

Annex 1

Sender

Country:

Subject

Implementation of the Resolution on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients.

Questionnaire

Some clarifying remarks concerning the XX regulation for pharmacy preparations in your country:

| Resolution text | question | Comments |
|--|--|----------|
| 3.1. (pharmaceutical equivalents on the national market) and | - is it implemented in legislation that a pharmacy preparation is not advisable if a pharmaceutical equivalent is available on the national market? | |
| 3.2. (added value and responsibility of health care professionals) | - are the responsibilities of the preparing pharmacy and the dispensing pharmacy (if these pharmacies are not identical) defined in: a/ regulations? b/ a contractual agreement? | |
| 4. (preparation process) | - is GMP applicable for high risk preparations? | |
| 5. (product dossier) | - are product dossiers, as described in note 2, required for stock preparations? | |
| 6. (marketing authorisation) | - has the regulatory authority considered establishing the requirement for obtaining a marketing authorisation for pharmacy preparations? | |
| 7. (labelling) | - is this implemented in your country? | |
| 8. (compliance with pharmacopoeial requirements) | - is this implemented in your country? | |
| 10.1 (authorisation of pharmacies) | - is there an additional authorisation or licence for preparation? | |
| 10.2 (licence for companies) | - in case you have such companies: is a licence for manufacture mandatory for these companies? | |
| 11 (transparency and safety) | | |
| 11.1 (reporting of quality and safety issues) | - is there an adequate system for reporting quality and safety issues? (please attach) | |

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| 11.2. (notification or announcement system) | <p>- do you have a notification system concerning the preparation activities performed in each pharmacy?</p> <p>(please attach details)</p> | |
| 11.5 (surveillance) | <p>- does the competent authority performs risk-based inspections? (11.5)</p> <p>(please provide details how this is performed)</p> | |
| 11.3 (inventory for pharmacy preparations) | <p>- do you have a national inventory for pharmacy preparations?</p> | |
| 13. (Distribution of pharmacy preparations?) | <p>- do pharmacies or companies, preparing medicinal products upon the request of pharmacies, have to comply with good distribution practices (GDP) in your country (13.1)?</p> | |
| | <p>- does export or import of pharmacy preparations take place in your country (13.2)?</p> | |