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17. december 2020

J.nr. 2018-581-0001
Dok.nr. 294644
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Sent with Digital Post

Approval of the binding corporate rules of the Coloplast Group

The Danish Data Protection Agency considers that the binding corporate rules of the Coloplast Group ('Coloplast') provide appropriate safeguards for the transfer of personal data in accordance with Article 46(1), 46(2)(b), 47(1) and (47)(2) of the Data Protection Regulation¹.

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1. Appropriate guarantees

Before applying binding corporate rules, the exporter transferring personal data from a Member State shall be responsible for assessing whether the level of protection required by Union law is respected by the third country to which the personal data are transferred. In this assessment, any further transfer shall also be taken into account. The purpose of the assessment is to determine whether the obligations of binding corporate rules can be complied with in practice, taking into account the risk of a possible limitation of the fundamental rights which the legislation of the third country may entail and the circumstances surrounding the transfer. If this is not the case, the exporter shall assess, if necessary with the help of the importer of the personal data, whether further measures need to be taken to ensure a level of protection that is essentially equivalent to that existing within the Union.

If the exporter transferring personal data from a Member State is not in a position to take additional protective measures to ensure a level of protection that is essentially equivalent to that existing in the Union, personal data may not be transferred under these binding corporate rules. Such a transfer must therefore be interrupted or terminated. Nevertheless, if a member of the group intends to transfer data to third countries, it shall inform the competent supervisory authority in advance in order to allow the supervisory authority to assess whether the proposed transfer should be suspended or prohibited in order to ensure an adequate level of protection.

The approved binding corporate rules do not require any specific authorisation from the data protection authorities concerned within the EU/EEA.

The Danish Data Protection Agency assumes that Coloplast informs the Danish Data Protection Agency of amendments to the binding corporate rules, which in turn must be forwarded to all the data protection authorities concerned within the EU/EEA.

¹Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Regulation on data protection)

The authorisation may be revoked if Coloplast processes personal data in a manner contrary to the binding corporate rules or other provisions of the Data Protection Regulation.

In accordance with Article 58(2)(j), the Data Protection Regulation has the power of the EU/EEA data protection authority concerned to order the transfer of personal data out of the EU to a recipient in a third country or international organisation if the appropriate safeguards in Coloplast's binding corporate rules are not complied with.

2. Application

Coloplast has applied to the Danish Data Protection Agency to approve Coloplast's binding corporate rules for the transfer of personal data to companies in third countries within the Coloplast Group.

The Danish Data Protection Agency, in its capacity as responsible data protection authority, has approved the binding corporate rules of Coloplast in accordance with the cooperation procedure in WP263 Rev.01. The application has also been approved by two European data protection authorities. In addition, the Data Protection Agency has given all data protection authorities within the EU/EEA the opportunity to review the application and submit comments.

Under the cooperation procedure, Coloplast amended its binding corporate rules. The other EU/EEA data protection authorities have left it to the Danish Data Protection Agency to assess and decide whether Coloplast's binding corporate rules can be considered as appropriate safeguards for the transfer of personal data in accordance with Article 47 of the Data Protection Regulation.

3. Background for approval

Pursuant to Article 47 of the Data Protection Regulation, the Data Protection Agency shall approve binding corporate rules, provided that they comply with the requirements laid down in that Article.

The review carried out in accordance with the cooperation procedure in WP263 rev.01 has shown that Coloplast's binding corporate rules comply with the requirements of Article 47 of the GDPR and WP256 Rev.01.

The European Data Protection Council (EDPB) has issued an opinion, number 27/2020, in accordance with Article 64(1)(f) of the Data Protection Regulation on the binding corporate rules of the Coloplast, which has been taken into account by the Danish Data Protection Agency.

Kind regards,

Andreas Arnsel