EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

Brussels, 11 April 2018

MEETING OF THE STANDING COMMITTEE ON MEDICINAL PRODUCTS FOR HUMAN USE HELD IN BRUSSELS ON 9 APRIL 2018

SUMMARY RECORD

Chairperson: Ms O. Solomon

1. Opening and adoption of the Agenda

The agenda of the meeting was adopted without changes.

2. Item on which the Opinion of the Committee was asked under the examination procedure:

Draft Commission Implementing Decision of XXX concerning, in the framework of Article 107i of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations of medicinal products for human use which contain the active substance "hydroxyethyl starch (HES), solutions for infusion"

Pursuant to Article 107i of Directive 2001/83/EC based on concerns resulting from the evaluation of pharmacovigilance data, Sweden initiated a procedure on 17 October 2017 on medicinal products containing hydroxyethyl starch solution for infusion.

On 24 January 2018, the co-ordination group for mutual recognition and decentralised procedures for human use (CMDh), having considered the Pharmacovigilance Risk Assessment Committee (PRAC) recommendation dated 19 January 2018 with regards to medicinal products containing hydroxyethyl starch solution for infusion (HES), reached a position by majority that the marketing authorisations for the concerned medicinal products should be suspended. The CMDh position was forwarded to the European Commission.

On 27 February 2018, on the basis of the CMDh position, the Commission services submitted to the Standing Committee on Medicinal Products for Human Use for an opinion by written procedure a draft decision suspending the marketing authorisations for the medicinal products concerned. During the written procedure the Czech Republic, France and Spain raised concerns about the draft decision and requested the Commission to convene a meeting of the Standing Committee on Medicinal Products for Human Use. In accordance with Article 8(3) of the Rules of Procedure of the Standing Committee on

Medicinal Products for Human Use, the written procedure was terminated and a plenary meeting was convened to consider whether there were questions of a scientific or technical nature which the opinion of the European Medicines Agency ("the Agency") had not addressed.

On 9 April 2018, the Commission presented the above mentioned draft Commission decision to the plenary meeting of the Standing Committee.

The delegations of the Czech Republic, France and Spain presented their scientific and legal concerns regarding the basis of the draft Commission decision.

A number of Member States supported the Commission draft decision. Several members of the Standing Committee raised concerns with regard to CMDh position and PRAC recommendation. Some considered that questions remained regarding any unmet medical need and options for risk minimisation measures.

The written observations of the Member States submitted prior to the meeting and the content of the discussion during the meeting led the Chair of the Standing Committee to conclude that there were new questions of a scientific or technical nature, in particular with regard to any unmet medical need and the feasibility and likely effectiveness of risk minimisation measures, which had not been sufficiently addressed in the CMDh position and in the PRAC recommendation on which the position was based.

In light of these new questions, it was agreed that the Commission would suspend the decision making procedure and refer the CMDh position/PRAC recommendation back to the Agency for further consideration.

3. AOB

No additional point was added on the agenda.

Attendance List for the Standing Committee for Human Medicinal Products

9 April 2018

Member State	Organisation
Austria	Federal Ministry of labour, Social Affairs, Health and Consumer Protection
Belgium	Federal Agency for Medicines and Health Products
Croatia	Agency for Medicinal Products and Medical Devices
Cyprus	Ministry of Health, Cyprus
Czech Republic	State Institute for Drug Control
Czech Republic	Permanent Representation of Czech Republic to the EU
Denmark	Danish Medicines Agency
EMA	European Medicines Agency
Estonia	State Agency of Medicines
Finland	Finnish Medicines Agency (Fimea)
France	ANSM - Agence nationale de sécurité du médicament et des produits de santé
Germany	Federal Institute for Drugs and Medical Devices (BfArM)
Germany	Federal Ministry of Health
Hungary	Permanent Representation of Hungary to the EU
Ireland	Department of Health
Ireland	Health Products Regulatory Authority
Italy	Agenzia Italiana del Farmaco (AIFA) - Italian Medicines Agency
Latvia	State Agency of Medicines
Luxembourg	Ministry of Health Luxembourg, Health Directorate, Division of Pharmaceuticals
Malta	Malta Medicines Authority
Netherlands	Medicines Evaluation Board (CBG-MEB)

Poland	Permanent Representation of Poland to the EU
Portugal	INFARMED (National Authority of Medicines and Health Products, I.P.)
Romania	National Agency for Medicines and Medical Devices
Slovakia	Ministry of Health
Slovenia	Permanent Representation of the Republic of Slovenia to the EU
Spain	Spanish Agency of Medicines and Medical Devices
Sweden	Swedish Medical Products Agency
United Kingdom	Medicines and Healthcare products Regulatory Agency (MHRA)