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in healthcare

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email: sanco-pharmaceuticals@ec.europa.eu
European Commission
Directorate-General for Health and Consumers (DG SANCO)
Unit SANCO/D/3
B-1049 Brussels - Belgium,

Dear Sir or Madam

Public consultation on the concept paper submitted for public consultation about implementing measures in order to harmonise the performance of the pharmacovigilance activities for in directive 2001/83/EC and regulation (EC) No 726/2004

COSTEFF is a European association promoting the interests of its members – healthcare companies and organisations – determined to bring cost-efficiency and innovation to the heart of health policies in Europe. Created in July 2009 by a group of private healthcare companies, COSTEFF is a pan-European advocacy group that seeks to create a new alliance around the issue of cost-efficiency and innovation in healthcare, including both public and private actors. COSTEFF wants to promote free movement of goods, fair competition in the healthcare sector and the development of an EU legal framework conductive to greater dialogue across the various branches of healthcare.

The implementing measures on the performance of the pharmacovigilance activities should additionally describe the scope and content of the implementing measures for parallel distributors, particularly for parallel traded drugs which are centrally authorised according the regulation (EC) No 726/2004. Parallel distributors want to share in the new pharmacovigilance activities introduced by the amended pharmacovigilance legislation, but they are not able to fulfil all proposed requirements as those are partly too far-reaching. Parallel distributors cannot determine the risk-benefit balance of a drug. Hence, they should not be imposed more cost-spending and complex measures than maintaining pharmacovigilance system master files as well as appropriate reasonable activities. As a meaningful and sufficient contribution to the forthcoming European pharmacovigilance system it could be seen the obligation for parallel distributors which is limited to the reporting on any serious adverse reactions only to the national authorities. All other adverse reactions should be collected, assessed and recorded in internal individual case safety reports being available to the national authorities on request at any time.

Having looked into the concept paper the following items shall be commented.

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II.A.3. Content (5)
With respect to the current, well-established, useful procedure performed: A specific validation is neither practically feasible nor reasonable for parallel distributors.

II.A.3. Content (6)
For parallel distributors none of the topics listed are relevant and important to be fulfilled and therefore they should not be required from parallel distributors.
Exception 6 (c): Parallel distributors perform "Individual case safety report collection, assessment and reporting *of serious cases*" (please add: "*of serious cases*").

II.A.7. Audit
As findings are confidential a note concerning the main findings of the audit should not be placed on the pharmacovigilance master file.
Consultation item no. 4
No, there should not be any copy of the audit report retained in the master file.

II.C.13. Resource management
As parallel distributors do not perform any clinical studies or post-authorisation safety studies, for parallel distributors it is neither useful nor necessary to have access to a medically qualified person.

II.C.14. Compliance management (b)
The retrospective evaluation of the currently performed procedure demonstrates that for parallel distributors it is useful and adequate to submit only data on serious cases to their national competent authority. Other cases are collected, assessed and recorded so that they can be submitted if requested at any time.

II.C.14. Compliance management (c)
It is useful and feasible for parallel distributors to fulfil the requirements written in the first half of the sentence: "ensure ...master files". However, it is not reasonable, relevant and feasible to fulfil the requirements stated in the second half: "risk management system....post-authorisation studies".

II.C.14. Compliance management (d)
For parallel distributors it appears to be sufficient to check the medicines web-portal on weekly basis.

II.C.15. Record management
The time spans mentioned (10 years and 30 years) seem to be too long. Moreover, the necessity for that is not obvious. Proposal: 6 years appears be sufficient in both cases.

II.E.20. General
As it is neither feasible nor relevant for parallel distributors, they should be excluded from the requirements: "The MA holders shall monitor...been detected".

II.E.21. Changed risks/new risks
As it is neither feasible nor relevant for parallel distributors, they should be excluded from the requirements: "The detection of a signal shall...detection of a signal".

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II.E.23. Signal management procedure
Instead of: "Any signal ....shall be validated" it should be stated: "Any signal ....shall be investigated"
Consultation item no. 9
No, there should not be any risk in cumulating all tasks.

II.G.29. Transmission of suspected adverse reaction and Annex I
Due to their core business and their well-experienced procedure parallel distributors are currently doing in this matter, it is not necessary to maintain electronic transmissions or submissions. It is sufficient and adequate to facilitate furthermore paper forms for submitting the required information to the national competent authorities.

II.G.30. Risk management plans and Annex II
For parallel distributors it means too much and unfeasible work in proportion to too less impact which is not reasonable. Parallel distributors should be excluded from this obligation.

II.G.31. Periodic safety update reports and Annex III
Due to the core business and the enormous assortment parallel distributors very often have: The experience and knowledge gained over the past demonstrates that for parallel distributors it is unfeasible, not useful as well as not necessary to proceed in such a way. They should be excluded like already today. So, the current procedure should be maintained.

II.G.32. Post authorisation safety studies and Annex IV
As parallel distributors are neither involved in clinical nor in official post-authorisation safety studies they should be excluded from this obligation.

Annex I Electronic submissions, 4. (o)
With respect to the current knowledge of employees involved, it should be optional and not mandatory to use an official EU language, other than English, e.g. German, in total.

Kind regards

Thilo Bauroth
Member of the Board