

Contents

Introduction	1
1. General policy	3
1.1 Cross-cutting pharmaceutical quality assurance issues	3
1.2 International collaboration	6
2. Quality control - specifications and tests	8
2.1 <i>The International Pharmacopoeia</i>	8
2.1.1 Updates	8
2.1.2 Workplan 2016-2017	8
2.2 Specifications for medicines, including children's medicines and radiopharmaceuticals	10
2.2.1 Maternal, newborn, child and adolescent health medicines	10
2.2.2 Antituberculosis medicines	11
2.2.3 Antiviral medicines	12
2.2.4 Medicines for tropical diseases	12
2.2.5 Other anti-infective medicines	13
2.2.6 Other medicines	14
2.2.7 Radiopharmaceuticals	14
2.3 General monographs for dosage forms and associated method texts	15
2.4 General policy	16
3. Quality control - International Reference Materials (International Chemical Reference Substances and Infrared Reference Spectra)	20
4. Quality control - national laboratories	21
4.1 External Quality Assurance Assessment Scheme (EQAAS)	21
4.2 Guidance on testing of "suspect" substandard/spurious/falsely-labelled/falsified/counterfeit medicines	21
4.3 Recommendations from the meeting on regulatory guidance for multisource products	22
5. Prequalification of quality control laboratories	23
5.1 Update on the prequalification of quality control laboratories	23
5.2 Update on WHO quality monitoring projects	23
5.3 Revision of the procedure for assessment of quality control laboratories	24
6. Quality assurance - collaboration initiatives	25
6.1 International meetings of world pharmacopoeias	25
6.2 Good pharmacopoeial practices	25
6.3 Inspection guidelines and good practices	26
7. Quality assurance - good manufacturing practices	27
7.1 Update of WHO good manufacturing practices: validation	27
7.2 Heating, ventilation and air-conditioning (HVAC)	27
7.3 Update and recommendations from the inspectors' meeting	28
8. Regulatory frameworks	29
8.1 Local manufacturing of essential medicines	29
8.2 WHO Global Model Regulatory Framework for Medical Devices	30

9. Regulatory guidance	31
9.1 Biowaiver list based on the WHO List of Essential Medicines	31
9.2 International Comparator Products List for equivalence assessment of interchangeable multisource (generic) products	31
9.3 Good regulatory practices	32
9.4 Collaborative procedure for stringent regulatory authority-approved medicines	32
9.5 Recommendations from the meeting on regulatory guidance for multisource products	33
10. Prequalification of priority essential medicines and active pharmaceutical ingredients	37
10.1 Update on the prequalification of medicines	37
10.2 Update on the prequalification of APIs	37
11. Nomenclature, terminology and databases	39
11.1 Quality assurance terminology	39
11.2 International Nonproprietary Names (INN) for pharmaceutical substances	39
11.3 Revision of guidance on representation of graphic formulae	39
12. Closing remarks	41
13. Summary and recommendations	42
Acknowledgements	48
Annex 1	
WHO guidelines for selecting marker substances of herbal origin for quality control of herbal medicines	71
Annex 2	
<i>The International Pharmacopoeia: revised concepts and future perspectives</i>	87
Annex 3	
Prequalification of quality control laboratories: procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies	91
Annex 4	
WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices	103
Annex 5	
General background notes on the list of international comparator pharmaceutical products	179
Annex 6	
Equilibrium solubility experiments for the purpose of classification of active pharmaceutical ingredients according to the Biopharmaceutics Classification System, as an appendix to the WHO guidelines on <i>Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability</i> (Annex 7, WHO Technical Report Series, No. 992,2015)	181