

Contents

Introduction	1
Open session	2
Introduction to the ECSP	2
1. General policy	4
1.1 Cross-cutting pharmaceutical quality assurance issues	4
1.2 International collaboration	10
2. Quality control - specifications and tests for <i>The International Pharmacopoeia</i>	14
2.1 Update and workplan	14
2.2 General policy	14
2.3 General chapters	17
2.4 General monographs for dosage forms and associated method texts	17
2.5 Specifications for medicines, including children's medicines and radiopharmaceuticals	17
3. Quality control - international reference materials (International Chemical Reference Substances and Infrared Reference Spectra)	26
3.1 Report of the custodian centre	26
3.2 Update on International Chemical Reference Substances, including report of the dedicated Expert Committee on Specifications for Pharmaceutical Preparations subgroup on International Chemical Reference Substances	26
3.3 General policy	27
4. Quality control - national laboratories	28
4.1 External Quality Assurance Assessment Scheme	28
4.2 Considerations for requesting analysis of medicines samples and model certificate of analysis	28
4.3 Guidance on testing of "suspect" falsified medicines	29
5. Prequalification of quality control laboratories	30
5.1 Update on the prequalification of quality control laboratories	30
5.2 Update on WHO quality monitoring projects	30
6. Quality assurance - collaboration initiatives	31
6.1 International meetings of world pharmacopoeias	31
6.2 Good pharmacopoeial practices	31
6.3 Inspection guidelines and good practices	33
7. Quality assurance - good manufacturing practices	34
7.1 Guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems	34
7.2 WHO good manufacturing practices: validation, including main principles and specific texts (water, cleaning, computerized systems, qualification of systems and equipment, non-sterile)	34

7.3	Guidance on good practices for desk review for good manufacturing practices, confirmation in lieu of on-site assessment	35	Annex 7		
7.4	Update and recommendations from the inspectors' meeting	35		Good pharmacopoeial practices: Chapter on monographs on herbal medicines	241
8.	Regulatory guidance	37	Annex 8	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products	249
8.1	Regulatory requirements on stability testing of active pharmaceutical ingredients and finished pharmaceutical products	37	Annex 9	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions	271
8.2	Biowaiver list based on the WHO Model List of Essential Medicines	37	Annex 10	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products	309
8.3	Collaborative procedure for the assessment and accelerated national registration of medicines and vaccines approved by stringent regulatory authorities	39	Annex 11	Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities	353
8.4	Good practices for implementing the collaborative procedures	40			
8.5	Good regulatory practices	40			
8.6	Quality management systems for national regulatory authorities	41			
9.	Prequalification of priority essential medicines and active pharmaceutical ingredients	42			
9.1	Update on the prequalification of medicines	42			
9.2	Update on the prequalification of active pharmaceutical ingredients	42			
10.	Nomenclature, terminology and databases	43			
10.1	Definition of "stringent regulatory authority"	43			
10.2	Quality assurance terminology	44			
10.3	Guidelines and guidance texts adopted by the Committee	44			
10.4	International Nonproprietary Names for pharmaceutical substances	44			
10.5	Guidance on the graphic representation of pharmaceutical substances	45			
11.	Miscellaneous	46			
11.1	WHO Department of Essential Medicines and Health Products: Strategic vision	46			
12.	Closing remarks	47			
13.	Summary and recommendations	48			
	Acknowledgements	56			
	Annex 1				
	WHO guidelines on good herbal processing practices for herbal medicines	81			
	Annex 2				
	Guidelines on good manufacturing practices for the manufacture of herbal medicines	153			
	Annex 3				
	Considerations for requesting analysis of medicines samples	179			
	Annex 4				
	Model certificate of analysis	187			
	Annex 5				
	WHO guidance on testing of "suspect" falsified medicines	193			
	Annex 6				
	Good pharmacopoeial practices: Chapter on monographs for compounded preparations	235			