EUROPEAN COMMISSION

STRATEGY TO BETTER PROTECT PUBLIC HEALTH BY STRENGTHENING AND RATIONALISING EU PHARMACOVIGILANCE:

Comments by COMBINO PHARM to Public Consultation on legislative proposals

1. Simplify informing the authorities about the company pharmacovigilance system.

We think that also would be interesting other more initial option: the possibility that any change in the information of the Description of the Pharmacovigilance System wouldn´t require presentation of any Type II Variation, only communication to the concerned Authorities. We think, from a safety point of view, that is better to manage or have access to all information about the details of the MAH´s Pharmacovigilance System and really the presentation of Type II variations for each product and each National Authority is totally unrealist. If the above mentioned is not possible, we consider that the EC proposal about the creation of a Pharmacovigilance System Master File is acceptable.

2. Rationalise risk management planning

We think is appropriate to adapt the requirement of RMP presentation according to the safety profile of a drug, but in this context it is necessary to establish clearly " when there is a public safety concern".

3. Fast robust EU decision-making on safety issues

We think is essential to coordinate the European Medicines Agency with National Agencies, These can not follow different ways and requeriments, because safety is a global problem in a global European market. We totally agree with the creation of a new Committee with full power for coordinating all the National Agencies.

4. Simplify reporting of ADR case reports

It is obvious that the duplicity of ADR case report communication to Eudravigilance and others national databases is not logical. Eudravigilance has to capitalize all safety information because it will allow to save a lot of costs and time and it will be more useful for signal detection.

5. Patients Reports

It is an interesting way for increasing the case report communication coming from patients but at the same time this mechanism has to stimulate the confirmation by a physician, because as result we can obtain a lot of useless information if it is not confirmed by a health professional.

By the other hand we think is very important to encourage the health professional communication by new mechanisms and it has to be reflected by legal requirements and effective educational programs. Both, patients and health professionals must feel that they are essentials constituents of a global Pharmacovigilance System.

Also, we have to consider that the patient communication through websites is limited because all patients haven´t access to this kind of technology.

5. Literature search by the EMEA

It is a great measure for maximising the available resources but It will be necessary to clarify which kind of literature review have to continue doing the MAHs. (PSURs…)

This point has to be widely clarified.

6. Simplify PSURs submission

It is necessary to define what is an "old established product".

We also think that is important to establish a list for all products regarding its International Birth Dates and DLP and establish the requeriment that all MAHs should follow the same cicle for the same active principle because it would be in line with the global objectives of this European Commission proposal.

7. Clearer safety warnings in product information

The new section in SPC " Key safety information" has to be clarified because it can include several sections of the current SPC (warnings, contraindications, adverse reactions….)