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Comments on the legislative proposals from EC for strengthening and rationalising pharmacovigilance in the EU

The State Institute for Drug Control, Czech Republic, welcomes the harmonised conception of pharmacovigilance in the EU. However, national specificities across EU exist particularly in respect to clinical practice (population specificities, traditions, health care systems ....). These specificities should be taken into consideration in the process of strengthening and rationalising pharmacovigilance in the EU.
We wish to point out that the goal should be to enhance safety by shifting focus of pharmacovigilance from reactive to proactive (and hence minimize risks), not to allow premature products enter the market.

1. Decision-making and Roles&Responsibilities

Establishing of a committee on pharmacovigilance is proposed. It seems that real competences of the new Committee on Pharmacovigilance and involvement of CHMP into pharmacovigilance processes will be very similar to current state. Committee on Pharmacovigilance competences should be clearly defined or even its independence on CHMP should be considered.

CHAPTER 6

Article 101 k

Balance between benefits and risks and organisational costs of public hearings should be considered. The proposed public hearings are not recommended for two reasons: firstly, a public hearing can hardly change a scientific opinion, and secondly and more importantly: regardless any technical aides, the possibility to attend would be dramatically different to European citizens from different areas of Europe. In particular the language barrier would be a major hindrance to equal possibilities.. The only acceptable approach would include fully – and timely – translated documentation and simultaneous interpretations.

Regulation (EC) No 726/2004 Article 61(1 and 2)

Proposal for membership of representatives of health professionals and patient association bring about some questions.
First of all how could these people represent diversity of patients and HCP within different health care systems across 27 MSs?
While the importance of consumer involvement is fully recognised in general, practical effectiveness of patient representatives in PhVC is questionable. Moreover, the question is, by whom and how these two members would be elected from the huge amount of diseases and different organisations. Why a certain disease or organisations would be preferred to others.

Further, as many patient organisations receive funding from the industry, there is at least a theoretical risk of being a target of lobbying.
Analogously with this section above, it is questionable, how and by whom the representatives for medical professionals would be elected.
We do not support membership of those additional representatives in the Committee on Pharmacovigilance.

2. Simplification of Reporting , Patient Reporting, EV and GVP

Change within Directive 2001/83/EC - Article 1(11) and Article 1(16)
Directive 2001/83/EC Article 1(11)
Adverse reaction: A response to a medicinal product which is noxious and unintended. ~~*and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.*~~
Directive 2001/83/EC Article 1(16)
~~*Abuse of medicinal products : Persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects.*~~
Omission of Abuse definition and proposed new definition of Adverse reaction could lead to underreporting. Abuse is often related to intended response to a medicinal product (even noxious), therefore many cases would not fulfil Adverse reaction criteria. Thus obligation to report Abuse would not be clear.

Articles 54 and 59

From the national point of view we do not support direct Patient reporting of all adverse reactions to MAH. See comment on *Article 101 e* .

Chapter 1

Article 101 a
The Member States may impose specific requirements on doctors and other health -care professionals in respect of the reporting of suspected serious or <u>unexpected</u> adverse reactions.

Omission of unexpected adverse reaction [Directive 2001/83/EC - Article 1(13), see page 11 of EC document for public consultation] is proposed. Use of the term „<u>unexpected</u> adverse reactions“ within Article 101 a is not meaningful without an existing definition.

Chapter 2

Article 101 b
„…the use of internationally agreed terminologies, including medical terminologies, for mats and standards for the conduct of pharmacovigilance“

In relation to the above, the quality of maintenance for MedDRA or other internationally agreed terminologies should be guaranteed. We have a recent negative experience with MedDRA update and maintenance. Some serious mistranslations were implemented by MSSO into 10.1 Czech MedDRA translation. These cause serious problems in practical usage of current Czech MedDRA

version (e.g. within scope of SPC) for RA staff and industry as well. National authorities have very limited possibilities to persuade MSSO to keep national MedDRA translations in line with actual national medical language.

Article 101 e (1)

It should be clarified whether it is optimal to have huge amount of unserious expected adverse reaction reports. We are in doubt as for the effectiveness of this direct patient adverse reaction reporting. Even though some member states presented positive experiences, our own experience is different. Patient reporting can further exhaust the regulatory system, be an additional burden to the industry, and also endanger direct feedback to the physician. Hence a pilot study is suggested; in the future its results, taking into account the impact on resource allocation and cost-effectiveness, should guide further development.

3. RMPs, Intesified Monitoring, PASS, PSURs and Worksharing for PSURs

Article 8 (3) (iaa)

It should be clarified whether it is appropriate to submit RMPs for all generic application. This requirement could be replaced by the obligation for generics to follow RMP measures of originators as such solution would be more cost and resource effective (both for the industry and regulators).

Article 101 f

Practical aspects should be clarified. Especially the role of Agency in relation to different authorisation procedures. Does this article mean that PSURs for all products (not only for CAP, but authorised nationally/MRP/DC) would be submitted to the Agency and the Agency will forward PSURs to all or to concerned MSs? To avoid administrative burden PSUR should be forwarded only to MSs where the product is authorised .

4. PI, Transparency and Communication

In view of the wide spectrum of existing national specificities, these should be reflected also in the communication or in activities taken. Fully identical communication could be sometimes inadequate to local situation in some MSs (medical practice, health care system, accessibility of some therapies, traditions, etc.)

Article 11

The definition of “key safety information” should be clarified. The “key safety information” itself should be useful but without a proper definition it could only prolong SmPC text via multiplying the same information.

Chapter 5
Article 101 i (1)

Details of EU medicines safety web portal should be clarified (e.g. languages, range of information provided on RMPs and PSUR-ARs)

We do not support direct adverse reactions reporting into EudraVigilance via one central web interface. We recommend that under point c) only general information about adverse reactions and the links to all NCA websites should be published.

Article 101 i (2)

We suggest to add c) information on adverse reactions reporting to the competent authorities (see comment on Article 101 i, 1c above)

Article 101 i (5)

See general comment on national specificities.

Article 101 j

The role and possible consequences of publication of the intensive monitoring list should be clarified.