Medical Device Regulatory Roadmap

SAMED Conference

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Registrar of Medicines

Status in RSA: 2 December 2015

Legislation: Bill 6D, 2014

- Defines MD and IVDs
- Licensing of Manufacturers, Importers, Wholesalers and Distributors
- Registration: MD, IVD
- Regulations: regulatory oversight
- Guidelines

Regulatory office

- Establish Medical Device office
- Establish MD Expert Committee on MCC
- Appoint MD staff
- Radiation officers part of office
- SANAS accreditation

Definition of Medical Device: Bill 6D, 2014

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) —

(a) 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

(b) 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

Definition of IVD: Act 72, 2008

IVD *(in-vitro* diagnostic)

means a medical device, whether used alone or in combination, intended by the manufacturer for the *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes’’

Definition of Establishment: Act 72, 2008

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;

Combination Medical Devices

Combination of medical device and medicinal product

- Where a device is intended to administer a medicinal product, that device shall be governed by the Regulations on Medical Device
- Where a device is placed on the market in such way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by the Regulations on Medicines i.e. Pre-filled syringe, e.g. single-dose vaccine

Key players in the MD and IVD arena

- Competent Authorities
- Notified Bodies (Conformity Assessment Bodies)
- Manufacturers
- Authorized representative
- National Regulatory Authority (MCC, SANAS)

Who is responsible for what

Shared responsibilities between:

- **Manufacturers (Importer/Distributor)**
- **National Competent Authorities: MCC and SANAS**
- **Notified Bodies (NB)**

- Manufacturers responsibility:
  - Quality and Risk Management
  - Liaise with Competent authority and Notified bodies
  - Design, manufacture, packaging & labelling , name and address on MD label
  - conduct of conformity assessment procedure
  - keep technical files/design dossier available
  - vigilance and post-market surveillance procedures
  - issues Declaration of Conformity
  - Appointment of Authorized Representative

Who is responsible for what …cont

- National Competent Authorities
  - Designation of Notified Bodies
  - Perform market surveillance
  - Identify standards
  - Approve clinical studies
  - Conduct inspections
- Notified Bodies evaluate:
  - Pre-market assessment of MD (evaluate product)
  - Medical devices safety, quality and performance
  - Audit manufacturers and evaluate quality system
  - Issue conformity certificates (i.e. SABS certificate)

Authorised Representative

any natural person, resident in the Republic of South Africa,

- who has the written mandate to represent a manufacturer, importer, distributor, wholesaler, retailer or service provider in the Republic and
- to act on his or her behalf for specified tasks with regard to the latter's obligations and
- who has submitted an application for the registration of a medical device or IVD and
- in whose name the manufacturer licence, wholesaler licence and or certificate of registration is issued.

The authorised representative is responsible for all aspects of the medical device or IVD, including quality, safety and compliance with conditions of registration

Roadmap on Regulatory oversight of Medical Devices & IVDs

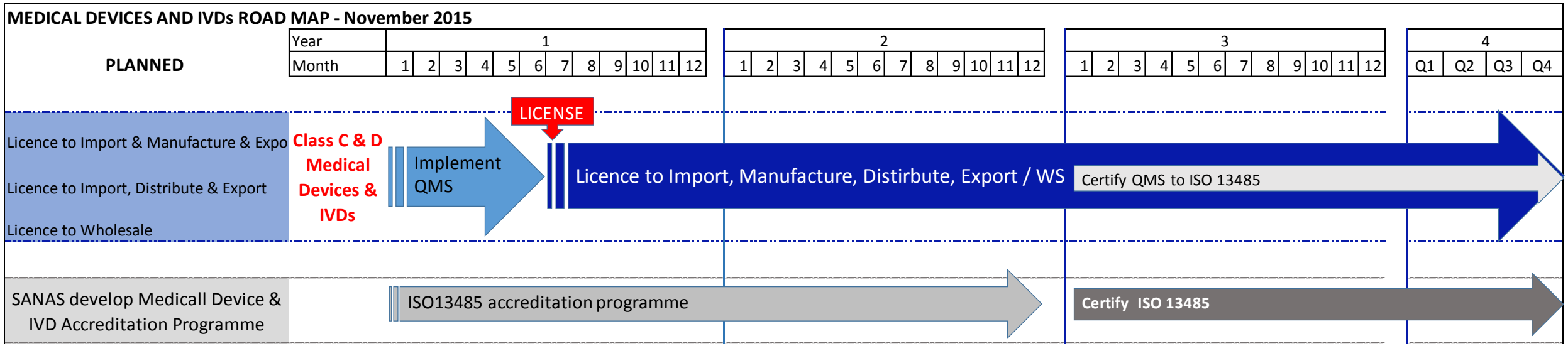
Two key pathways:

1. License to import, manufacture, distribute or export medical devices and IVDs
   - Act 101 Section 22C (1)b
2. Registration of medical devices and IVDs
   - Act 101 Section 14 read with Section 15
   - Act 101 Regulations addressing MD and IVDs
   - Guidelines addressing regulatory oversight of MD and IVDs

First priority: License

- Implement Quality Management System for License to Import, distribute & export medical devices & IVDs;

- SANAS develop Medical Device & IVD Accreditation Programme



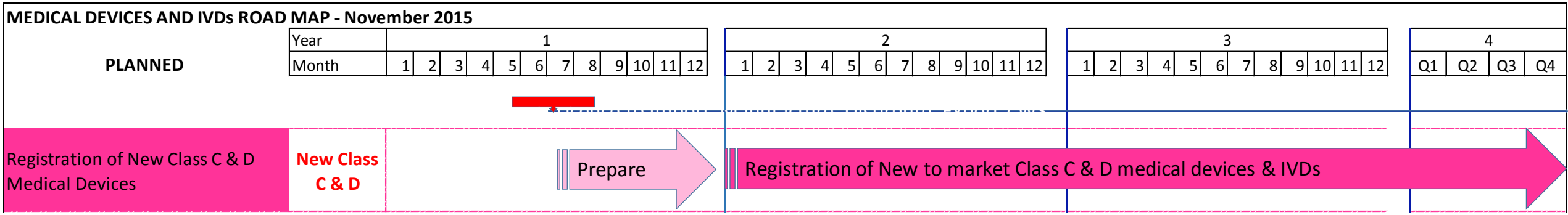
Requirements for License to import

- **Class C & D products**
  - Pre market approval / registration in one or more of following jurisdiction:
    - Australia - TGA
    - Brazil - ANVISA
    - Canada - Health Canada
    - Europe – CE
    - Japan - MAH
    - United States America CDRH - PMA or 510k

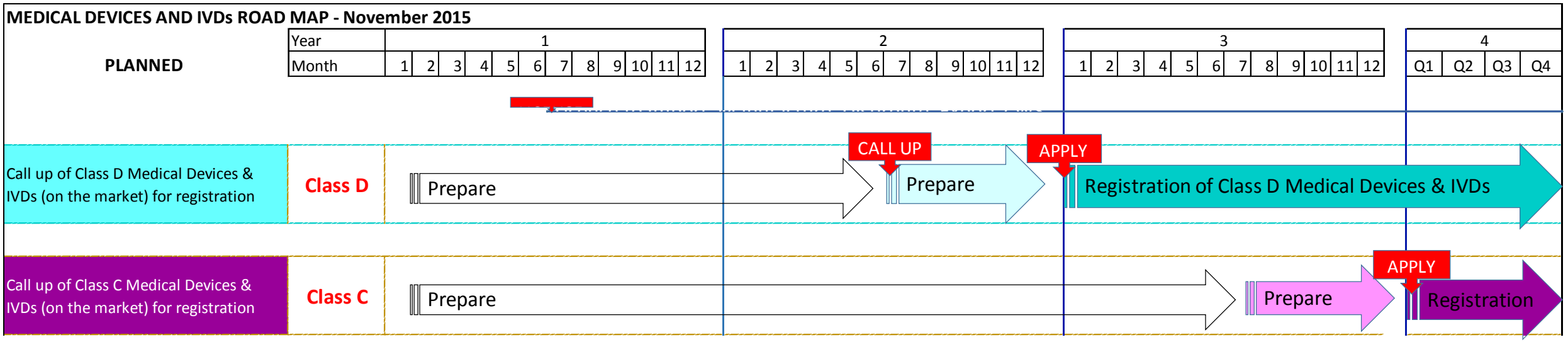
    = “Originating approval/s”

  - Certificate of Free Sale
  - Summary Technical Documents (STeD) for Class C and Class D medical device & IVD.
  - Where relevant, certificate of conformance / analysis
  - Quality Management System

Registration of NEW devices: Class C & D medical devices & IVDs

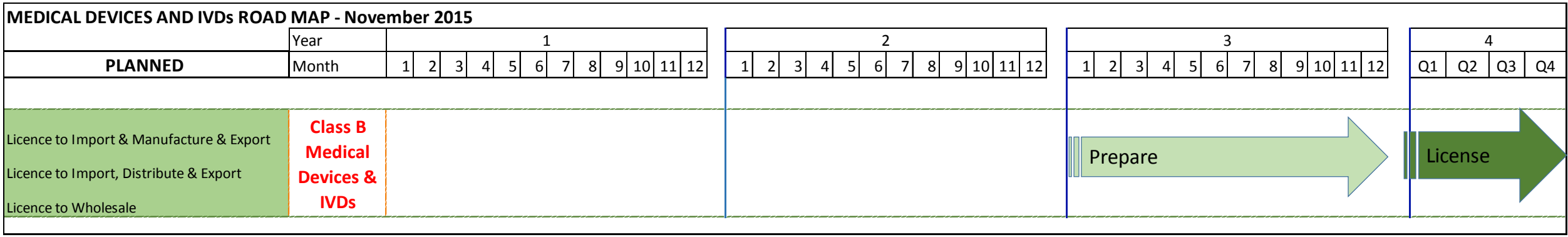


Call up categories of Class D & then Class C medical devices & IVDs (currently on market)

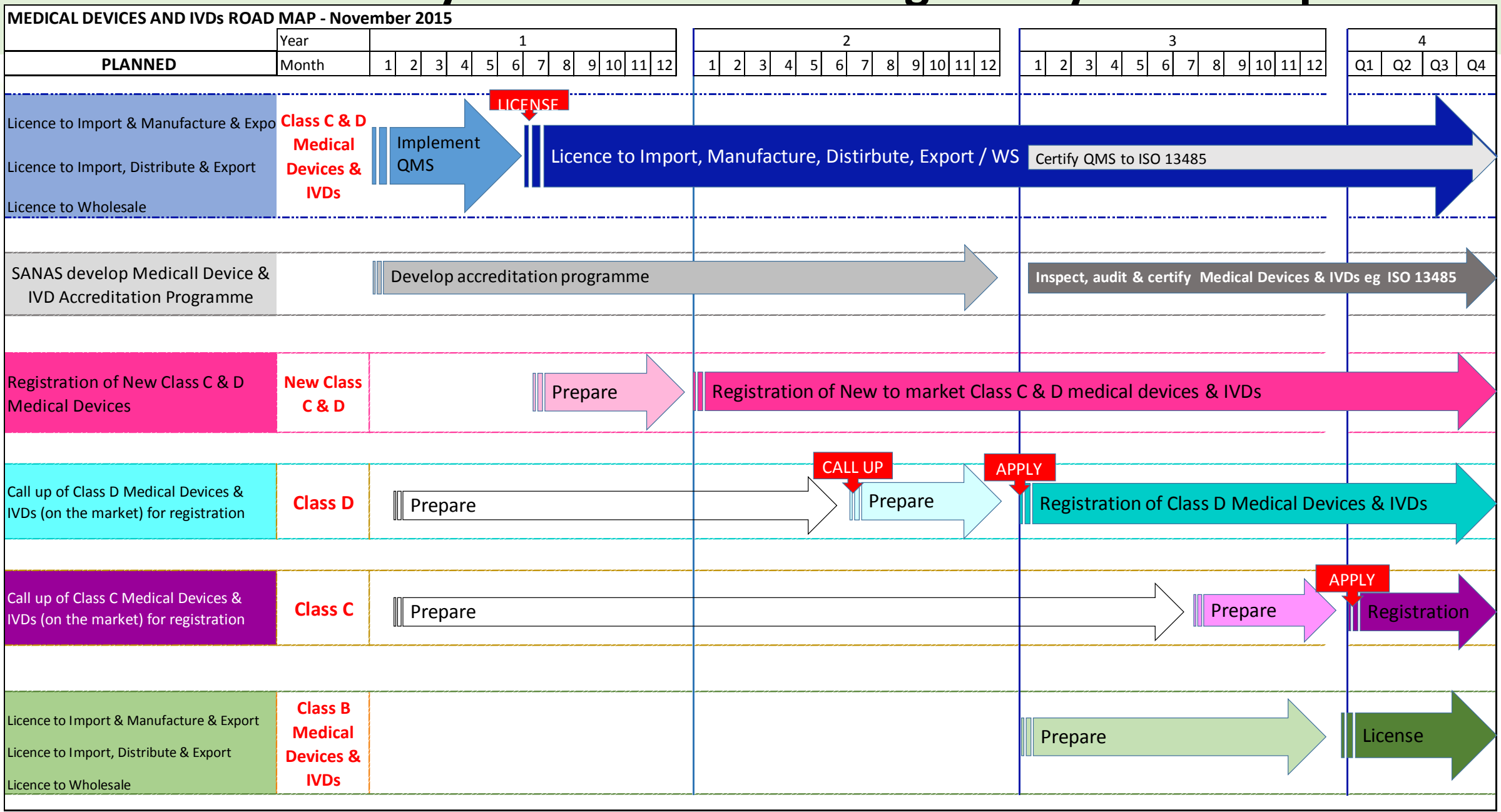


Medical Device Regulatory Road Map …cont
Class B

- License to import, manufacture, distribute & export or wholesale Class B Medical Devices & IVDs



Summary: Medical Device Regulatory Road Map



Roadmap for the Regulator

Four key pathways:

1. Finalise SANAS agreement / MoU
   - SANAS to develop accreditation scheme for MD and IVDs
2. Establish Regulatory office for MD and Expert Committee of MCC
   - Regulatory staff appointed
   - Guidelines finalised and implemented
   - Contact and finalise Global Medical Device Nomenclature (GMDN) access
3. Legislation
   - Enact Bill 6/2014 and Act 72 /2008
   - Act 101 Regulations addressing MD and IVDs
   - Fees published for comment and implementation
4. Personnel competency and training
   - Reviewer, External experts
   - Collaboration and leveraging