EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 July 2023
EMA/335710/2023

# Records of data processing activity for the user test of the Critical Medical Device Shortages (CMDS) system

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| 1. | Last update of this record, version number: | 24 July 2023, Version number 1.3 |
| 2. | Reference number: | EMA/335710/2023 |
| 3. | Name and contact details of controller: | European Medicines Agency<br>Internally: The Head of Regulatory Science and Innovation Task Force<br>Contact: Datacontroller.Horizonscanning@ema.europa.eu. |
| 4. | Name and contact details of DPO: | dataprotection@ema.europa.eu |
| 5. | Name and contact details of joint controller (where applicable) | Not applicable |
| 6. | Name and contact details of processor (where applicable) | The Agency engages third parties to process data on behalf of the Agency, in particular, to carry out the following activities:<br>To provide the software tools enabling users to carry out their tasks for the purposes listed below.<br>The contact details of the data processor(s) are the following: European Commission, Directorate-General for Health and Food Safety (DG SANTE), Unit R4 – Information Systems, 1049 Bruxelles/Brussel, Belgium. |

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| | | To process personal data on behalf of the Agency in the course of performing this user test and providing secretariat support.<br><br>The contact details of the data processor(s) are the following: PwC EU Services EESV, Woluwedal 18, 1932 Zaventem, Belgium and Intellera Consulting S.p.A., via Gaetano de Castillia n. 23, 20124, Milan, Italy. |
| 7. | Purpose of the processing | The purpose of this data processing activity is to perform the user test of the webform applicable to National Competent Authorities (NCA) of EMA's CMDS. The Agency asks participants of the test to provide feedback on the usability of the webform and for specific feedback on the data fields. The testing does not require the submission of any operational data for the purpose of this usability test. Entering random and fictive test information is sufficient. |
| 8. | Description of categories of persons whose data EMA processes and list of data categories | Members of the MD SPOC Working Party established pursuant to Article 21(5) of the Regulation (EU) 2022/123; Experts designated by the NCAs; Experts designated by the Member States. |
| 9. | Time limit for keeping the data | Participants' personal data will remain available until the results of the user test have been fully analysed (no later than 3 months after the user test is completed). Should the user test prove unsuccessful, or elements have been identified that make it necessary to perform another user test, participants might be contacted again at a later stage for a re-run. |
| 10. | Recipients of the data | Relevant EMA personnel, relevant DG SANTE personnel, relevant personnel of PwC EU Services EESV and Intellera Consulting S.p.A |
| 11. | Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards? s | No |
| 12. | General description of security measures, where possible. | The Agency has put in place appropriate technical and organisational measures (security policies and procedures) to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to your personal data. The Agency takes all the necessary measures to |

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| | | ensure the maximum safety and security of personal data held. The data provided in the usability testing exercise are held in a secured and protected IT system hosted by the European Commission and EMA. |
| 13. | For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement: | Details concerning the processing of your personal data are available on the Agency's website at:<br>https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement |