

UPDATE: Regulatory Framework for Medical Devices in South Africa

Africa Health

30 May 2019

Andrea Keyter

Deputy Director: Medical Devices



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

LICENSING OF MEDICAL DEVICES



LIST F LICENCE
HOLDERS

AMENDMENTS



1 SEPTEMBER
2019

FEES

**MEDICINES
SEPTEMBER
2015**

**MEDICINES
24 MAY 2019**

**MEDICAL
DEVICES
?**

**RETENTION
FEES:
PAYABLE 30
JUNE 2019
R 4000**



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REGULATORY AUTHORITY

REGISTRATION OF MEDICAL DEVICES

Regulations

Fees

Guidelines

Capacitate MDU

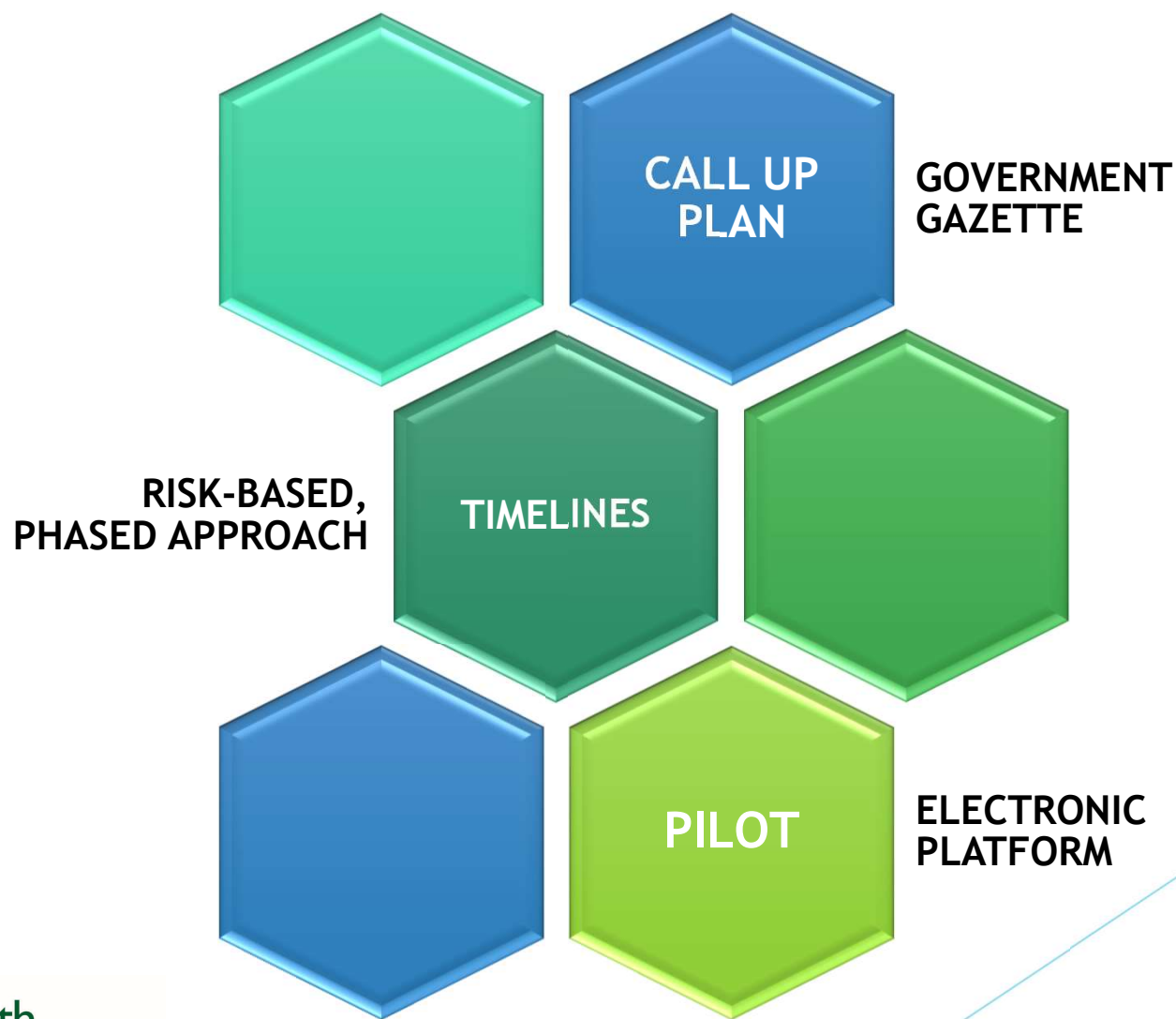


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REGISTRATION OF MEDICAL DEVICES



DELIVERIES, COLLECTIONS AND ENQUIRIES

- ▶ Deliveries of licence applications must be made to the SAHPRA Reception located at:

CSIR, Building 38A, Meiring Naude Road, Brummeria, Pretoria

- ▶ Licence collections will be facilitated by appointment only.
- ▶ Enquiries regarding licence collections and appointments for licence collections may be made through the following contact:

June Searela (june.searela@sahpra.org.za); 012 842 7580

- ▶ Please note that no walk-ins will be permitted.
- ▶ Enquiries regarding medical device establishment licences via email are preferred and may be directed to the following contacts:

012 842 7580 / 012 842 7585

- ▶ Telephone enquiries may be made:

Monday - Friday from 10:00 - 12:00 and 15:00 - 16:00



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CONTACT DETAILS

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- ▶ Geena Le Roux - Geena.Leroux@sahpra.org.za
- ▶ June Searela - June.Searela@sahpra.org.za

- ▶ 012 842 7580
- ▶ 012 842 7585



Thank You

