



SAHPRA

South African Health Products Regulatory Authority

GUIDELINES and FORMS TABLE OF CONTENTS

1	Guidelines and Forms
1.01	Index to Guidelines and Forms
2	Human Medicines
2.01	General information
2.02	Pharmaceutical and Analytical
2.03	Alcohol content of medicines*
2.04	Post-importation testing*
2.05	Stability *
2.06	Biostudies
2.07	Dissolution*
2.08	Amendments*
2.09	Clinical
2.10	Substitution of medicines
2.11	Adverse Drug Reactions Reporting
2.12	Completing clinical trial applications (to be updated)
2.13	Implementation of the post-registration amendments guideline
2.14	Patient Information Leaflet (PIL)
2.15	Proprietary names for medicines
2.16	Package Inserts for human medicines
2.17	Safety-related Package Insert Notifications (SR-PINs)
2.20	Package Insert standardised texts
2.21	ZA eCTD Module 1 Technical
2.22	eCTD Validation Criteria
2.23	Submission in eCTD format
2.24	Guidance for the Submission of the ZA CTD / eCTD – General & Module 1
2.25	Pharmaceutical & Analytical for CTD
2.26	CTD Implementation Road Map
2.27	eCTD Checksums
2.28	eCTD Questions & Answers
2.30	Biosimilars

2.31	Fixed Dose Combination Products for HIV/Aids, Tuberculosis, and Malaria
2.32	Wound Dressings
2.33	Adverse Drug Reactions reporting post-marketing
2.35	Labelling of medicines containing sugars
2.36	Scheduling of medicines
2.37	Scheduling of substances for prescribing by authorised prescribers
2.38	SI International metric system
2.39	Biological Medicines Pre-registration Consultation Meeting
2.40	Multiple Applications of the same application with different proprietary names
2.41	Emergency Procedures for Clinical Trial Sites
2.42	Post Clinical Trial Drug Access <i>for comment</i>
2.43	Oversight and Monitoring in Clinical Trials
2.44	Cultivation of Cannabis and manufacture for medicinal and research purposes <i>for comment</i>
2.45	Borderline Products <i>for comment</i>
2.46	Co-packaging of medicines – <i>for comment</i>
2.47	Clinical Trial Investigators
2.48	Exemptions – <i>for comment</i>
2.49	Capacity building & transformation in clinical trials research – <i>for comment</i>
2.50	Medicines & Human Reproduction <i>for comment</i>
3 Veterinary Medicines	
3.01	General information for Veterinary medicines
3.03	Bioavailability and bioequivalence
3.04	Efficacy of and GCP for veterinary medicines
3.05	Pre-clinical safety for veterinary medicines
3.06	Efficacy of veterinary biological medicines
3.07	Maximum residue limits and withdrawal periods
3.08	Safety of veterinary biological medicines
3.09	Reporting of adverse drug reactions
3.10	Recall of veterinary medicines
3.11	Completing section 21 application form
3.12	Veterinary Orphan Products- <i>for comment</i>
3.13	Veterinary Antimastitis Medicines
4 Good Manufacturing Practice (GMP)*	
4.01	SA guide to Good manufacturing Practice (GMP)
4.02	SA Guide to Good Wholesaling Practice + <i>amended for comment</i>
4.03	Aerosol manufacturing
4.04	Isolator technology
4.05	Cephalosporin manufacture
4.06	Penicillin manufacture
4.07	Radiopharmaceutical manufacture
4.08	Site master file
4.08	Inspections involving GMP Inspectors
4.10	Exporting of medicines by Wholesalers

GCP guidelines
5 Miscellaneous
5.01 Importation and exportation of medicines*
5.02 Parallel importation of medicines (PIM) *
5.03 Annual returns: international control*
5.05 Destruction of schedule 5 medicines*
5.06 Destruction of schedule 6 medicines*
5.07 Recalls
5.07 Recall / withdrawal of medicines, medical devices and IVDs - <i>for comment</i>
5.08 Donations*
5.09 Lodging a complaint on a medicine
6 Forms
6.01 MRF1 Medicine Registration Application (Human) - <i>replaced by ZA-CTD</i>
6.02 MRF2 Screening of Application*
6.03 MRF4 Package Insert Amendments*
6.04 ARF1 Adverse Drug Reaction Reporting
6.05 CTF1 Clinical Trial Application
6.06 CTF2 Clinical Trial Protocol Amendments
6.07 CTF3 Clinical Trial Investigators and Sites Amendments
6.08 VMRF1 Veterinary Medicine Registration
6.09 PIF1 Parallel Importation Amendments
6.10 Licence application to manufacture, import or export*
6.11 Licence application to act as wholesaler or distributor**
6.12 Section 21 Application form
6.13 Guideline comments form
6.14 Application for the Donation of Medicine to South Africa
6.15 Screening Template for New Applications for Registration
6.16 Validation Template for eCTD
6.17 Licence application for Wholesaler to export
6.19a FPP record sheet
6.19b API record sheet
6.20 Pre-registration Consultation Meeting Check-list
6.21 Licence application to manufacture, import, distribute or export medical devices
6.22 Licence application to import, distribute or export medical devices
6.24 Licence application to wholesale medical devices and IVDs
6.25 Licence application to cultivate, manufacture or import Cannabis for medicinal purposes
6.26 Licence application to wholesale medical devices v2
6.27 CT Six monthly progress report form
Module 1.2.1 Application Form for ZA-CTD
ZA-CTD
ZA util

7	Complementary Medicines (CAMs)
7.01	Complementary Medicines –Quality, Safety, and Efficacy
7.02	Roadmap for Complementary Medicines
7.03	CAMs Use of ZACTD format in preparation of registration application
7.04	Health Supplements – Safety and Efficacy
7.04	Health Supplements – Safety and Efficacy – <i>Annexures for comment</i>
7.05	Complementary Medicines Registration Application ZA-CTD – Quality
7.06	Complementary Medicines – Caffeine and Menthol – <i>for comment</i>
	Government Gazette 38133 Vitamins and Minerals
8	Medical Devices and <i>In Vitro</i> Diagnostics
8.01	General Information – Medical Devices and IVDs – <i>for comment</i>
8.02	Medical Devices and IVDs Essential Principles – <i>for comment</i>
8.03	Medical Devices and IVDs – Conformity Assessment Procedures – <i>for comment</i>
8.04	Adverse event and post-marketing vigilance reporting of medical devices and IVDs – <i>for comment</i>
8.05	Classification of medical devices and IVDs
8.06	Access to and control of medical devices and IVDs – <i>for comment</i>
8.07	Medical Device Quality Manual - <i>for comment</i>
8.08	Medical device IVD technical dossier – <i>for comment</i>
8.09	Medical device non-IVD technical dossier – <i>for comment</i>
	ZA CH1.04: Administrative Information – Application form – Application for registration of a Medical Device
9	Communication with Industry / All Stakeholders
9.01	Registration of antiretroviral medicines
9.07	ADR terminology used in package inserts
9.08	Dear Healthcare Professional Letter (DHCPL) and Medicines Safety Alerts (MSA)
9.13	Urgent Safety Restriction Notification (USRN)
9.15	Regulation of Complementary Medicines
9.16	Scheduling matters
9.17	Meeting dates 2017
9.22	Scheduling Matters - Accessibility of Malaria Prophylaxis Medicines
9.24	Screening Aug09
9.25	Enoxaparin Dec08
9.28	Cancellation or withdrawal
9.33	Payments made to the Registrar of Medicines
9.38	Implementation of CTD
9.40	Changes during the Registration Process
9.41	Important Medicine safety Information – withdrawal of dextropropoxyphene-containing medicines
9.42	Safety-related Package Insert Notification (SR-PINs) Submission Dates for Pilot Phase
9.46	eCTD Pilot Phase
9.49	Scheduling of Meprobamate - <i>for comment</i>
9.52	Audit of clinical package insert amendments

9.53	Clinical Trial Committee meeting and submission dates 2017
9.55	Scheduling of Codeine
9.56	Correction Notice to GG38133 on vitamins and minerals of Nov 2014
9.57	Process for implementation of amended Regulations 9 and 10 of Nov 2014
9.59	Electronic submission of clinical trial documents
9.61	Scheduling of Aspirin
9.65	Proposal to amend scheduling of codeine and dihydrocodeine - <i>for comment</i>
9.66	Rejections and Comments on rejection
9.68	Scheduling of Ibogaine
9.69	Rescheduling of Diclofenac
9.71	Expression of interest - API full assessment pilot
9.73	Rescheduling of ephedrine, ephedra alkaloids and phenylpropanolamine
9.74	ZA CTD implementation
9.75	Expression of interest - Pilot for electronic submission of ADR reports
9.77	Backlog action plan
9.78	Position statement: Status of Disinfectants, Antiseptics and Germicides
9.79	Medical Device Establishments: Licence requirements
9.80	eCTD Go-live in South Africa
9.81	Workshop re expression of interest on API full assessment pilot
9.82	Rescheduling of acetylcysteine
9.83	Workshop re clinical trial related matters
9.84	Clinical Trial Investigators
9.85	Clarification of process to obtain a licence to grow cannabis for use as a medicine
9.86	2.33 Post-marketing reporting of ADRs to human medicines in South Africa v4.1
9.87	Complementary medicines - Licence application to manufacture and/or wholesale
9.89	MCC wishes to appoint technical evaluators of applications for registration of complementary medicines
9.91	Clinical Trials Workshop
9.92	Rescheduling of albendazole
9.93	Scheduling matters - Regulatory status of cetylpyridinium chloride containing products
9.94	Post-Importation Testing Workshop
9.95	Medical Device Workshop
9.97	Rescheduling of diclofenac
9.96	Transitional arrangements for medical devices
9.98	Meeting between the chief executive officers (CEOs) of pharmaceutical industry, the Chairperson of the Medicines Control Council and the Registrar of Medicines
9.99	Rescheduling of cannabidiol
9.100	Indian Walnut
9.101	Communication with Council or Committees
9.102	MCC wishes to appoint quality and bioequivalence evaluators of applications for registration of medicines
9.103	Tissue Engineering Products
9.104	Rescheduling of Atovaquone & Proguanil
9.105	Section 21 authorisation of sale of unregistered medical devices
9.106	Position statement: Class A Medical Devices
9.107	Medical Device Workshop

9.108 Meeting with CEOs
9.109 Meeting with Medical Device CEOs
9.110 Meeting with Complementary Medicines CEOs
Industry Task Group meeting minutes Nov 2014 (revised Dec 2014), March 2015, June 2015, March 2016
10 Media Releases
10.04 Nevirapine 28/07/2003
10.07 Withdrawal of rosiglitazone-containing medicines from the South African (SA) market
10.08 High Court Judgment on Adcock Ingram's DPP-Containing Medicines
10.09 The Safety of Cough and Cold Medicines in Children
10.10 Registration of Complementary Medicines
10.12 MCC warns against use of the unregistered medicine, Miracle Mineral Solution (MMS) and similar products for the treatment of medical conditions
10.13 MCC alerts the public to the risks and harm associated with the inappropriate and non-prescribed use of testosterone-containing medicines
10.14 MCC clarifies access to Cannabis for the treatment of medical conditions
Withdrawal of VIOXX (rofecoxib) from the South African market
PICs press release Paris 2014
PICs press release Rome 2014
PICs press release Geneva 2015
12 Notification of Registration
12.01 – 12.91
12.100 Notification of registration until July 2017
16 Licensing*
16.01 Licence to manufacture, import or export
16.02 Licence to act as wholesaler or distributor
16.03 Guideline for licence to manufacture, import, export or distribute medical devices and IVDs
16.04 Licence to act as a wholesaler of medical devices & IVDs
17 Fees
17.02 Bank Details
17.03 Retention Fees registration of human and veterinary medicines, and licences
17.04 Fees for Complementary Medicines - <i>for comment</i>
9.33 Payments made to the Registrar of Medicines
Fees payable Government Gazette 39154 notice 784 01 September 2015
18 Exemptions
18.01 Exemptions in terms of Section 36 of Act 101 – Aug 2005
20 Licences Issued
20.14 Licences issued to manufacturers, importers, exporters, wholesalers, distributors
20.15 Licences issued until September 2017

20.16	Licences suspended March 2015
21	Medicines Safety Alerts (MSA)
21.1	MSA Ketoconazole and Domperidone May06
21.2	MSA Promethazine Apr07
21.3	MSA Rotarix Feb08
21.4	MSA Atypical antipsychotics Jun09
21.5	MSA Gamma benzene hexachloride May09
21.6	MSA Cough and Cold Medicines no longer to be used in Children under the age of two years
	Other documents
	Acts and Regulations
	Policies
	Conflict of interest
	Workshops and Conferences

* Also applicable to Veterinary medicines