AMENDMENTS 001-006
by the Committee on the Environment, Public Health and Food Safety

Report
Linda McAvan **A7-0165/2012**
Pharmacovigilance (amendment of Directive 2001/83/EC)

Proposal for a directive (COM(2012)0052 – C7-0033/2012 – 2012/0025(COD))

Amendment 1

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(2) In addition, voluntary action by the marketing authorisation holder should not lead to a situation where concerns related to the risks or benefits of a medicinal product authorised in the Union are not properly addressed in all Member States. Therefore, provisions should be made for the marketing authorisation holder to inform competent authorities of the reasons for the withdrawal of a medicinal product, for interrupting the placing on the market of a medicinal product, for requests for revoking a marketing authorisation, or for not renewing a marketing authorisation.	(2) In addition, voluntary action by the marketing authorisation holder should not lead to a situation where concerns related to the risks or benefits of a medicinal product authorised in the Union are not properly addressed in all Member States. Therefore, provisions should be made for the marketing authorisation holder to inform competent authorities ***and the Agency*** of the reasons for the withdrawal of a medicinal product, for interrupting the placing on the market of a medicinal product, for requests for revoking a marketing authorisation, or for not renewing a marketing authorisation.

Amendment 2

Proposal for a directive
Article 1 – point 2
Directive 2001/83/EC
Article 31 – paragraph 1 – subparagraphs 3 a and 3 b (new)

Text proposed by the Commission	*Amendment*
	The Member State concerned or the Commission shall clearly identify the question which is referred to the Committee for consideration and shall inform the applicant or marketing authorisation holder accordingly.
	The Member States and the applicant or marketing authorisation holder shall supply the Committee with all available information relating to the matter in question.

Justification

It is useful to reinsert these two obligations which make the Article 31 referral procedure work more smoothly. This text was deleted in the Commission's proposal.

Amendment 3

Proposal for a directive
Article 1 – point 3 a (new)
Directive 2001/83/EC
Article 59 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(3a) In Article 59(1) the following point is inserted:
	"(aa) Drug-Fact-Box - a brief description of essential/necessary facts and details of the medicinal product, which are required by the patient to understand the usefulness as well as possible risks of the medicinal product and to use it in a safe and proper way. The information contained in the Drug-Fact-Box shall be presented in a clear and legible way, and shall bedistinguishable from the rest of the text form.
	The Commission shall submit guidelines and the content of the Drug-Fact-Box shall be checked and approved by the regulatory authorities.".

Amendment 4

Proposal for a directive
Article 1 – point 5
Directive 2001/83/EC
Article 123 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The marketing authorization holder shall be obliged to notify Member States forthwith of any action taken by him to suspend the marketing of a medicinal product**,** to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with the reasons for such action. The marketing authorisation holder shall in particular declare if such action is linked to any of the grounds set out in Articles 116 and 117. ***In such case, Member States shall ensure that this information is brought to the attention of the Agency.***	2. The marketing authorization holder shall be obliged to notify Member States ***and the Agency*** forthwith of any action taken by him to suspend the marketing of a medicinal product**,** to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with the reasons for such action. The marketing authorisation holder shall in particular declare if such action is linked to any of the grounds set out in Articles 116 and 117.

Justification

The Agency should be notified of all withdrawals / non renewals etc., not just those actions linked to safety or efficacy concerns, i.e. the grounds set out in Articles 116 and 117.

Amendment 5

Proposal for a directive
Article 1 – point 5
Directive 2001/83/EC
Article 123 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The marketing authorisation holder shall also make the notification pursuant to paragraph 2 if the action is taken in a third country and such action is based on any of the grounds set out in Article 116 and Article 117(1).

Justification

It would be useful for regulators to know if a company withdraws / does not renew etc. a

marketing authorisation in a third country.

Amendment 6

Proposal for a directive
Article 1 – point 5 a (new)
Directive 2001/83/EC
Article 123 – paragraph 4

Text proposed by the Commission	*Amendment*
	(5a) Article 123(4) is replaced by the following:
	"4. The Agency shall make public annually a list of the medicinal products for which marketing authorisations have been refused, revoked or suspended, whose supply has been prohibited or which have been withdrawn from the market*, including the reasons for such action*.".

Justification

In the interests of transparency the Agency should not just publish the list of products which have been withdrawn etc. but should also state the reasons for such action. They are already given this information.