) GDPR and the Danish Data Protection Agency hereby approves the Controller BCRs of Lundbeck Group.
6. However, before making use of the BCRs it is the responsibility of the data exporter in a Member State, if needed with the help of the data importer, to assess whether the level of protection required by EU law is respected in the third country of destination, including onward transfer situations. This assessment has to be conducted in order to determine if the guarantees provided by BCRs can be complied with in practice, in light of the circumstances of the possible impingement created by the third country legislation with the fundamental rights and the circumstances surrounding the transfer. If this is not the case, the data exporter in a Member State, if needed with the help of the data importer, should assess whether it can provide supplementary measures to ensure an essentially equivalent level of protection as provided in the EU.
7. Where the data exporter in a Member State is not able to implement supplementary measures necessary to ensure an essentially equivalent level of protection as provided in the EU, personal data cannot be lawfully transferred to a third country under these BCRs. Therefore, the data exporter is required to suspend or end the transfer of personal data.
8. The approved BCRs will not require any specific authorization from the concerned SAs.
9. In accordance with Article 58(2)(j) GDPR, each concerned SA maintains the power to order the suspension of data flows to a recipient in a third country or to an international organization whenever the appropriate safeguards envisaged by the Controller BCRs of Lundbeck Group are not respected.

ANNEX TO THE DECISION

The Controller BCRs of Lundbeck Group that are hereby approved cover the following:

a. Scope

Only members of the Lundbeck Group acting as Controllers that are legally bound by the BCRs *[A list of members of the Lundbeck Group covered by these BCRs is available in Annex 4]*

b. EEA countries from which transfers are to be made *[Annex 1 BCR Policy]*

c. Third countries to which transfers are to be made *[Annex 1 BCR Policy]*

d. Purposes of the transfer *[Annex 1 BCR Policy]*

e. Categories of data subjects concerned by the transfer *[Annex 1 BCR Policy]*

f. Categories of personal data transferred *[Annex 1 BCR Policy]*

Kind regards,

Line Sørensen