Proc. 4063/2018

: NATIONAL COMMISSION

, DATA PROTECTION

OPINION No. 10/2018

I. Order

The Office of the Minister of Health sent this Commission, for an opinion, the Draft Decree-Law that amends the legal regime for medicines for human use, transposing Directive (EU) 2017/1572, of the European Commission into the national legal system.

The Commission called upon to comment, issues an opinion under the terms and for the purposes of article 23, no. 1, subparagraph a) of Law no. No. 103/2015, of August 24 (Personal Data Protection Law -LPDP).

II. Of Appreciation

According to the preamble of the draft diploma, it is intended not only to transpose Directive (EU) 2017/1572, of the European Commission, but also to introduce changes that prevent counterfeit medicines from existing in the legal supply chain, thus avoiding , serious threats to public health. Thus, the draft diploma under analysis also aims to adapt the current Medicines Statute to the Commission's Delegated Regulation (EU) 2016/161.

After analyzing the project, it appears that the new legal provisions can be traced back to aspects related to the manufacture of the drug and to all the operations that are part of it, to its importation, to its safety, introducing a «quality control system» , being the same subject of regulation in some legal provisions (cf. Article 62(3)(m) and(5) and Article 63).

With regard to the 'quality system', Article 65 provides for the existence of a 'document' which contains 'the description of the person's functions! management and supervision, including qualified persons responsible for applying and respecting good manufacturing practices, as well as their hierarchical relationship'.

Rua de São Bento, 148-3° • 1200-821 LISBON

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It is also established the obligation of certification by the “qualified person” that a certain medicine complies with the provisions of the Medicines Statute.

At stake is, therefore, a register that, necessarily and obligatorily, contains the identification of the individuals responsible for the management, inspection, certification and application of good practices in the manufacture of medicines, in addition to other related information. To that extent, it constitutes a processing of personal data, under the terms of subparagraphs a) and b) of article 3 of the LPDP.

Article 71 of the draft also provides for the processing of personal data, as a consequence of the manufacturer's obligation to have a system for recording and analyzing complaints. While the claimants may be individuals, who will obviously be identified, the hypothesis that the claims contain health data relating to identified or identifiable individuals does not seem to be ruled out.

If the legislator, considering the need for detailed health information in the complaints and in the respective registration, does not expressly rule out this possibility, then the processing of personal data that article 71 presupposes or implies affects or may affect sensitive data, under the terms of paragraph 1 of article 7 of the LPDP

We are therefore dealing with two processing of personal data, with different purposes. Both treatments, because they are not sufficiently densified in this project, in accordance with the provisions of article 30 of the LPDP, must be notified to the CNPD, for consideration and regulation of the terms in which they must be processed. It is certain that after May 25, 2018, with the application of Regulation (EU) 2016/670 - General Data Protection Regulation (RGPD), such notification will not be necessary, and it is up to the controller to ensure and demonstrate compliance with the principles and GDPR rules.

In Article 69(3) of the draft, we find a reference to "electronic systems" for data processing, indicating that the "stored data" must be made available, immediately and in a readable format, to the authorities authorities who so request.

Considering the reference of paragraph 4 to the previous article, it seems to be intended to guarantee the security of the data in the register referred to in paragraph 1 of article 68 of the

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project. In this assumption, we believe that such aspects are safeguarded with the proposed wording.

Finally, the CNPD considers it essential to include a general rule that states that the processing of personal data is subject to the legal regime for the protection of personal data and, also, a specific rule that regulates the exercise of the right of access by part of the natural persons to whom the processed information relates, specifying the form of this exercise (e.g., in writing to the data controller).

As there are no further questions regarding the protection of personal data, this is the opinion of the CNPD.

Lisbon, March 23, 2018

Filipa Calvão (President, who reported)

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