EUROPEAN
COMMISSION

Brussels, 23.11.2017
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COMMISSION IMPLEMENTING DECISION

of 23.11.2017

concerning, in the framework of Article 31 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations for gadolinium-containing contrast agents for human use which contain one or more of the active substances "gadobenic acid, gadobutrol, gadodiamide, gadopentetic acid, gadoteric acid, gadoteridol, gadoversetamide and gadoxetic acid"

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[1], and in particular Article 34(1) thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 20 July 2017 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) Medicinal products for human use authorised by the Member States must meet the requirements of Directive 2001/83/EC.

(2) A question has been referred to the European Medicines Agency under Article 31(1) of Directive 2001/83/EC, in a specific case where the interests of the Union are involved, as to whether the marketing authorisation concerned should be maintained, varied, suspended or withdrawn.

(3) As the procedure resulted from the evaluation of data relating to pharmacovigilance, the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency issued a recommendation on 6 July 2017.

(4) The scientific assessment performed by the Committee for Medicinal Products for Human Use, the conclusions of which are set out in Annex II to this Decision, shows that, in the interests of the Union, a decision should be taken amending the marketing authorisations for the medicinal products referred to in Annex IA.

(5) The scientific assessment performed by the Committee for Medicinal Products for Human Use, the conclusions of which are set out in Annex II to this Decision, shows that, in the interests of the Union, a decision should be taken suspending the marketing authorisations for the medicinal products referred to in Annex IB.

(6) Some of the medicinal products referred to in Annex IB may be considered critical by the individual Member State(s), based on the evaluation of the potential unmet medical need, considering the availability of suitable alternative medicinal products in

[1] OJ L 311, 28.11.2001, p. 67.

the respective Member State(s) and, as appropriate, the nature of the disease to be treated. Where a medicinal product is considered critical, the suspension of the concerned marketing authorisations may be then provisionally deferred.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The Member States concerned shall amend the national marketing authorisations for the medicinal products referred to in Annex IA on the basis of the scientific conclusions set out in Annex II.

Article 2

The national marketing authorisations referred to in Article 1 shall be amended on the basis of the changes to the summary of the product characteristics, the labelling and the package leaflet set out in Annex III.

Article 3

The Member States concerned shall suspend the national marketing authorisations for the medicinal products referred to in Annex IB on the basis of the scientific conclusions set out in Annex II.

The conditions for the lifting of the suspension of the national marketing authorisations for the medicinal products referred to in Annex IB are set out in Annex IV.

A Member State may defer the suspension of the marketing authorisation for the medicinal products referred to in Annex IB, if it considers that a medicinal product is critical.

When a Member State considers whether a medicinal product is critical it shall base its decision on the evaluation of the potential unmet medical need, considering the availability of suitable alternative medicinal products in the respective Member State.

This period of deferral shall not exceed 12 months from the date of the adoption of this Decision. If during this period a Member State considers a medicinal product not being critical anymore, the Member State shall suspend the concerned marketing authorisation.

Article 4

The Member States shall take account of the scientific conclusions set out in Annex II for the assessment of the efficacy and safety for gadolinium-containing contrast agents for human use which contain one or more of the active substances “gadobenic acid, gadobutrol, gadodiamide, gadopentetic acid, gadoteric acid, gadoteridol, gadoversetamide and gadoxetic acid” that are not included in Annex I.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 23.11.2017

For the Commission

Xavier PRATS MONNÉ
Director-General

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For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION