Introduction to the Technical Supplements

Annex 9: Model guidance for the storage and transport of time and temperature–sensitive pharmaceutical products

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Acknowledgments

Dr Umit Kartoglu (WHO, Geneva) has overall responsibility for the Technical Supplement series and Andrew Garnett (WHO consultant, London, UK) is the series editor. Authorship of the individual Supplements is acknowledged in each of the accompanying documents.
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1. The technical supplement series

This series of technical supplements has been written to amplify the recommendations given in WHO Technical Report Series No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products*. This document sets out the principal requirements for the safe storage and distribution of time-and temperature-sensitive pharmaceutical products (TTSPPs).

The introduction to the guidance documents states that: *... supplementary materials will be developed to show how the requirements can practically be achieved, particularly in resource constrained settings.* The technical supplements, which make up this volume, are intended to provide this additional material; each one is linked back to a specific clause or clauses in the parent document. All 16 documents are written in a standard format and each contains a reference section with hyperlinks to relevant supporting materials. In the majority of cases these are available free on-line. References to print publications have minimized in order to avoid the difficulties associated with purchasing books and journals.

1.1 Topics covered

The following table lists the titles of the supplements and the model guidance sections to which each one refers.

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*Introduction to technical supplements*
1.2 Target readership

The target readership for the model guidance, and for the technical supplements, includes regulators, logisticians and pharmaceutical professionals in industry, government and the international agencies.

1.3 Document development and review process

The Technical Supplements have been written by specialist authors. All sixteen supplements passed through an editorial and public review process as follows:

1. Each document was prepared over the course of several drafts in consultation with the series editor.
2. Acronyms and glossary definitions were harmonized throughout.
3. Public consultation drafts were posted on the WHO website in mid-2014. Review comments were received from the following people and organizations:
   - Prof. Mª Rosa Jiménez-Castellanos: Seville University Dept of Pharmacy and technology.
   - FIP (International Pharmaceutical Federation)
   - IFPMA (International Federation of Pharmaceutical Manufacturers & Associations).
   - Mikhail Kazanchuk: (Novonordisk).
   - Dr Zvonimir Majic: (Head of Quality Assurance EU Logistics).
   - Merck.
   - Novartis.
   - VAPI-UPIP (Belgian Association of the Pharmacists of the Pharmaceutical industry).
4. Reviews were consolidated by the series editor and sent to the individual authors for initial comment.
5. Based on these comments, amended documents were prepared containing the consolidated comments as ‘accepted’, rejected and ‘for discussion’. These new drafts were sent back to the individual authors for further comment.
6. The series editor prepared final drafts based on the authors’ responses and these drafts were checked, reviewed and signed off by Dr Kartoglu.
7. On the basis of these final comments, clean versions were prepared for the ECBS review.
## Revision history

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