MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

DIRECCIÓN DE LA
AGENCIA ESPAÑOLA
DE MEDICAMENTOS Y
PRODUCTOS SANITARIOS

EXTERNAL STUDY ON THE AVAILABILITY OF MEDICINAL PRODUCTS FOR HUMAN USE.

COMMENTS SUBMITTED BY THE SPANISH AGENCY OF MEDICINES AND MEDICAL DEVICES (AEMPS)

First of all, from the AEMPS we would like to thank the European Commission for providing us the results of the study on the availability of medicinal products for human use.

We consider that this study addresses the issue through a theoretical approach but the problem has not been properly addressed throughout the study. It has been made based on the consultation of stakeholders, and the study often includes opinions of particular stakeholders, without analyzing them, which makes it less reliable. In the same line, the methodology used is not clear as well as the selection process of the countries consulted.

In our opinion, the study does not deal with two of the main issues that cause supply problems: the different prices among Member States and the lack of mechanisms to regulate the markets.

Regarding the recommendation to remove or revise the Sunset Clause provision that invalidates the marketing authorisation if the product is not placed on the market for 3 consecutive years or not present on the market for 3 consecutive years, we totally disagree with this recommendation. It depends on the situation of the market in each country, but in Spain the Sunset clause is very useful for our market.

Regarding the use of the Article 126a of Directive 2001/83/EC, (also known as the "Cyprus clause") that allows Member States to authorize in justified public health reasons the placing on the market in its territory of a medicinal product authorized in another Member states, it could be useful in small markets but in the bigger ones, is less useful. We inform you that the AEMPS has not authorised any medical product under the Article 126a.

Regarding the use of Article 81 of Directive 2001/83/EC to address supply disruptions and shortages; in several times the study states the recommendation of "ensure more effective transposition and implementation of the article 81". In the Spanish legislation this article is already transposed and implemented. But more effective transposition and implementation of article 81 should be ensured because this is a problem that affects to most Member States.

Finally from the AEMPS we agree with one of the conclusions of this study related to the possibilities of issuing rewards to incentive MAHs to authorise and supply medicinal products in more European markets. The Paediatric Regulation, which awards patent extensions to MAHs authorising products for use in the paediatric population, is considered a potential blueprint.

CORREO ELECTRÓNICO

sdaem@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 50 28
FAX: 91 822 50 10