From: Horváth Beatrix Dr. [mailto:beatrix.horvath@emmi.gov.hu]
Sent: Tuesday, May 20, 2014 1:21 PM
To: SANCO PHARMACEUTICALS D5
Cc: Bencze László - BEU (Laszlo.Bencze@mfa.gov.hu) (Laszlo.Bencze@mfa.gov.hu); Biró Eszter dr.; Novák Katalin Andrea; Kontor Csaba Dr.; hanko.balazs@gyemszi.hu; Köszeginé Szalai Hilda (koszegine.szalai.hilda@gyemszi.hu)
Subject: FW: Válasz 72nd Pharmaceutical Committee - Action points / GYEMSZI-OGYI

Dear Colleagues,

We have prepared the answers for the questions raised during the previous Pharmaceutical Committee meeting. We do appologize for our late answer. Please find the Hungarian answers bellow in the given order:

(…)

IV. **Agenda point: AOB 2.** Update on external study on availability
Action: Submit comments on the study and, as applicable, an up-to-date list of products authorised under Article 126a*

(comments will be subsequently published with the study report)
Hungarian Answer:

Overall the study report is acceptable from the Hungarian point of view, however we propose the following amendments.

The chapter *Channels to bring into the country unauthorized products onto the market* is proposed to be amended by the text below.

In Hungary there are three different routes to bring medicinal product without valid marketing authorization for Hungary.

1. **Authorization of individual medicine import:** Medicinal products which have no marketing authorization in Hungary (in the EEA or outside the EEA) can be imported both for the outpatient and bedpatient service. On a request of physicians the Hungarian competent authority may approve on a name patient basis the individual import of medicines licensed by EU or non EU countries.
2. **Authorization of off-label use of medicines:** Off-label use authorization on a name patient basis is also possible in Hungary, similarly to the Italian procedure, when no therapeutic alternative is available.
3. **Authorization of the import of a defined quantity of a medicinal product:** Authorization of substitute medicines authorized in the EEA or outside the EEA can be issued in case of the national market supply is threatened. This procedur is regulated by national law (44/2004 ESzCsM) which allows the competent authority to of issue authorization for a defined quantity of medicinal product. Hungarian product information is usually provided.

Transfer of marketing authorization at page 63 need to be deleted as it is addressed above.

~~***"Transfer of marketing authorization***~~

~~*Finally, Hungary also allows for the government to purchase a product license or allow other persons or businesses authorized in a State other than Hungary to engage in the wholesale distribution and/or retail supply of medicinal products when a MA holder of a medicinal product that has received public financing intends to discontinue or is unable to continue the marketing of such product. This is done in cases where being deprived of the medicinal product in question is likely to result in severe or persistent disability for the patients treated with such products; and where there is no other medicinal product with similar active ingredients, pharmaceutical form and strength available in Hungary."*~~

The Chapter *parallel trade* is proposed to be amended as follows

So far parallel trade has not been proved to be major reason for product unavailability in Hungary, though there are signs of an increased parallel export activity due to the relatively low price level of medicines. Parallel export can be temporarily prohibited in Hungary by the competent authority in case national market supply is threatened.

Comments on the conclusion

1. **Sunset clause**
   The study proposes the remove or revision of the Sunset Clause provision (Article 24 of Directive 2001/83/EC). From our point of view, this provision is agreeable since authorization in place facilitates the alternative products supply; with other words it may increase the overall availability of products. Nevertheless, the remove of Sunset Clause conflicts with the *more effective transposition and implementation* of Article 81 as, to our understanding, Sunset Clause may force the holder of marketing authorization to put and to hold the product on the market.
   An obligation for the marketing authorization holder to notify the possibility and duration of the availability issues is recommended to consider as an amendment of the directive
2. **Clarification of the responsibility of individual actors when using Cyprus Clause is fully supported and highly recommended by the Hungarian Agency.** Please find attached the table of the marketing authorisation granted based on Article 126a in Hungary. (name of the excel document: Article 126a marketing authorisation table. xls)

Kind regards,

Beatrix Horvath
Mrs Beatrix Horvath
head of department
Department of Pharmaceuticals and Medical Devices
Ministry of Human Resources
Budapest, Arany János utca 6-8.
1051
tel: +36 1 795 1143
fax:+ 36 1 795 0173
emial: beatrix.horvath@emmi.gov.hu