EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medical products: quality, safety and innovation

AD-HOC TECHNICAL MEETING UNDER THE PHARMACEUTICAL COMMITTEE ON SHORTAGES OF MEDICINES

25 May 2018

Subject: Minutes of the Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines

25 May 2018, **10.00 am – 5.30 pm**

Venue: Centre Albert Borschette, 36, rue Froissart, Brussels, meeting room **AB-4C**

AD-HOC TECHNICAL MEETING UNDER THE PHARMACEUTICAL COMMITTEE ON SHORTAGES OF MEDICINES

MINUTES
25 May 2018
Centre Albert Borschette, Brussels, **AB-4C**

AGENDA

1. WELCOME

SANTE opened the meeting and welcomed the participants.

The meeting was organised in order to discuss the results of the Commission Questionnaire on Member State implementation of Articles 23a and 81 of Directive 2001/83/EC[1]. This survey was launched as a response to the calls of both the Council[2] and the European Parliament[3] for the Commission to monitor the obligation of continuous supply and highlighted a number of national initiatives to address shortages, which have been compiled in a Summary Report.

2. QUESTIONNAIRE ON MEMBER STATE MEASURES UNDER ARTICLE 81 OF DIRECTIVE 2001/83/EC

SANTE gave a presentation summarising the replies received from Member States concerning national measures and implementation in the context of the obligation of continuous supply. This included the responsibilities of marketing authorisation holders, wholesale distributors, and manufacturers and their limits, national definitions of shortages, measures for critical medicines, the obligation to notify temporary or permanent interruption of supply, export restrictions and penalties.

IT outlined measures taken by the IT authorities in order to deal with shortages, including the implementation of a national traceability system and working more closely with wholesalers to ensure adequate supply to the Italian market.

Member States did not have substantive comments on the Summary Report and agreed to its publication after the meeting.

3. DISCUSSION PAPER ON SHORTAGES OF MEDICINES

SANTE presented a discussion paper on shortages of medicines in order to agree a common understanding between MS on the implementation of Articles 81 and 23a of Directive 2001/83/EC, in particular the obligations of marketing authorisation holders and wholesale distributors of medicinal products. Some participants asked to clarify the

[1] 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 (OJ L 311, 28.11.2001, p. 67)
[2] Informal Meeting of Health Ministers, Informal EPSCO – Health Agenda, 3-4 October 2016
[3] http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A8-2017-0040&format=XML&language=EN

status of the paper because it is evident that the article on the obligation of continuous supply is not functioning well. SANTE clarified that the paper will provide a common understanding of Member States expectations and the Commission understanding of the obligation to supply. It is intended to be published on the Commission's website to be used by the authorities for enforcing the Article or to change/amend the national laws. SANTE did not receive a call from all Member States to change the legislation on medicinal products. SANTE explained that although the paper outlines a common understanding it does not constitute a formal interpretation of Union Law.

Member States expressed strong support for the paper and indicated that it would be helpful when determining the responsibilities of actors in relation to shortages. Some comments/suggestions were made by MS (BG, CZ, EE, ES, FI, FR, IE, LT, NO, NL, PL, PT, SE and UK), mainly related to the limits of the responsibilities of marketing authorisation holders and wholesale distributors and restrictions that MS can introduce in order to mitigate the risk of shortages of medicines.

In addition, SANTE stressed that, according to Article 23a, marketing authorisation holders shall provide, upon request by the competent authority, all data relating to the volume of sales of the medicinal product, and any data in their possession relating to the volume of prescriptions. This information is very important to determine and monitor shortages nationally.

In this regard, EMA highlighted that the EMA-HMA Task Force on Availability of Authorised Medicines is currently working on a document concerning notification procedures.

The discussion paper was agreed during the meeting and will be published in the coming weeks on the SANTE website.

4. UPDATE FROM THE HMA/EMA TASK FORCE

The Co-chair of the EMA-HMA Task Force on Availability of Authorised Medicines gave a presentation of their activities. This included the context of the work, the structure of the task force, the thematic areas (Theme 1: Marketing of authorized medicinal products, Theme 2: Supply Chain Disruption and Theme 3: Communication) and the key deliverables. The presentation also touched upon Brexit, next steps and the initial feedback received from patients, consumers, healthcare professionals and from biosimilar/generic industry.

It was agreed that the HMA/EMA task force is the ideal forum to continue the discussions of measures to address shortages in the EU.

5. MEMBER STATES ACTIONS TO ADDRESS SHORTAGES OF MEDICINES

5.1. PRESENTATIONS

Four Member States gave a short presentation of their national measures (ES, PT, FR and NL):

i. ES presented their pre-export notification system and the introduction of restrictions to supply certain medicines outside of Spain. Member States were

particularly interested in the enforcement of the restrictions, notification deadlines and the list of medicines subject to prior notification (IE, IT and PL).

ii. PT presented their ex-ante notification mechanism. This system only applies to listed medicines where a direct relationship between lack of access and high levels of parallel trade has been demonstrated. The notification system is managed through an electronic platform (SiExp), where wholesalers must submit information about their intention to sell medicines that are included on the list outside of Portugal. Member States expressed interest in the list of medicines, the notification deadlines and the number of wholesaler distributors authorised in Portugal.

iii. FR presented their implementation of new measures to address shortages in 2016. These include a legal definition of shortages, the requirement for marketing authorisation holders to develop shortage management plans, and to notify the FR authorities, healthcare professionals and patients, and to set up emergency call centres. PT expressed interest in the problems/disruptions related to parallel trade in FR.

iv. NL presented information on marketing authorisation holders notifications and actions taken to address shortages (parallel import, deviating packaging, accelerated mutual recognition of marketing authorisations extending shelf-life, selective dispense, Article 126a authorisation and/or import based on a physician declaration).

5.2. DISCUSSION

The presentations were followed by a general discussion between Member States.

PL explained their notification system for export, which is similar to those in Spain and Portugual. PL also presented plans to introduce criminal penalties for illegal wholesale distributors who buy medicines from pharmacies in order to sell them abroad, which is not legal in PL.

* * * * * *