Regulatory update
Sultanate of Oman

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Director , Medical Device Control

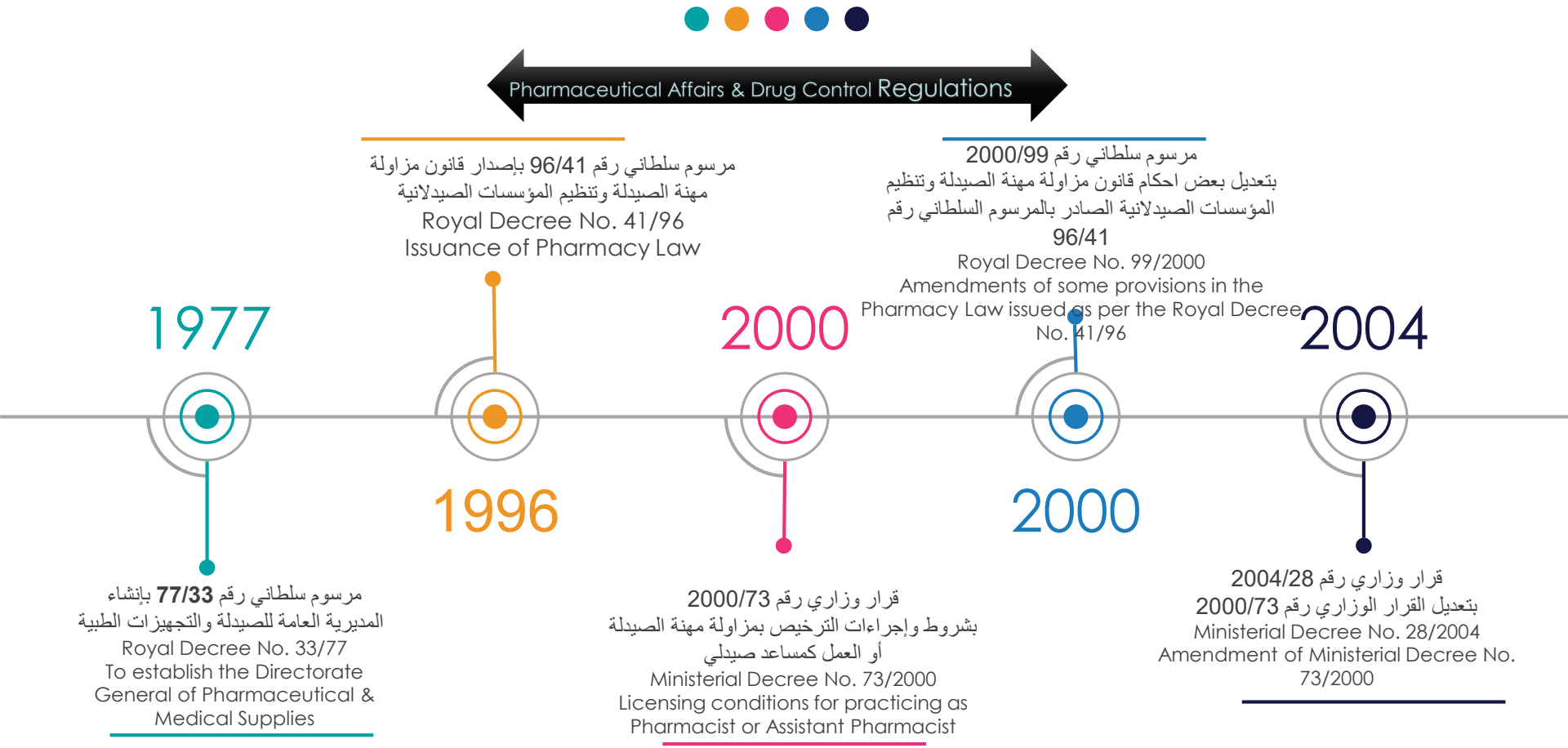
Ministry of Health

Directorate General of Pharmaceutical and Drug control

AHWP 2019 11-14 November 2019 Muscat , Oman

- Oman regulatory time line
- Medical Device Dept.
- Achievement
- Challenges
- Plan of Action

The development of the regulation time line in Oman



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Royal Decree 35/2015 promulgates the Law on Regulating the Profession of Pharmacist and Pharmaceutical Establishments

مرســوم ســلطاني

رقـم ٢٠١٥/٣٥

بإصدار قانون تنظيم مزاولة مهنة الصيدلة والمؤسسات الصيدلانية

نحن قابوس بن سعيد سلطـان عمـان

بعد الاطلاع على النظام الأساسي للدولة الصادر بالمرسوم السلطاني رقم ٩٦/١٠١ ،

وعلى قانون مزاولة مهنة الصيدلة وتنظيم المؤسسات الصيدلانية الصادر بالمرسوم السلطاني رقم ٩٦/٤١ ،

وبعد العرض على مجلس عمان ،

وبناء على ما تقتضيه المصلحة العامة .

رسمنـا بمـا هـو آت

المـادة الأولـى

يعمل بأحكام قانون تنظيم مزاولة مهنة الصيدلة والمؤسسات الصيدلانية المرفق .

المـادة الثانيـة

ينشر هذا المرسوم في الجريدة الرسمية .

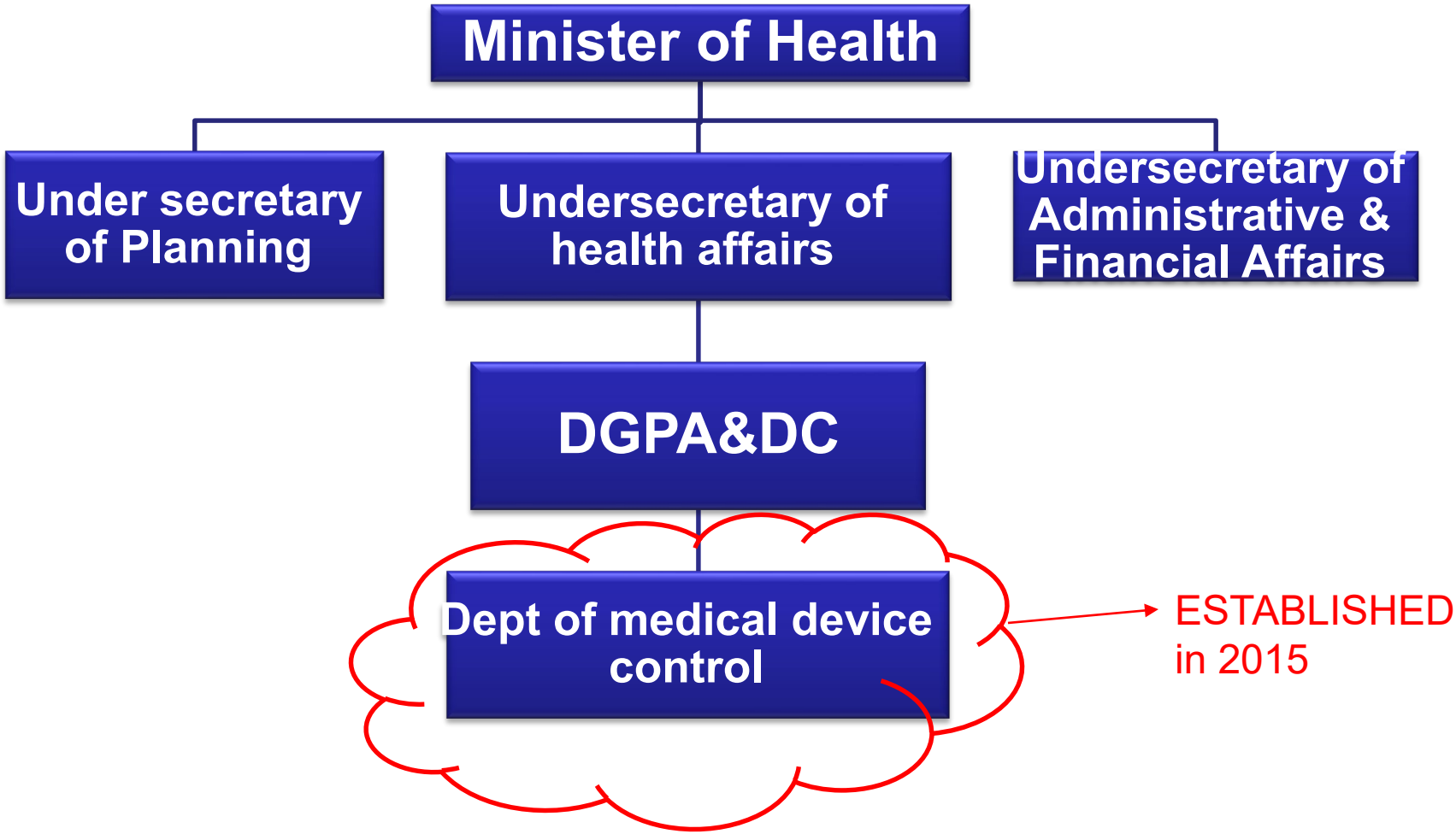
صدر في : ٢١ من ذي الحجـة سنـة ١٤٣٦هـ

الموافـق : ٥ من أكتوبـــر سنـة ٢٠١٥م

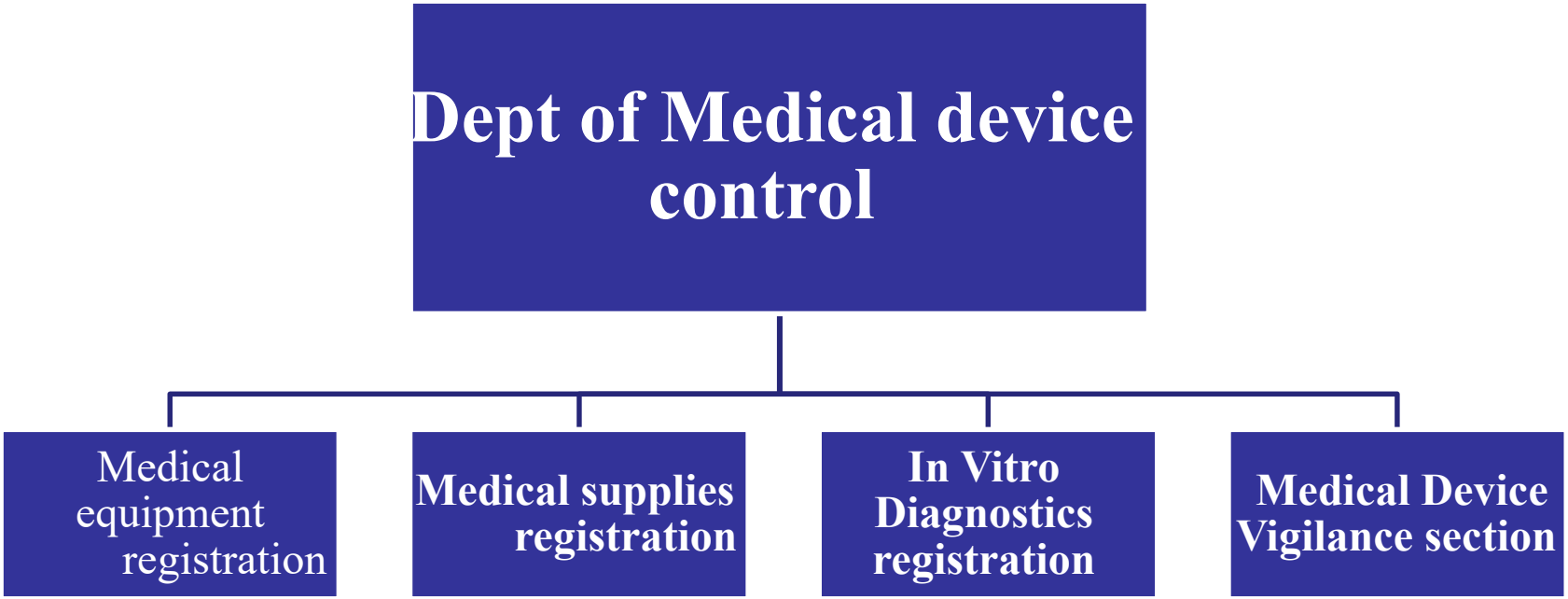
قابوس بن سعيد

سـلطـان عمـان

Addition to the Organizational chart



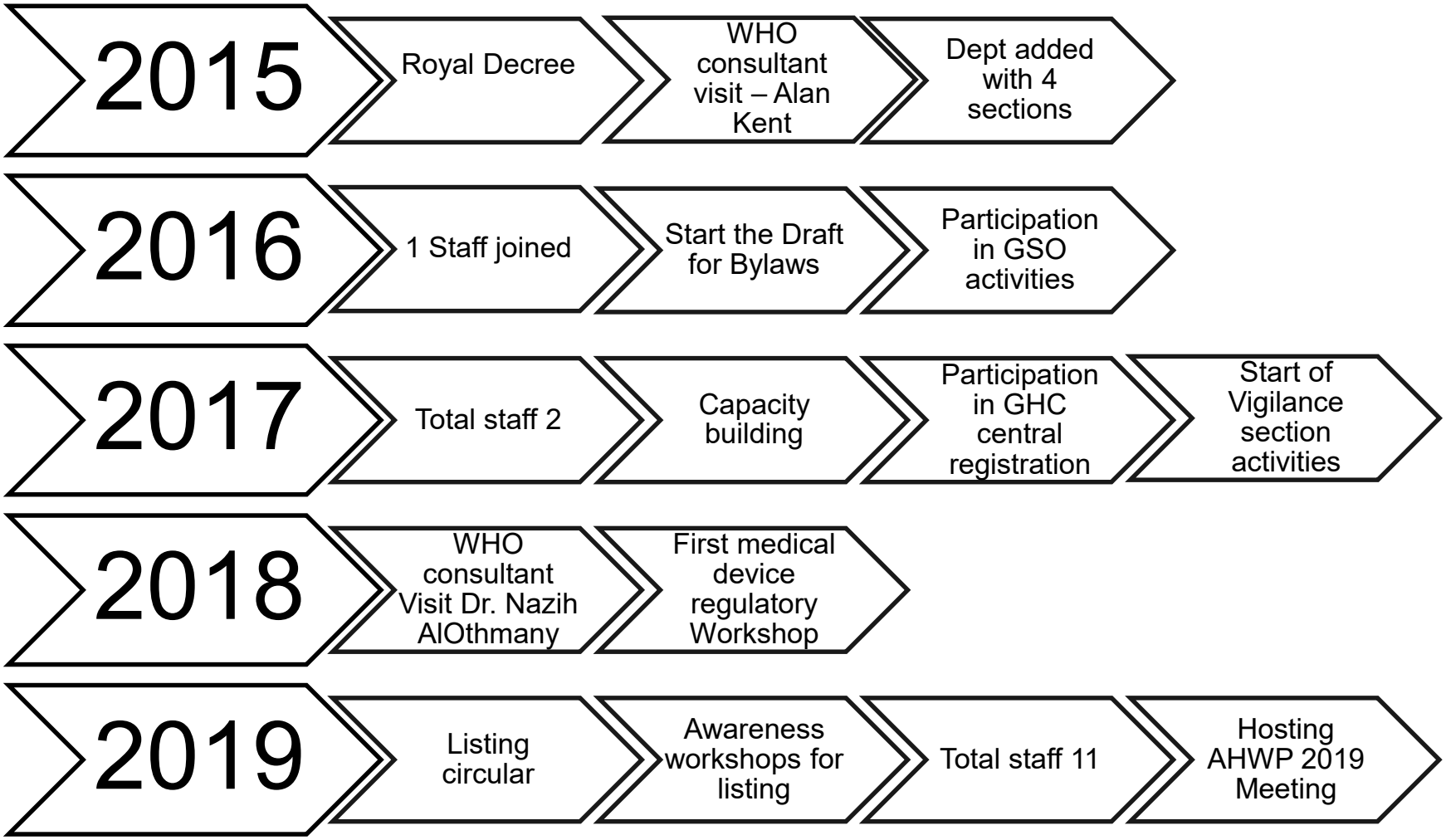
Organogram of the Directorate sections



Role of the Directorate of medical device control in Ministry of Health

- Pre market control for medical devices.
- On market control of medical devices
- Post market control of medical devices.

Medical Device dept. time sequence



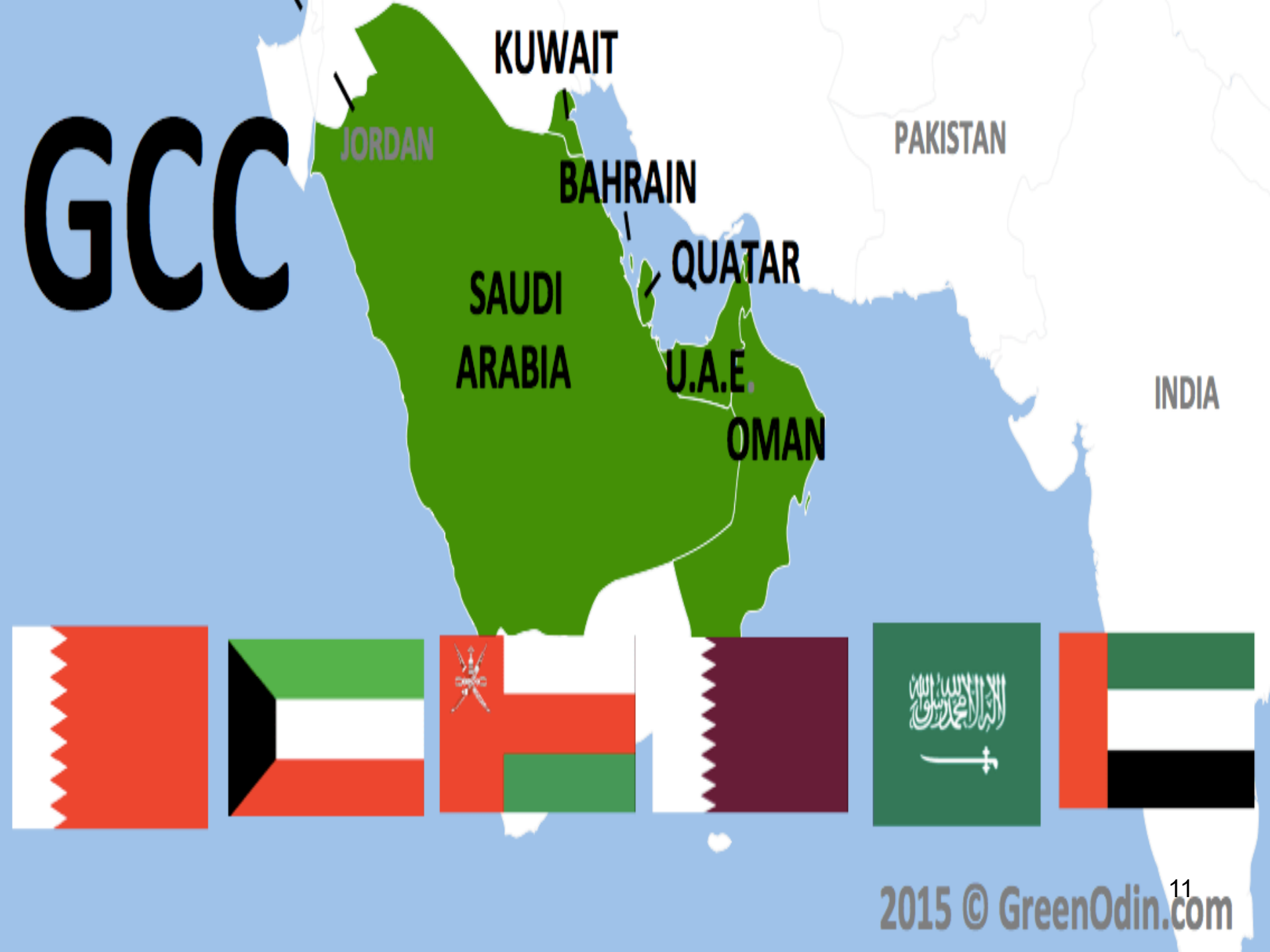
Dept. Achievements

- Started the listing and creation of MD Database in Oman in 2019

- Part of Medical Device registration committee

- Which Consist of GCC member states (Kingdom of Saudi Arabia, Bahrain, Qatar, UAE, Oman, Kuwait and Yemen)

مجلس الصحة
لدول مجلس التعاون
Gulf Health Council


GCC
KUWAIT
JORDAN
PAKISTAN
BAHRAIN
QUATAR
SAUDI
ARABIA
U.A.E.
INDIA
OMAN
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- The main purposes of Medical device central registration committee :
- Harmonized Registration for medical devices centrally among GCC countries.
- Harmonizing classification rules for medical devices between GCC countries
- Harmonized bylayws
- Ease of access to the GCC market

- Close Cooperation in many MD fields.

- Receiving Post market surveillance reports through the NCMDR system

- 2 consultancy project
- awareness Workshops
- Close Cooperation and follow-up

World Health Organization

- Members in ISO TC 210 and TC 121

- Part of TC-11 GCC committee for Medical Devices.

- Role Of recognizing International standards

هيئة التقييس

لدول مجلس التعاون لدول الخليج العربية

GCC Standardization Organization


SFDA
الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority


مجلس الصحة
لدول مجلس التعاون
Gulf Health Council


Republic of Turkey
Ministry of Health
Medicines and Medical
Devices Agency of Turkey


ISO
International
Organization for
Standardization


AHWP
ASIAN HARMONIZATION
WORKING PARTY


World Health
Organization


GSO
هيئة التقييس
لدول مجلس التعاون لدول الخليج العربية
GCC Standardization Organization

Challenges

- Moving from unregulated market to regulated market .
- Lack of awareness in MD regulations from all types of stakeholders.
- Non availability of MD consultants for Medical Device companies in Oman.
- Lack of licensing system for Biomedical Engineers/Technicians.

Plan of Action

1. List Medical Device and Establishment
2. Start Import Controls
3. Prevent non licensed companies and products from entering into ALL healthcare facilities tenders. (give grace period of 6-8 months)
4. **Reject non licensed companies and products** from entering through the ports of entries. (give grace period of 6-8 months)

Plan of Action

- Continue Awareness on Regulation and plan Multiple workshop in this regards

- Engage with other National Regulatory Authorities to maximize benefits, share knowledge and exchange expertise.
- Building capacities for newly joined regulators

Thank you