EUROPEAN
COMMISSION

Brussels, 23.6.2017
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COMMISSION IMPLEMENTING DECISION

of 23.6.2017

concerning, in the framework of Article 31 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisation applications and marketing authorisations of medicinal products for human use for which clinical and/or bioanalytical parts of the bioequivalence studies were performed at the Micro Therapeutic Research Labs

(Text with EEA relevance)

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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 Articles 34(1), 26 and 116 thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 23 March 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the Union are involved, as to whether the marketing authorisations concerned should be maintained, varied, suspended or withdrawn.

(3) The conclusions of the scientific assessment performed by the Committee for Medicinal Products for Human Use are set out in Annex II to this Decision.

(4) According to the conclusions of the scientific assessment set out in Annex II, bioequivalence vis-à-vis the EU reference medicinal product has been established for the marketing authorisations and marketing authorisation applications referred to in Annex IA. The marketing authorisations for medicinal products referred to in Annex IA should therefore be maintained and the national authorities should take account of the scientific conclusions when assessing marketing authorisation applications referred to in Annex IA.

(5) According to the conclusions of the scientific assessment set out in Annex II, the particulars supporting the marketing authorisations for medicinal products referred to in Annex IB are incorrect and the risk-benefit balance of these marketing authorisations is not favourable. The marketing authorisations for medicinal products

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

referred to in Annex IB should therefore be suspended, in accordance with Article 116 of Directive 2001/83/EC.

(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 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) According to the conclusions of the scientific assessment set out in Annex II, the particulars submitted in support of the marketing authorisation applications listed in Annex IB are incorrect and the benefit-risk balance is not favourable . Therefore, the marketing authorisation applications listed in annex IB do not satisfy the criteria for authorisation pursuant to Article 26 of Directive 2001/83/EC. The national authorities should take account of the scientific conclusions when assessing marketing authorisation applications for medicinal products referred to in Annex IB.

(8) 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 maintain national marketing authorisations for the medicinal products referred to in Annex IA on the basis of the scientific conclusions set out in Annex II to this Decision.

Article 2

The Member States concerned shall take account of the scientific conclusions set out in Annex II for the assessment of the marketing authorisation applications referred to in Annex IA.

Article 3

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

The conditions for lifting the suspension are set out in Annex III.

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 and, as appropriate, the nature of the disease to be treated, as set out in the criticality criteria in Annex II.

This period of deferral shall not exceed twenty-four 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 taking into consideration the criticality criteria set out in Annex II, the Member State shall suspend the concerned marketing authorisation.

The Member State shall for the medicinal products considered critical provide that the marketing authorisations holders shall submit a bioequivalence study within 12 months from the date of the adoption of this Decision.

Article 4

The Member States concerned shall take account of the scientific conclusions set out in Annex II for the assessment of the marketing authorisation applications referred to in Annex IB according to which the marketing authorisation applications listed in Annex IB do not satisfy the criteria for authorisation.

Article 5

The Member States shall take account of the scientific conclusions set out in Annex II for the assessment of the efficacy and safety of medicinal products that are not included in Annex IA or Annex IB and which are supported by a dossier which include(s) clinical part of bioequivalence study(ies) performed at Micro Therapeutic Research Labs Pvt. Ltd Rajam Bhavanam, No. 6 , Kamarajar Salai, Selaiyur, East Tambaram, Chennai - 600 059, India and Micro Therapeutic Research Labs Pvt. Ltd, No. 29 A, Krishna Madhuravanam, Vellokinar Pirivu, Thudiyalur, Coimbatore-641029, Tamil Nadu, India

Article 6

This Decision is addressed to the Member States.

Done at Brussels, 23.6.2017

For the Commission

Xavier PRATS MONNÉ
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION