CORRIGENDA


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Page 207, lines 10–13

Delete: Additional wording was instead added to section 2.2 indicating that a Member State or a regional authority should possess an effective marketing authorization, vigilance and market surveillance and control systems for pharmaceutical products.

Insert: Additional wording was instead added to section 4.2 indicating that a Member State or a regional authority should possess an effective marketing authorization, vigilance and market surveillance and control systems for pharmaceutical products.

Page 208, lines 24–26

Delete: In order to participate, a certifying authority should comply, additionally, with the requirements stipulated in section 2.2.

Insert: In order to participate, a certifying authority should comply, additionally, with the requirements stipulated in section 4.2.

Page 209, lines 21–38

Delete: Membership as a certifying member and/or requesting member should be declared by notifying in writing to the Director-General of the WHO of:
- its willingness to participate in the Scheme as a certifying member and/or a requesting member;
- any significant reservations it intends to observe relating to this participation;
- the commitment of implementing the WHO guideline “WHO Certification scheme on the quality of pharmaceutical products moving in international commerce”, the WHO
Model Certificates (WHO template) and provision of the certificates when requested by a requesting member;
- the name and address (including email address, telephone and website address) of its medicines regulatory authority or other competent authority;
- the commitment to notify any change of the information submitted related to the certifying and/or requesting member details; and
- a declaration to comply with the requirements for a certifying member as stipulated in section 2.2.

Insert:  4.3 Membership as a certifying member and/or requesting member should be declared by notifying in writing to the Director-General of the WHO of:
- its willingness to participate in the Scheme as a certifying member and/or a requesting member;
- any significant reservations it intends to observe relating to this participation;
- the commitment of implementing the WHO guideline “WHO Certification scheme on the quality of pharmaceutical products moving in international commerce”, the WHO Model Certificates (WHO template) and provision of the certificates when requested by a requesting member;
- the name and address (including email address, telephone and website address) of its medicines regulatory authority or other competent authority;
- the commitment to notify any change of the information submitted related to the certifying and/or requesting member details; and
- a declaration to comply with the requirements for a certifying member as stipulated in section 4.2.

Page 210, lines 1–4

Delete:  4.4 A consolidated list of information on the notification submitted by Member States and regional authorities in accordance with the provision in sections 2.3 and 2.5 will be available through WHO’s official website (see also section 3.3).

Insert:  4.4 A consolidated list of information on the notification submitted by Member States and regional authorities in accordance with the provision in sections 4.2 and 4.3 will be available through WHO’s official website (see also section 3.3).

Page 210, lines 8–13

Delete:  5.1 Two documents, if available by the certifying authority, can be requested within the scope of the Scheme:
- a certificate of a pharmaceutical product (CPP) and;
a batch certificate of a pharmaceutical product (for more details, please see sections 3.14 and 3.15 and the Explanatory notes in Appendix 2).

Insert: 5.1 Two documents, if available by the certifying authority, can be requested within the scope of the Scheme:
- a certificate of a pharmaceutical product (CPP) and;
- a batch certificate of a pharmaceutical product (for more details, please see sections 5.14 and 5.15 and the Explanatory notes in Appendix 2).

Page 210, lines 1–4

Delete: 5.3 A list of addresses of national and regional authorities participating in the Scheme that are responsible for the registration of pharmaceutical products for human and/or veterinary use, together with details of any reservations they have declared regarding their participation in the Scheme, will be available on the WHO official website as indicated in section 2.4.

Insert: 5.3 A list of addresses of national and regional authorities participating in the Scheme that are responsible for the registration of pharmaceutical products for human and/or veterinary use, together with details of any reservations they have declared regarding their participation in the Scheme, will be available on the WHO official website as indicated in section 4.4.

Page 211, lines 1–2

Delete: For the product information to be attached to the certificate, please see section 4.7.

Page 211, lines 10–13

Delete: 5.10 When any doubt arises about the status or validity of a certificate, the requesting authority should request verification of the validity of the certificate from the certifying authority, as provided for under section 4.8 of these guidelines.

Insert: 5.10 When any doubt arises about the status or validity of a certificate, the requesting authority should request verification of the validity of the certificate from the certifying authority, as provided for under section 6.7 of these guidelines.
Page 214, lines 8–12

Delete: 6.4 When the applicant is not the manufacturer of the finished dosage form, the certifying authority should similarly satisfy – in so far as it has the authority to inspect the records and relevant activities of the applicant – that it has the applicant’s consent to release relevant reports on the same basis, as described in section 4.3 (b) above.

Insert: 6.4 When the applicant is not the manufacturer of the finished dosage form, the certifying authority should similarly satisfy – in so far as it has the authority to inspect the records and relevant activities of the applicant – that it has the applicant’s consent to release relevant reports on the same basis, as described in section 6.3 (b) above.

Page 215, lines 1–4

Delete: 6.8 The certifying authority should establish a standard time frame for the issuance of certificates, ideally within 30 working days. It should endeavor to issue a certificate within this period, as soon as the applicant submits sufficient documents, as requested in section 3.7.

Insert: 6.8 The certifying authority should establish a standard time frame for the issuance of certificates, ideally within 30 working days. It should endeavour to issue a certificate within this period, as soon as the applicant submits sufficient documents, as requested in section 5.7.

Page 227, lines 19–20

Delete: It shall ensure that it possesses the capacities listed in section 2.2 of the guidelines.

Insert: It shall ensure that it possesses the capacities listed in section 4.2 of the guidelines.

Page 227, lines 27–31

Delete: The extent of participation should be indicated in the notification to the WHO Director-General as stipulated in section 2.3 of the guidelines. WHO makes available a continuously updated list of addresses of competent authorities and the specific conditions for participation (see section 2.5 of the guideline).

Insert: The extent of participation should be indicated in the notification to the WHO Director-General as stipulated in section 4.3 of the guidelines. WHO makes available a continuously updated list of addresses of
competent authorities and the specific conditions for participation (see section 4.4 of the guideline).

Page 231, lines 31–34

Delete: This refers to the document prepared by some medicines regulatory authorities that summarizes the technical basis on which the product has been licensed (see section 4.6 of the guidelines and Explanatory note 3 of the product certificate contained in Appendix 1).

Insert: This refers to the document prepared by some medicines regulatory authorities that summarizes the technical basis on which the product has been licensed (see section 6.5 of the guidelines and Explanatory note 3 of the product certificate contained in Appendix 1).

Page 235, Table, column 1, lines 8–10

Delete: Reservation as per section 2.3 of the Scheme for posting on the WHO website (if any)

Insert: Reservation as per section 4.3 of the Scheme for posting on the WHO website (if any)

These corrections have been incorporated into the electronic file.