South African Health Products Regulatory Authority

Registration of Medical Devices and Call-up Plan

1 February 2018

Contents

1. Introduction - Context and current situation

Significant amendments to the Medicines and Related Substances Act 101 of 1965, which now establishes provision for the control of medicines and scheduled substances and medical devices, were brought into effect on 1 June 2017. Where previously the focus was on safety and efficacy of medicines, the amended Act 101 also empowers governance for safety and performance of medical devices in South Africa.

The Regulatory Authority (Medicines Control Council [MCC]) crafted a phased implementation for implementation of regulatory control of medical devices.

The implementation of –

1) quality assurance through mandatory quality management systems for all stakeholders to be licensed in the supply chain, and

2) registration of medical device products,

were identified as the two key phases of the high level strategic approach to enable smooth transition and minimal disruption to a previously unregulated medical device sector.

Global harmonisation of regulatory control of medical devices is well established, and South Africa has positioned itself to implement international best practises, including the use of a third party external conformity assessment framework where relevant and suitable to the South African health requirements.

As per global practise and work of the International Medical Device Regulators Forum (IMDRF) – medical devices are categorised into either In-vitro Diagnostic (IVD) medical devices and Non-IVD medical devices and the foundation to regulatory controls utilises a risk based approach, where risk is to either the patient, user or to public health is considered.

All medical devices (i.e. IVDs and NON-IVDs) are classified into the following four risk classes, determined according to published classification rules.[1]

(a) Class A - Low Risk;
(b) Class B - Low-moderate Risk;
(c) Class C - Moderate-high Risk;
(d) Class D - High Risk,
where risk relates to the patient, user or to public health.[2]

[1] MCC 8.05 Classification of Medical Devices and IVDs April17 v2
[2] Regulations Relating to Medical Devices and *In-vitro* diagnostic Medical Devices (IVDs) Government Gazette 9 December 2016 No 40480. Regulation 11(1)

While the licensed Applicant is responsible for determining the classification of a medical device using a set of classification rules supplied by the Regulatory Authority[3], based on the:

- manufacturer's or distributor's intended use of the device or IVD;
- level of risk to patients, users and other persons (the probability of occurrence of harm and the severity of that harm);
- degree of invasiveness in the human body; and
- duration of use and exposure–

the Regulatory Authority has the responsibility and authority to determine the final classification.

1.1 Implementation Phase 1

While the longstanding Section 22C in Act 101 of 1965 as amended, identified the requirement for licensing of a medical device establishment[4], the requirements for persons importing, manufacturing, exporting and wholesaling medical devices were not determined and implemented until December 2016 when the specific regulations for Medical Devices were published. [2]

No medical device establishment, manufacturer, distributor or wholesaler shall manufacture, distribute or wholesale any medical device unless s/he is **licensed** for the relevant activities [Act 101 Section 22C1) b)].

The publication of the medical device regulations which identified the requirements for licensing of a medical device establishment[5] together with the MCC licensing guideline[6] initiated the primary implementation phase for regulatory control of medical devices.

Transitional arrangements existed for legal importation / manufacture / distribution until 24 August 2017, at which time all medical device establishments conducting the above-mentioned activities were required to make application for a licence to conduct either manufacturing (i.e. including importation, manufacturing, distribution and export) or distribution (i.e. including importation, distribution and export) activities in South Africa.

The transitional time line for licensing of medical device establishments which conduct wholesaling activities, (i.e. local procurement from licensed importers / manufacturers and sale of medical devices to end users) is until 24 February 2018.

[3] MCC 8.05 Classification of Medical Devices and IVDs April17 v2
[4] Act 101 as amended: Definition: **"**medical device or IVD establishment" means a facility used by a manufacturer, wholesaler, distributor, retailer, service provider or an importer of medical devices or IVDs for conducting business;
[5] Regulations Relating to Medical Devices and *In-vitro* diagnostic Medical Devices (IVDs) Government Gazette 9 December 2016 No 40480. Regulation 5. Licence to manufacture, import, export, or act as a distributor or wholesaler of medical devices or IVDs
[6] MCC 16.03 Guideline for a Licence to Manufacture, Import, Export or Distribute Medical Devices or IVDs v1

Those persons (legal or natural) who made application for a licence prior to the deadline dates may continue to trade while the application for a licence is under evaluation.

1.2 Implementation Phase 2

The Medicines and Related Substances Act 101 empowers the South African Health Products Regulatory Authority [SAHPRA] to determine that a medical device or part of any class or category of medical device shall be subject to **registration** in terms of the Act.[7] This is communicated through a published declaration commonly referred to as a "call-up" notice. It is relevant to note that such a declaration may relate to products already available for sale in the market or to products which were not available in South Africa prior to the publication date (i.e. new medical devices not yet marketed).

Such a "call-up" / declaration will be published in the Government Gazette with a notice period of six months. Current transitional arrangements[8] for medical devices mean that unregistered medical devices may be sold legally until the call-up notice period for registration has expired.

The purpose of this document is to establish a plan of action for registration of medical devices. The variety and number of types of medical devices (IVDs and Non-IVDs) available is extremely large and broad, and it is for this reason that the plan for registration of medical devices is based on the recognition of the risk to the patient, user or to public health, i.e. a risk based approach. Furthermore, the plan recognises the burden of disease and the role of medical devices (IVDs and NON-IVDs) associated with providing healthcare in South Africa.

TRANSITIONARY RISK MITIGATION

A review of the high number of types of medical devices (e.g. there are over 22 000 Global Medical Device Nomenclature [GMDN] term names[9] / types of medical devices recognised in the GMDN data set) indicates a long process to be conducted over many years. This infers that there may be moderate to high risk and high risk medical devices on the market for several months / years which are not registered. To mitigate the risk involved with unregistered medical devices in the market without any regulatory oversight, the Regulatory Authority implemented the following conditions for importation of class C and D medical

[7] Act 101 of 1965, as amended. Section 14 Prohibition on the sale of medicines, medical devices or IVDs which are subject to registration and are not registered

[8] Regulations Relating to Medical Devices and *In-vitro* diagnostic Medical Devices (IVDs) Government Gazette 9 December 2016 No 40480. Regulation 28. Transitional arrangements - unregistered medical devices and IVDs.

[9] GMDN Agency www.gmdnagency.org

devices as an element of the mandatory medical device establishment licensing process for importers of medical devices.

a) The medical device establishment is required to appoint an Authorised Representative [AR] (i.e. a natural person residing in South Africa) who is held responsible for compliance, safety and performance of the medical devices imported / manufactured and sold in South Africa. The AR is required to make a legal declaration that the medical device(s) imported /manufactured and sold meet the "Essential Principles of Safety and Performance"[10] and to identify which quality assurance procedures are in place within the establishment;
b) For class C and D medical devices (IVDs and NON-IVDs) – a condition of importation is that the licensed importer holds evidence of a pre-market authorisation from at least one of six jurisdictions i.e. either European CE mark to show conformity to the EU medical device directive(s), USA FDA's Premarket Approval (PMA) or Premarket Notification 510(k) clearance; registration by Australia's TGA; Health Canada; Japan's PMDA market authorisation or approval and registration by Brazil's ANVISA; or evidence of IVDs approved under the World Health Organisation (WHO) Prequalification of In Vitro Diagnostics Programme;
c) For all class C and D medical devices imported /manufactured the supporting technical documentation must be available to the Regulatory Authority if required;
d) For all class B, C and D medical devices – a condition of importation is that the licensed importer holds a Certificate of Free Sale (referred to as a Certificate of Foreign Government by USA), which indicates that the product is legally sold or distributed in the open market, freely without restriction and approved by the regulatory authorities in the country of origin; and
e) A certificate of conformance or certificate of analysis must be available where relevant.

In addition to the above requirements, as per the Hazardous Substances Act 15 of 1973, as amended – importers of Group III and IV Hazardous Substances (commonly referred to as electromedical and radiation devices) are required to be licensed with the Department of Health Radiation Control Directorate. The requirement is to provide evidence of approval to market in Europe (CE mark) with supporting brochures

2. Registration Call-up Rationale using a Risk Based Approach

The global harmonised regulatory approach to regulatory control of medical devices is premised on a risk based approach – where the patient, user and public health are considered.

As noted above the common framework used by most countries is a four-class system, albeit termed differently in different jurisdictions, and the fundamental premise is where there

[10] MCC 8.02 Medical Devices and IVDs Essential Principles of Safety and Performance v1

is higher risk of use or non-performance of the medical device then there are greater requirements to substantiate safety and performance prior to authorisation to market.

As noted in section 1.1 above, the amended Act 101 empowers SAHPRA to call-up both medical devices currently on the market and those yet to be brought to the South African market (i.e. new medical devices) for registration.

The sequence of the registration call-up plan is segmented into call-up of

A. all new class B, C and D medical devices (IVDs and NON-IVDs); and
B. medical devices (IVDs and NON-IVDs) currently on the market.

The high burden of disease in South Africa centres around both communicable diseases and non-communicable diseases. Most often use of an *in-vitro* diagnostic (IVD) medical device is a critical tool to diagnose these diseases. Hence IVDs which perform as intended in a consistent manner are imperative to facilitate correct diagnosis, treatment and monitoring of patients. IVDs of inferior quality may compromise public health.

IVDs to test, diagnose and monitor communicable diseases such as HIV, TB and malaria are considered priorities for registration.

Similarly, IVDs which are used to establish and to monitor the clinical parameters of patients with non-communicable diseases, will by nature of classification, be prioritised.

Medical devices which incorporate a medicine or scheduled substance (refer definition of a medical device[11]) or biological material, often loosely referred to as a "combination medical device" – are inherently of higher risk and considered as priorities for registration.

Implantable medical devices can be life-savers and life-extenders for many patients and by nature of the implantation of a foreign body into living tissue carry a high risk to the patient.

The information provided above is a high-level synopsis of the types of medium to high and high risk medical devices. This is provided to give understanding of the risk based approach which will be used together with the Global Medical Device Nomenclature (GMDN) system in the registration call up plan.

Medical Device nomenclature:

The Global Medical Device Nomenclature (GMDN)[12] Agency is responsible for the nomenclature used to identify medical devices.

"The Global Medical Device Nomenclature (GMDN) is a list of generic names used to identify all medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans.

The main purpose of the GMDN is to provide health authorities and regulators, health care providers, manufacturers and others with a naming system that can be used to exchange medical device information and support patient safety.

The GMDN is recommended by the International Medical Device Regulators Forum (IMDRF) and is now used by over 70 national medical device regulators to support their activity. The GMDN is managed by the GMDN Agency, a registered charity, which has a Board of Trustees, which represent regulators and industry.

The GMDN is updated by member change requests. New and updated GMDN terms are published on the member website, the GMDN Database. Information in the form of a 5-digit numeric GMDN Code is cross-referenced to a precisely defined Term Name and Definition, as seen in this example:

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[11] ***"medical device"*** *means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973)—*
intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following:
(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(iii) investigation, replacement, modification or support of the anatomy or of a physiological process;
(iv) supporting or sustaining life;
(v) control of conception;
(vi) disinfection of medical devices; or
(vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and
which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means.

[12] GMDN Agency https://www.gmdnagency.org/About/Database

- *GMDN Term Name: Scalpel, single-use*
- *GMDN Code: 47569*
- *GMDN Definition: A sterile, hand-held, manual surgical instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue. The blade is typically made of high-grade stainless-steel alloy or carbon steel and the handle is often made of plastic. This is a single-use device."*

It should be noted that the GMDN is a relational database (i.e. a complex dataset), rather than a linear data base.

One of the main uses of the GMDN is as a hierarchical categorisation system using GMDN Collective Terms[13] [CTs]. Once a manufacturer/ user is registered on the GMDN Agency system it is possible to identify different terms names and associated GMDN codes with a Collective Term. The South African Regulatory Authority is a registered user of the GMDN dataset.

THE GMDN website allows for view of Collective Terms by

- Name
- Use
- Clinical Specialties
- Device Attribute Assortment
- Device Invasiveness
- Device Material
- Device Power/Operation
- Device Sterility
- Device Use Frequency

Within the database there are 2525 Collective Terms. (This may change as new devices types are added and other obsoleted).

[13] *GMDN Definition "Collective Term": Terms which share common features and are identified in the GMDN and intended to be used for example; 1) To illustrate the scope of certificates issued by Notified Bodies when assessing which groups, families or types of medical devices are covered within a manufacturer's quality system, 2) To be used to identify the range of skills and general technological abilities for which a Notified Body has been approved, and is so appointed by the relevant Competent Authority, and 3) For the exchange of information between Competent Authorities when general information on individual manufacturers capabilities is notified for inclusion in the European Database (EUDAMED). [Source: CEN/TR 15133:2005] www.gmdnagency.org*

When viewed "**By Use**" there are 21 categories, one of which is for IVDs and the rest are for NON-IVDs as noted below:

CT996: Anaesthesia and respiratory devices
CT997: Body fluid and tissue management devices
CT1007: Body tissue manipulation and reparation devices
CT145: Cardiovascular devices
CT343: Complementary therapy devices
CT998: Dental devices
CT1000: Disability-assistive products
CT1001: Ear/Nose/Throat (ENT) devices
CT366: Endoscopic devices
CT1002: Gastro-urological devices
CT149: General hospital devices
CT1004: Healthcare facility products and adaptations
CT954: In vitro diagnostic medical devices (IVDs)
CT202: Laboratory instruments and equipment
CT1005: Neurological devices
CT181: Obstetrical/Gynaecological devices
CT230: Ophthalmic devices
CT1006: Orthopaedic devices
CT275: Physical therapy devices
CT775: Plastic surgery and cosmetic devices
CT999: Radiological devices

This registration call-up plan is only for medical devices used for human use.

Where a medical device may appear within more than one GMDN Collective Term, the requirement for registration will be when the relevant Collective Term is first called-up by SAHPRA.

[Importers, manufacturers and wholesalers of all medical devices (IVDs and NON-IVDs) must be licensed as per Act 101, Section 22C.]

TECHNICAL REQUIREMENTS

The South African regulatory framework for medical devices is based on the principles of expert third party conformity assessment to specified requirements dependent on the risk of the medical device.

It is a requirement of the South African Authorised Representative [AR] to make a legal declaration that the technical documentation submitted for registration of a medical device does conform to all the standards as identified by SAHPRA for the type and risk class of medical device, and that all required evidence to substantiate that the relevant Essential Principles of Safety and Performance are met. It is for the South African Regulatory Authority to review the documentation submitted for relevance and quality prior to adding the specific medical devices to either the IVD medical device register or NON_IVD medical device register.

The Regulatory Authority will review the technical documentation submitted using a pre-determined framework. Such review will include verification of certificates, publications, references included in the technical file submitted by the Applicant.

3. Framework for Review of Applications for Registration

The technical requirements (as aligned to the IMDRF harmonised requirements) and a draft guideline for application for a registration of an IVD and a NON-IVD respectively were published for comment by stakeholders in quarter three of 2017. Comments are still to be reviewed following which there may be amendments to the requirements.

The third-party conformity assessment approach is aligned to that of multiple regulatory authorities, which recognises the work of external technical experts and helps to improve efficiency. This aligns to

a) the principles of global harmonisation where quality standards for accreditation of third party conformity assessment bodies (such as certification bodies and testing bodies) are recognised; and
b) the South African National Accreditation Standards Act (SANAS), implemented by the Department of Trade and Industry (DTI).

SAHPRA will appoint personnel with an understanding of medical devices and specifically either IVDs / medical devices used for cardiology / neurology / ENT etc and they will be trained to understand the conformity assessment requirements[14], the principles of the

[14] MCC 8.03 Conformity Assessment Procedures for Medical Devices and IVDs v1

accreditation of conformity assessment bodies within a conformity assessment framework and relevant regulatory science for medical devices.

While the scope of this document does not address relevant registration application fees for medical devices – it is noted that conformity assessment and certification of the quality management system (as per ISO13485[15]) and testing of products to meet specified standards e.g. sterility testing and performance testing, are significant for manufacturers. Since class C and class D medical devices will inherently require resources to review extensive technical documentation provided to substantiate that the Essential Principles of Safety and Performance are met – it is likely that the registration fee for a class D medical device will be higher than that for a class C medical device, and that in turn will be higher than that for a class B medical device. Therefore, it is likely that the quantum of the fee will be relative to the intensity / weight of the review required.

[15] ISO13485 Third Edition 2016-03-01 Medical devices — Quality management systems — Requirements for regulatorypurposes

4. REGISTRATION CALL UP SEQUENCE

A summary of the registration call-up plan is as follows:

Immediate call-up of all new medical devices, classified as class B or class C or class D. This will identify that as from six months from the date of publication of the declaration, all new medical devices must be registered. This means that within six months of the call-up, no new medical devices of class B, C or class D classification may be sold in South Africa without having made application and received confirmation of registration with SAHPRA. In parallel a call-up plan for medical devices currently sold in the market will be initiated with two “arms” – one for IVDs and the other for NON-IVDs.

Details of the above-mentioned call-up plans are provided below

4.1 NEW MEDICAL DEVICES

A declaration for call up of all NEW class B, class C and D medical devices (IVDs and Non - IVDs) will be published in the national government gazette. This notice will establish that six months from the date of publication of the declaration all new medical devices must be registered.

Each application for a new Class D medical device must include preparation and submission of a complete technical dossier[16], [17] and be accompanied by certified evidence of pre-market approval from at least two (2) of the following jurisdictions

- Australia’s Therapeutic Goods Administration (TGA) i.e. inclusion in the Australian Register of Therapeutic Goods;
- Brazil’s ANVISA (National Health Surveillance Agency) approval and registration;
- Canada’s Medical Device Licence to market;
- The European Union’s CE certificate, to show conformity to all obligations for medical devices as required by the Medical Devices Directives;
- Japan’s Marketing Authorization Holder (MAH) licence;
- USA’s FDA’s Center for Devices and Radiological Health (CDRH) Premarket Approval (PMA) or Premarket Notification 510(k) clearance.
- Evidence of IVDs approved under the World Health Organisation (WHO) Prequalification of In Vitro Diagnostics Programme will also be accepted

[16] ZA_Medical_Device_IVD_Technical_Dossier_Jun17_v1_for_comment.doc August 2017
[17] ZA_Medical_Device_non-IVD_Technical_Dossier_Jun17_v1_for_comment.doc August 2017

Each application for a new Class C medical device must include preparation and submission of a complete technical dossier[18], [19] and be accompanied by certified evidence of pre-market approval from at least one (1) of the following jurisdictions:

- Australia's Therapeutic Goods Administration (TGA) i.e. inclusion in the Australian Register of Therapeutic Goods;
- Brazil's ANVISA (National Health Surveillance Agency) approval and registration;
- Canada's Medical Device Licence to market;
- The European Union's CE certificate, to show conformity to all obligations for medical devices as required by the Medical Devices Directives;
- Japan's Marketing Authorization Holder (MAH) licence;
- USA's FDA's Center for Devices and Radiological Health (CDRH) Premarket Approval (PMA) or Premarket Notification 510(k) clearance.

Evidence of IVDs approved under the World Health Organisation (WHO) Prequalification of In Vitro Diagnostics Programme will also be accepted.

Each application for a new Class B medical device must include preparation and submission of a complete technical dossier [20, 21].

[18] ZA_Medical_Device_IVD_Technical_Dossier_Jun17_v1_for_comment.doc August 2017
[19] ZA_Medical_Device_non-IVD_Technical_Dossier_Jun17_v1_for_comment.doc August 2017

4.2 MEDICAL DEVICES IN THE MARKET

The Registration call-up plan is divided into two “arms” running in parallel;

4.2.1 An IVD Registration call-up plan and

4.2.2 A NON-IVD Registration call-up plan.

4.2.1 In-vitro Diagnostic (IVD) Registration Call-up Sequence

For the IVD medical devices already on the market, refer Collective Term CT954, the call-up priority high level Collective Terms are identified into phases and named alphabetically.

Within each alphabetical phase there will be sub-collective terms prioritised and identified numerically.

Phase A will be initiated first, with call-up of the divisions within Phase A staged at a monthly intervals.

Table 2. CALL-UP SEQUENCE by PHASE - IVDs

		Phase
CT954: In vitro diagnostic medical devices (IVDs)		IVD
	CT350: Analyte assay IVDs	A
	CT383: Electrochemical electrode IVDs	
	CT945: General laboratory ware IVDs	
	CT943: Instrument/Analyser IVDs	
	CT2314: Microbial-isolate IVDs	B
	CT922: Microbiological/Cell culture medium IVDs	
	CT944: Software IVDs	C
	CT936: Specimen receptacle IVDs	

Call-up sequence for IVDs by Collective Terms (by use)

Call up of all *in-vitro* diagnostic (IVD) medical devices within the Collective Term CT350 ANALYTE ASSAY IVDs will be phase A.

Within PHASE A the sequence the first ten categories for call-up will be as follows:

1. CT335 Viral infectious disease IVDs;
2. CT353 Bacterial infectious disease IVDs;
3. CT354 Fungal infectious disease IVDs;
4. CT923 Multiple type infectious microorganism IVDs;

5. CT356 Parasitic infectious disease IVDs;
6. CT825 Prion infectious disease IVDs;
7. CT568 Rapid test IVDs;
8. CT885 Immunohaematology IVDs;
9. CT891 Tissue typing IVDs; and
10. CT902 Human genetics IVDs

For the call-up sequence thereafter - refer to Annexure A.

4.2.2 NON-IVD Medical Device Registration Call-Up Sequence

For the NON-IVD medical devices already on the market, the sequence of call-up for registration of the medical devices will be prioritised as follows;

Phase A. class D medical devices as per Rule 13 and Rule 14 of the SA Classification Guidelines[20];

Phase B. devices for contraception or for prevention of sexually transmitted diseases[21];

Phase C. implants for long term use. i.e. duration of use is more than 30 days[22]; and

Phase D. devices intended for sterilising, disinfecting, cleaning and rinsing another medical device[23]

"Combination medical devices" includes any of the following:

- Medical devices that contain or are made of animal tissues that have been rendered non-viable or derivatives from such tissues also being non-viable, or microbial or recombinant tissues, cells or substances; and
- medical devices that incorporate a medicinal substance including stable derivatives of human blood and blood plasma that assists the function of the device.

The second tier of prioritisation will move to those class C and D medical devices which are used -

i) In direct contact with the cardiovascular system (i.e. the heart & the central circulatory system);
ii) in direct contact with the central nervous system;
iii) for orthopaedic purposes;
iv) for any other purpose; and
v) for cosmetic purposes.

Refer to Table 3. Call-up Sequence NON-IVD medical devices below

[20] MCC 8.05 Classification of Medical Devices and IVDs April17 v2 Rule 13 and Rule 14
[21] MCC 8.05 Classification of Medical Devices and IVDs April17 v2 Rule 16
[22] MCC 8.05 Classification of Medical Devices and IVDs April17 v2 Section 2.7
[23] MCC 8.05 Classification of Medical Devices and IVDs April17 v2 Rule 15.

Table 3. Call-up Sequence NON-IVD medical devices

	A. COMBINATION MEDICAL DEVICES	B. DEVICES FOR CONTRACEPTION OR PREVENTION OF SEXUALLY TRANSMITTED DISEASES	C. LONG TERM IMPLANTABLE D. MEDICAL DEVICES		E. DEVICES FOR STERILISING, DISINFECTING, CLEANING & RINSING ANOTHER MEDICAL DEVICE
Intended Use →	All uses	CT133 Contraception	CT983 Surgical Invasive medical devices	CT984 Non-Surgical invasive medical devices	CT390 Disinfectants; CT391 Sterilants; CT1110 Contact lens solutions
Class →	D	C & D	C & D	C & D	C
Used in direct contact with the Cardiovascular system (i.e. the heart & the central circulatory system).	A1		C1	C2	
Used in direct contact with central nervous system (CNS)	A2		C3	C4	
Orthopaedic Use	A3		C5	C6	
All other uses	A4	B1	C7	C8	D1
Cosmetic Use	A5		C9	C10	

The plan of action for registration call-up of NON-IVD medical devices is noted in ANNEXURE B, assuming first call up is published on 1 July 2018

5. CONCLUSION

The registration call-up for medical devices for human use is addressed in three key sections / arms:

- NEW Medical devices;
- In-vitro diagnostic (IVD) medical devices already on the market; and
- NON-IVD Medical devices already on the market

The sequence of call-up for medical devices already on the market is addressed by use for IVDs, and by type of materials and length of intended use for NON-IVD medical devices.

Finalisation of the technical requirements and the fee structure are critical requirements to be addressed with urgency.

In the interim it is suggested to publish the intended registration call-up plan for stakeholders to view and provide comment within one month.

ANNEXURE A:

Table 1. CALL-UP PHASE A - IVDs

CT954: In vitro diagnostic medical devices (IVDs)				IVD
	CT350: Analyte assay IVDs			A
		CT287: Clinical chemistry IVDs		
		CT869: Clinical chemistry autoimmune IVDs		A15
		CT1236: Clinical chemistry biological screening IVDs		
		CT836: Clinical chemistry electrolyte IVDs		
		CT827: Clinical chemistry enzyme IVDs		A16
		CT850: Clinical chemistry hormone IVDs		A17
		CT889: Clinical chemistry multiple constituent IVDs		A18
		CT974: Clinical chemistry protein IVDs		A18
		CT833: Clinical chemistry substrate IVDs		A18
		CT860: Clinical chemistry therapeutic drug monitoring IVDs		A19
		CT184: Clinical chemistry toxicology/drug detection IVDs		A19
		CT1237: Clinical chemistry trace element IVDs		A19
		CT845: Clinical chemistry tumour marker IVDs		A13
		CT847: Clinical chemistry vitamin and mineral IVDs		A19
		CT806: Haemoximetry and blood gas IVDs		A14
		CT870: Coagulation IVDs		A12
		CT292: Haematology IVDs		A11
		CT901: Histology/Cytology IVDs		A13
		CT902: Human genetics IVDs		A10
		CT885: Immunohaematology IVDs		A8
		CT701: Infectious disease IVDs		
			CT353: Bacterial infectious disease IVDs	A2
			CT354: Fungal infectious disease IVDs	A3
			CT923: Multiple-type infectious microorganism IVDs	A4
			CT356: Parasitic infectious disease IVDs	A5
			CT825: Prion infectious disease IVDs	A6
			CT355: Viral infectious disease IVDs	A1
		CT568: Rapid test IVDs		A7
		CT891: Tissue typing IVDs		A9

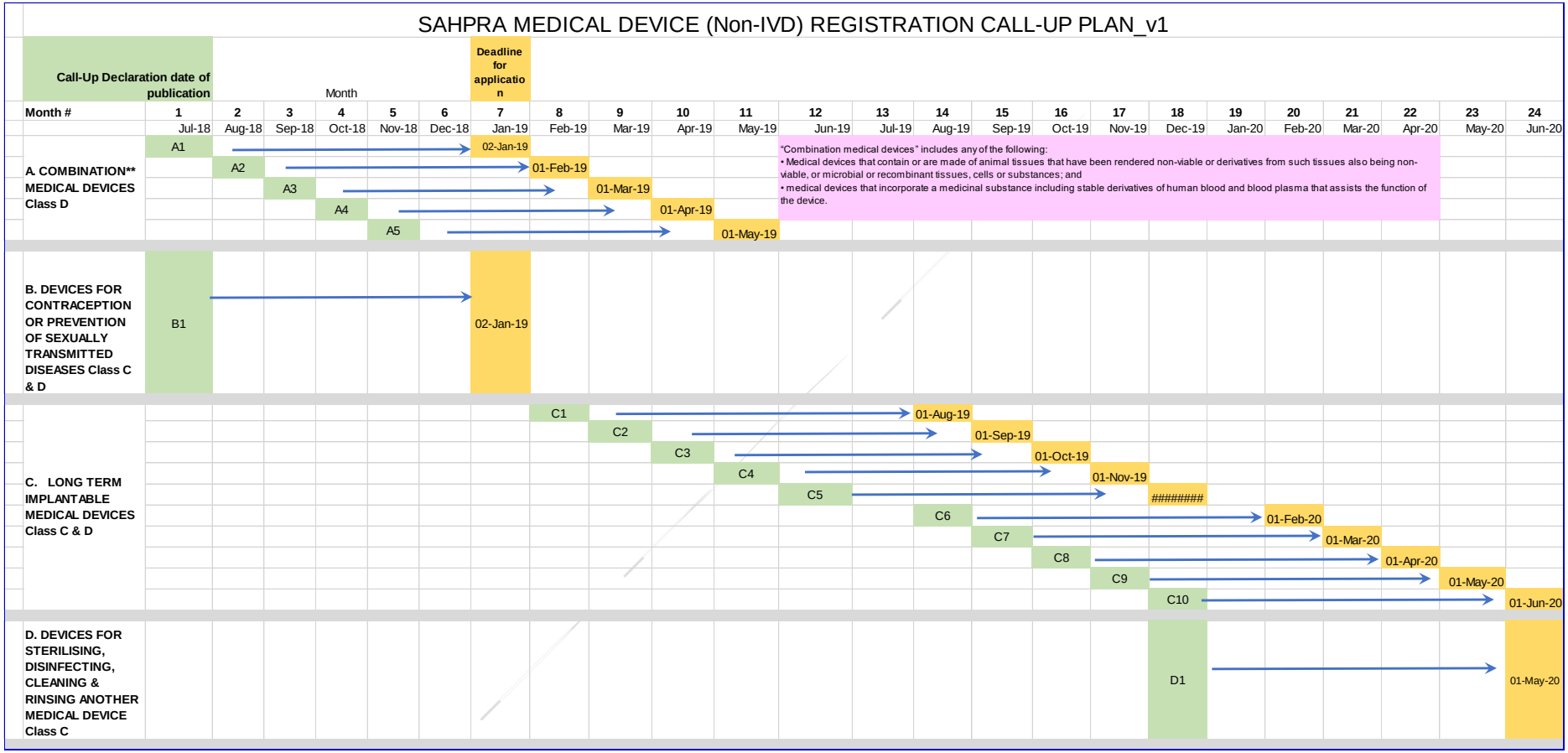
Table 2. CALL-UP PHASE B - IVDs

CT2314: Microbial-isolate IVDs			**B**
	CT1260: Antimicrobial susceptibility testing IVDs		**B1**
		CT750: Antimicrobial minimum inhibitory concentration (MIC) IVDs	**B1**
		CT942: Antimicrobial susceptibility testing disc IVDs	**B1**
	CT1261: Microbial-isolate identification and testing IVDs		**B2**
		CT2332: Differentiation disc IVDs	**B2**
		CT2236: Microbial-isolate agglutination IVDs	**B2**
		CT839: Microbial-isolate identification and antimicrobial susceptibility testing	**B2**

Table 3. CALL-UP PHASE C - IVDs

CT944: Software IVDs		**C**
	CT1250: Analyser software IVDs	**C1**
	CT910: Interpretive software IVDs	**C2**
	CT1251: Laboratory information system software IVDs	**C3**

ANNEXURE B: CALL UP PLAN NON-IVD MEDICAL DEVICES



6. UPDATE HISTORY

Date	Reason for update	Version & publication
February 2018	First draft for Medical Device Committee	v1