IMPLEMENTING MEASURES IN ORDER TO HARMONISE THE PERFORMANCE OF THE PHARMACOVIGILANCE ACTIVITIES PROVIDED FOR IN DIRECTIVE 2001/83/EC AND REGULATION (EC) NO 726/2004

It has been very interesting to read and present my comments on "THE CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION"

I found the document to be much user friendly as it is written in to precise detail, so helped understanding subsequent obligation.

I am submitting my comment as a private individual.
I work for a pharmaceutical company and it falls within the EU definition of a small and medium-sized enterprise

I authorize publication of my identity.

Consultation item no. 2:
It would be appropriate to require the marketing authorisation holder to notify modifications to the master file to the competent authorities , along with date and signature of two authorized representative. The date and signature of two authorized representative would prevent too frequent modification (unnecessary modification).

Consultation item no. 3: Is it necessary to be more precise on potential delegation, e.g. in the case of co-marketing of products? Please comment.
Perfect No comment

Consultation item no. 4: Should a copy of the audit report be retained in the master file? Would it be appropriate to require documentation of audit schedules?
Audit schedule documentation helps to inform the case processors and the company of an upcoming audit, which helps them to prepare well for the audit. I agree with documentation of audit schedules

Consultation item no. 5: Overall, do you agree with the requirements as regards the content and maintenance of the pharmacovigilance master file? Please comment.
I agree, It is a good practice. *Perfect so No comment*

B. Quality systems for the performance of pharmacovigilance activities – Common obligations

*Six Sigma and other quality improvement technique would certainly improve e*stablishing structures and planning integrated and consistent processes.

My openion is that Audits of the quality system be performed at regular intervals, on yearly basis to enhance its effectiveness.

C. Quality systems for the performance of pharmacovigilance activities by marketing authorisation holders

12. General

Perfect

13. Resource management

Perfect so No comment

14. Compliance management

Perfect so No comment

Consultation item no. 6: Is there a need for additional quality procedures, e.g. in relation to study reporting in accordance with Article 107p of the Directive, in relation to communication on pharmacovigilance between the marketing authorisation holder and patients/health professionals; in relation to processes for taking corrective and improvement actions or in relation to the detection of duplicates of suspected adverse reaction reports in the Eudravigilance database?

Perfect

15. Record management

Perfect so No comment

Consultation item no. 7: Do you agree with the requirements for marketing authorisation holders? Please comment.

I agree with Marketing authorisation holders as they contribute well to the parent company in revenue generation.

D. Quality systems for the performance of pharmacovigilance activities by national competent authorities and EMA

16. General

No comment

17. Resource management

No comment

18. Compliance management

No comment

19. Record management

No comment

Consultation item no. 8: Do you agree with the quality system requirements? Please comment, if appropriate separately as regards requirements for marketing authorisation holders, national authorities and EMA.

It is a must to have quality in the work of pharmacovigilance to reflect the real picture of health condition to the health authority.

E. Signal detection and risk identification

20. General

Perfect

21. Changed risks/new risks

Ok

22. Methodology

Fine

23. Signal management procedure

Good

24. Work sharing of signal management

Ok

Consultation item no. 9: For efficiency reasons a ‘work sharing’ procedure could be appropriate for the monitoring of medicinal products or active substances contained in

several medicinal product. However, do you see a risk in cumulating all tasks (for the authorisation, PSUR scrutiny and Eudravigilance monitoring) in one Member State, as thereby the benefits of parallel monitoring may be lost ("peer review" system)? Additionally, it may be envisaged to extend 'work sharing' to all medicinal products (including all centrally approved products) and to appoint a lead Member State in addition to EMA (Article 28a(1)(c) of Regulation (EC) No 726/2004). Please comment.
Centralisd approach would be better to reduce cost involved, it has advantages and also disadvantages, the disadvantages can be controlled by other member states actively monitoring the activity.

25. Signal detection support
Fine
26. Signal detection audit
Good
Consultation item no. 10: In the Commission's view the aim of this part is to establish common triggers for signal detection; to clarify the respective monitoring roles of marketing authorisation holders, national competent authorities and EMA; and to identify how signals are picked up? Are the proposed provision sufficiently clear and transparent or should they be more detailed? If so, which aspects require additional considerations and what should be required? Please comment.

F. Use of terminology

27. Use of internationally agreed terminology
I agree
Consultation item no. 11: Do you agree with the proposed terminology? Please comment.
I agree
28. Use of internationally agreed formats and standards
Good
Consultation item no. 12: Do you agree with the list of internationally agreed formats and standards? Please comment.
I agree

G. Transmission and Submission requirements

29. Transmission of suspected adverse reactions
Ok
Consultation item no. 13: Is there additionally a need for transitional provisions as regards certain aspects of this implementing measure, especially in relation to the specifications on format and content? Please comment.
I think additional development will come ahead, for the time being format and content should be uniform through out.
Annex I – Electronic submissions of suspected adverse reactions
1. Definitions
It is precise and elaborate.

Consultation item no. 14: Do you agree with the proposed format and content? Please comment.
It is Perfect to agree according to me
Annex II – Risk management plans

1.1. Content of the Risk Management Plan
Ok
1.2. Format of the Risk Management Plan
Ok
Part VII: Annexes
Ok
1.3. Updates of the Risk management plan
Ok
Consultation item no. 15: Do you agree with the proposed format and content? Please comment.
I agree
Annex III – Electronic periodic safety update reports
1.1. Content of the periodic safety update reports
Good
1.2. Format of the Periodic safety update reports
Good
Consultation item no. 16: Do you agree with the proposed format and content? Please comment.
I agree
Annex IV – Protocols, abstracts and final study reports for the post-authorisation safety studies
Ok
2. Format of the study protocol
Ok
3. Format of the abstract of the final study report
Ok
4. Format of the final study report
Ok
5. Milestones: Planned and actual dates for the following milestones:
Oκ
6. Rationale and background:
Fine
Consultation item no. 17: Do you agree with the proposed format? Please comment.
Yes, I agree, the format is good.

I agree with the view of the authors, according to me Authors have contributed good and it would be suitable for the Commission to adopt and approve the views after having a meeting with members among final authorizing commitee.

When published I would like to know what specific implementing Regulation was build on this consultation.

Kind regards
dr Sameer Shah