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Contents

([1]) Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

DECISIONS

COMMISSION DECISION (EU) 2021/1240

of 13 July 2021

on the compliance of the EU portal and the EU database for clinical trials of medicinal products for human use with the requirements referred to in Article 82(2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC ([1]), and in particular Article 82(3) thereof,

Whereas:

(1) The European Medicines Agency ('the Agency'), in collaboration with the Member States and the Commission, set up a portal at Union level as a single entry point for the submission of data and information relating to clinical trials ('EU portal'), as required by Article 80, first subparagraph, of Regulation (EU) No 536/2014.

(2) The Agency, in collaboration with the Member States and the Commission, set up an EU database at Union level, that will contain the data and information submitted in accordance with Regulation (EU) No 536/2014 ('EU database'), as required by Article 81(1) of that Regulation.

(3) On 25 March 2015, the Agency published the functional specifications for the EU portal and the EU database to be audited ([2]), which it had drawn up in collaboration with the Member States and the Commission as required by Article 82(1) of Regulation (EU) No 536/2014.

(4) On 21 April 2021, the Management Board of the Agency, on the basis of the independent audit report delivered on 8 April 2021, informed the Commission in accordance with Article 82(2) of Regulation (EU) No 536/2014 that the EU portal and the EU database have achieved full functionality and the systems meet the functional specifications published by the Agency.

(5) On the basis of the information provided by the Management Board of the Agency, the Commission verified that the EU portal and the EU database fulfilled the conditions of full functionality and of compliance with those functional specifications.

([1]) OJ L 158, 27.5.2014, p. 1.

([2]) https://www.ema.europa.eu/documents/other/functional-specifications-european-union-eu-portal-eu-database-be-audited_en.pdf

(6) Regulation (EU) No 536/2014 is to apply as from six months after the publication of a notice in the *Official Journal of the European Union* in accordance with Article 99, second paragraph, of that Regulation. This Decision should therefore enter into force as a matter of urgency,

HAS ADOPTED THIS DECISION:

Article 1

The EU portal and the EU database have achieved full functionality and meet the functional specifications, as referred to in Article 82(2) of Regulation (EU) No 536/2014.

Article 2

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 13 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

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