EUROPEAN
COMMISSION

Brussels, 16.7.2015
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COMMISSION IMPLEMENTING DECISION

of 16.7.2015

concerning, in the framework of Article 31 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations of medicinal products for human use which clinical part of bioequivalence studies were performed at GVK Biosciences Hyderabad site

(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 Articles 34(1) and 116 thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 21 May 2015 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the Union are involved, as to whether the marketing authorisations concerned should be maintained, varied, suspended or withdrawn.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 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 or maintaining the marketing authorisations for the medicinal products concerned.

(4) Marketing authorisations for medicinal products referred to in Annex IA should be maintained as the bioequivalence with the EU reference medicinal products has been demonstrated and the risk-benefit balance remains positive.

(5) Marketing authorisations for medicinal products referred to in Annex IB for which bioequivalence data or justification were not submitted or considered sufficient to establish the bioequivalence with a EU reference medicinal product, should be suspended as the particulars supporting the marketing authorisations are incorrect and the risk- benefit balance of these marketing authorisation is not positive.

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

(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) 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 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.

Member State shall, when it considers whether a medicinal product is critical, take into consideration the criticality criteria set out 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 3

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 I and which are supported by a dossier which include(s) clinical part of bioequivalence study(ies) performed at the concerned site of GVK Biosciences private limited Swarna Jayanthi commercial complex, Ameerpet, Hyderabad 500 038, India for the period from 2004 to 2014.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 16.7.2015

For the Commission
Ladislav MIKO
Acting Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION