25 March 2015
EMA/201512/2015

# EU Medicines Agencies Network Strategy to 2020 - Working together to improve health

Submission of comments

## Comments from:

| Name of organisation or individual |
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| EUROPEAN DATA PROTECTION SUPERVISOR (EDPS) |

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received. In your reply please indicate whether you are replying as a citizen, organisation or public authority.

Comments should be sent to the European Medicines Agency electronically and in Word format (not pdf).

Comments should be sent to EUnetworkstrategy@ema.europa.eu and must arrive by 30 June 2015.

## General comments

| General comment (if any) | Outcome (if applicable)<br>*<to be completed by the EMA/HMA>* |
|---|---|
| In general, we note and appreciate the effort, depicted by the 2020 Strategy, to rely on the network of authorities and on new technologies to shape policy which is responsive to the needs of patients and the complexity of the current economic scenario. In this sense, we see a number of points of contact with our 2015-2019 Strategy, which aims at promoting technologies to enhance privacy and data protection; to identifying cross-disciplinary policy solutions and to work with other authorities in order to speak with a single European voice.<br><br>In particular, we appreciate that the 2020 Strategy emphasises the opportunities and potential that Big Data may bring about for medical research and sets to explore such possibilities with an eye on data protection. We also focus on the social benefits of Big Data, particularly in the context of mHealth (see specific comments below), and are in the process of assessing the most adequate safeguards to allow a full exploitation of such potential to the benefit of patients and users. | |
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## Specific comments on text

| Line No. of the first line(s) affected | Comment and rationale; proposed changes | Outcome (if applicable) *<to be completed by the EMA/HMA>* |
|---|---|---|
| Line 338 ss | We share the opinion of the EMA that access to patients´ electronic health records and the use of Big Data will enhance the potential and opportunities of drug research and afford a more timely response to the needs of the population. At the same time, we consider that the use of Big Data brings with it substantial responsibilities in ensuring that individual rights to privacy and data protection are not harmed. In this respect, we point to our analysis of Big Data in the recently published EDPS Opinion of mobile health (mHealth), available at https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Consultation/Opinions/2015/15-05-21_Mhealth_EN.pdf | |
| Line 348 | We share EMA´s opinion that pharmacovigilance is a crucial activity in order to ensure good manufacturing, quality and safety of drugs, both in human and in animal health. To the extent that pharmacovigilance entails the reporting of personal information concerning the patients or the animal´s keepers and owners, however, data protection safeguards should apply, in order to preserve the individual rights of these persons. | |
| Line 353 ss | We welcome EMA´s commitment to keep personal data out of the public domain. In fact, as technology develops, opening new possibilities to apply it to healthcare, personal data will come under increasing pressure. It is important to preserve individual rights to privacy and data protection and ensure that individuals enjoy the right to choose how and for which purposes their data should be used. | |
| Line 678 | In the course of our activity, we have examined the data protection implications of possible solutions against drug counterfeiting. To the extent that such solutions entail the use of databases and record the personal information of natural persons involved in the supply chain (e.g. employees of the marketing authorisation holder, agents, pharmacists, etc.) data protection safeguards should apply to preserve the rights of these persons. | |