

EDPS comments on a draft Decision of the Management Board of the European Medicines Agency on internal rules concerning restrictions of certain rights of data subjects in relation to processing of personal data in the framework of administrative inquiries and disciplinary proceedings carried out by the European Medicines Agency

1. Introduction

- These comments refer to a draft Decision of the Management Board of the European Medicines (EMA) on internal rules concerning restrictions of certain rights of data subjects in relation to processing of personal data in the framework of administrative inquiries and disciplinary proceedings carried out by the EMA, herein after the ‘draft internal rules’. Our comments refer to the document submitted on 13 May 2019.
- We give these comments in accordance with Article 41(2) of Regulation (EU) 2018/1725 (hereinafter ‘the Regulation’)¹.

2. General comments

- The EDPS takes note that the rules are written in a clear and precise way.
- Concerning the right to information, we take note that the EMA is going to publish data protection notices on its website and intranet informing all data subjects of the potential restrictions of their rights related to personal data processing.
- The EDPS also takes note of the fact that the EMA will perform a necessity and proportionality test on the need for the restriction of data subjects’ rights, according to Article 3 (3) of the draft internal rules.
- The EDPS welcome that the EMA is documenting the restrictions for accountability purposes, namely to make the files available to the EDPS upon request.

3. EDPS recommendations

- The Article 1 (5) provides for an open list of possible restrictions of data subject’s rights. Since these should be exclusively based on the Article 25 of the Regulation EDPS recommends deletion of the words “in particular” therefore changing the character of the list into a close one.
- Additionally, despite being referred in Article 7 of the draft internal rules, the restriction of the right to portability (Article 22 of the Regulation) does not seem necessary in the context of the EMA’s activities. The portability of personal data refers to the right of the data subjects to receive personal data that they themselves have provided to the controller where the processing’s lawfulness is based either on consent or on necessity for fulfilling a contract. Its scope is thus very narrow – and where it does not apply, there can be no need to restrict it. Additionally, exercising

¹ OJ L 295, 21.11.2018, p. 39.

the right to data portability does not automatically mean the erasure of that data by the initial controller (see Article 22(1) of the Regulation). The right to erasure is an autonomous right established in Article 19 of the Regulation. Should the EMA fear that data portability may lead to evidence being lost, it should instead restrict the right to erasure (where it applies) following the exercise of data portability. Therefore, the EDPS recommends that the EMA **remove the reference to possible restrictions to the right to data portability in Article 7 of the draft internal rules, as well as any other references to Article 22 of the Regulation therein.**

- The EDPS **calls for limiting the ground for restriction listed in Article 3 of draft internal rules.** These grounds **should only reflect the specific processing operations, as justifying the restrictions.** For instance, administrative inquiries or disciplinary proceedings fall **under the Article 25 (1) (b) of the Regulation.** Therefore, the reference to all grounds listed in Article 25 of the Regulation should be limited to those justified in the light of specific processing operations performed by EMA, linking each specific purpose of processing with the applicable ground for restricting data subjects' rights.
- Despite the fact that some of the points mentioned in Article 25 (2) of the Regulation are referred to in the recitals of the internal rules, the EDPS recommends that **all the items should enlisted in Article 25 (2) of the Regulation be clearly included in the body of the internal rules.** Therefore, EDPS suggests moving the reference to (1) the categories of personal data as well as to (2) the specification of the controller or categories of controllers to the normative part of the draft internal rules.
- The EDPS recalls that the entry into force of the act must be set at a specific date or a date determined by reference to the date of its publication in the Official Journal of the European Union. In this regard, the EDPS recalls that **entry into force on the day of publication in the Official Journal of the European Union being an exception**, it must be justified by an overriding need — for example, to avoid a legal vacuum — and accompanied with a specific recital giving appropriate reasons for the urgency.
- The EDPS would like to remind that, according to Article 25(5) of the Regulation, this decision should be **signed at the highest management level.**

Brussels,

11 JUN 2019

