Presentation to Parliamentary Portfolio Committee on Health

Bill 6 of 2014

Medicines and Related Substances Amendment Bill

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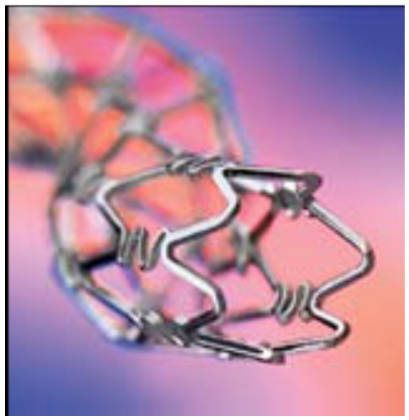
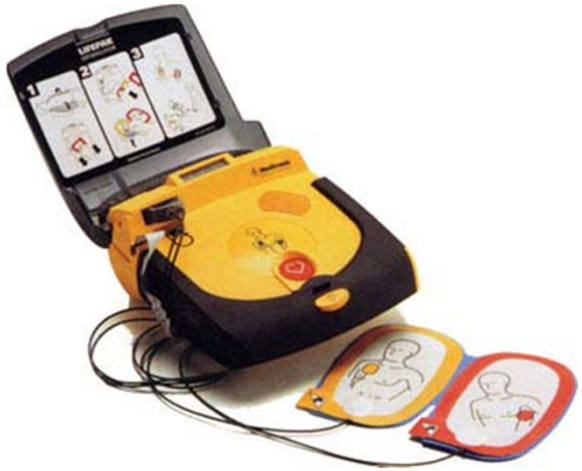
South African Medical Device Industry Association

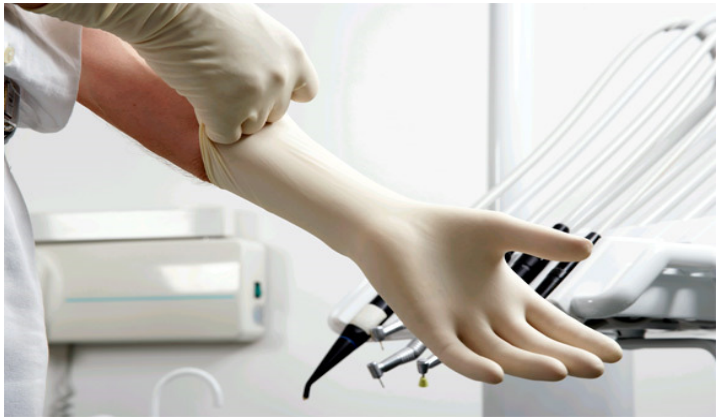
29 October 2014

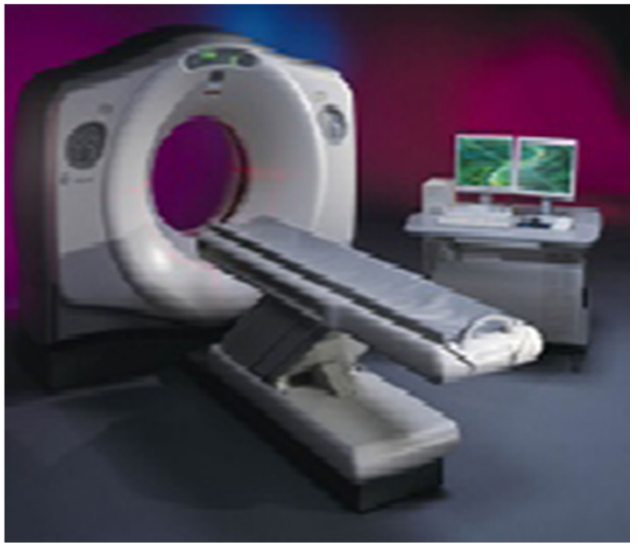
- SAMED is a trade association that represents the interests of a large proportion of manufacturers and importers of medical devices (> than 160)
- SAMED strongly supports a legislative framework that ensures that South African patients have access to medical devices that are safe, effective and of good quality
- **SAMED is concerned that Bill 6, if not amended, will have unintended consequences for the access to medical devices by South African patients**

Medical Devices – a wide variety of products









Medical devices are varied - appropriate regulation is therefore complex

± 1780 Medical devices introduced monthly in SA

(MediKredit 2014)

± 250 000 Medical devices available in SA

(MediKredit 2014)

± 500 000+ medical technologies, in 20 000 generic groups Eucomed 2014

South Africa must ensure it harmonises with international regulatory best practices

Differences in Medicine and Medical Devices

MEDICINES

- **Discovered**
- **Stable formulation developed**
- **Highly mechanised manufacture**
- **Consumed by use**
- **Systemic toxicity**
- **Large populations of exposure**
- **High % of self administration**
- **Patient may choose to stop use**
- **Use Medical Devices for administration (Needles & Syringes or Asthma pump)**

MEDICAL DEVICES

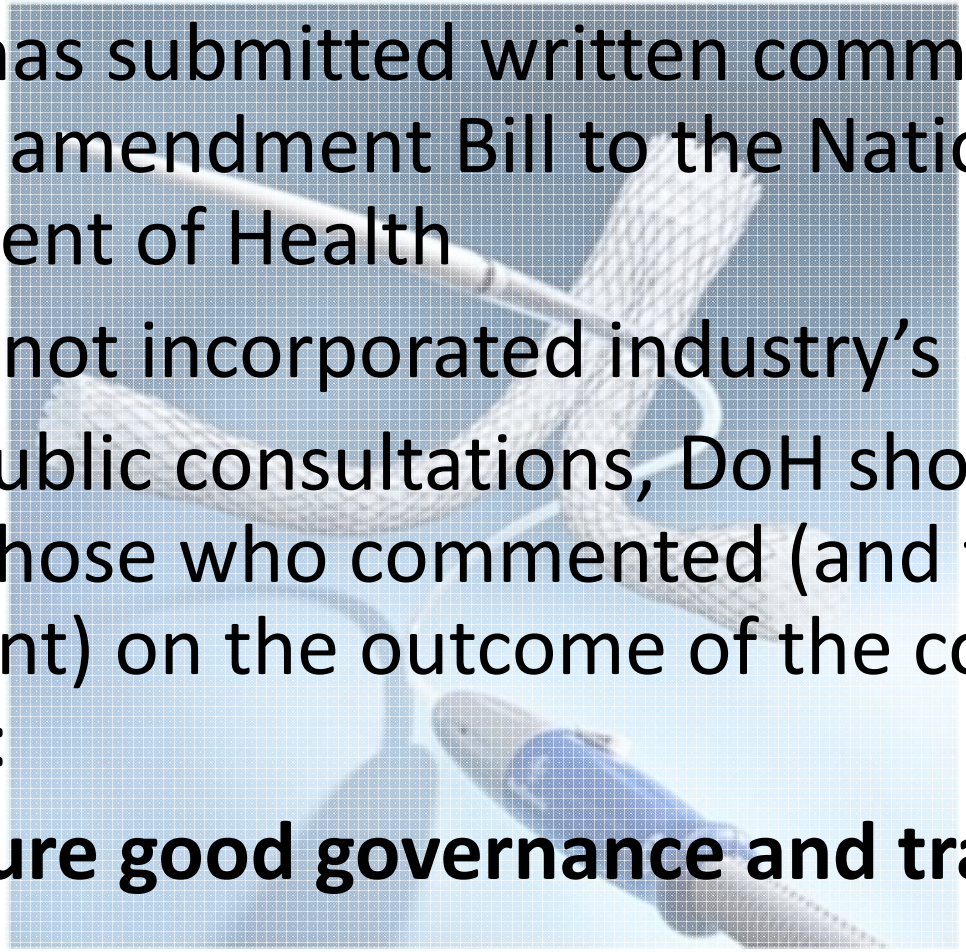
- **Designed**
- **Constant improvements or changes**
- **Often manufactured by hand operations**
- **Available for study after use**
- **Adverse events most often local in nature**
- **Relatively limited populations of exposure**
- **Mostly intended for professional use**
- **Self use mostly intended for monitoring**

It is crucial that industry has an opportunity to workshop the law line by line with the DOH

Approval of this Bill as it stands will introduce flaws into the law governing health products which will may have undesirable consequences for access of patients to medical devices and IVDs.

- Technical flaws
- Unclear composition of SAHPRA
- Capacity and Expertise
- Misalignment between Bill / Regulations / Guidelines
- Opens department to legal challenges

Difficulties with the public consultative process on the previous amendment Bill :



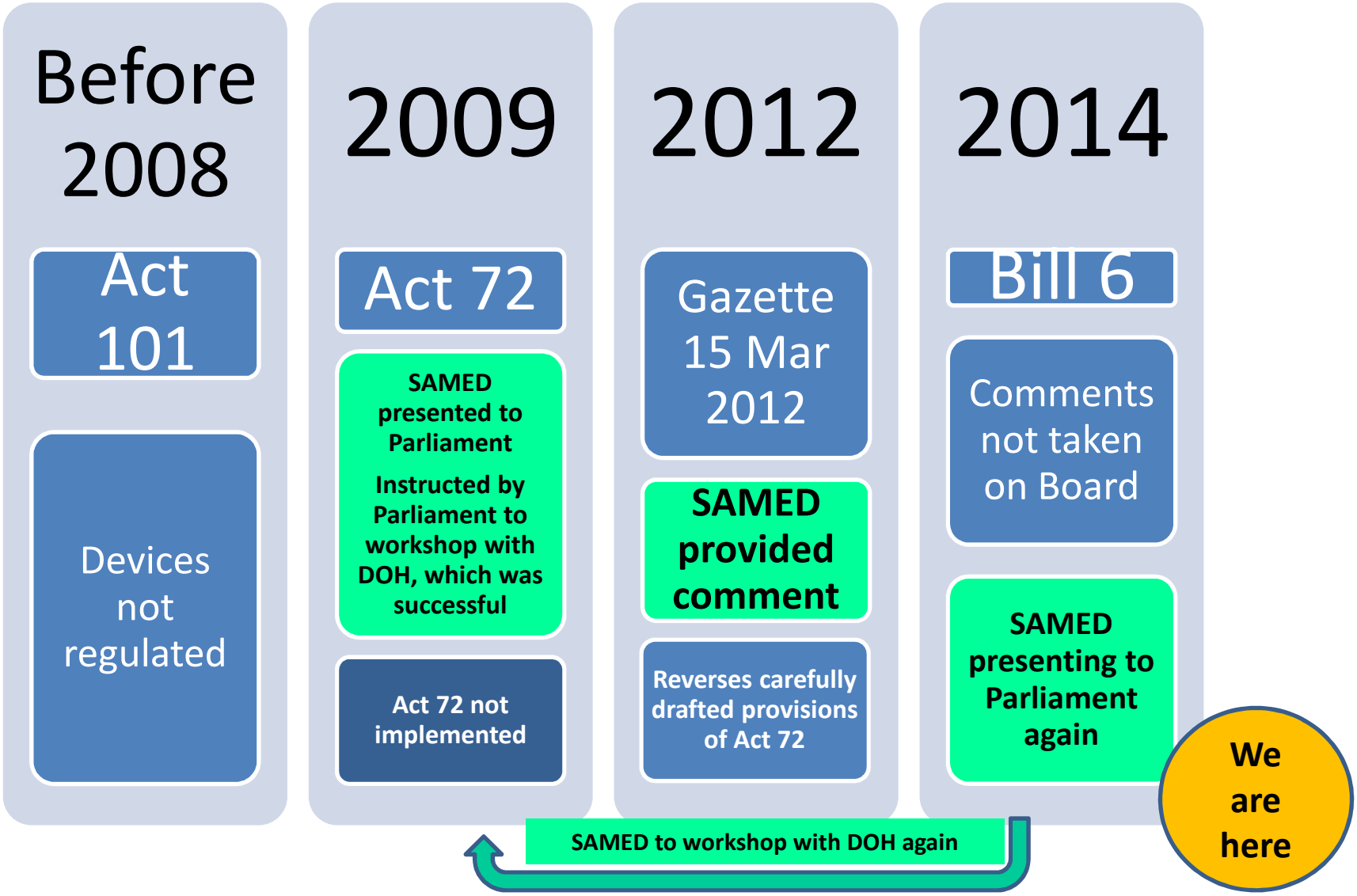
SAMED has submitted written comments on the previous amendment Bill to the National Department of Health

DoH has not incorporated industry's comments

During public consultations, DoH should report back to those who commented (and to Parliament) on the outcome of the comments supplied:

- **to ensure good governance and transparency**

Changes to Medical Device Legislation 2008 – 2014:

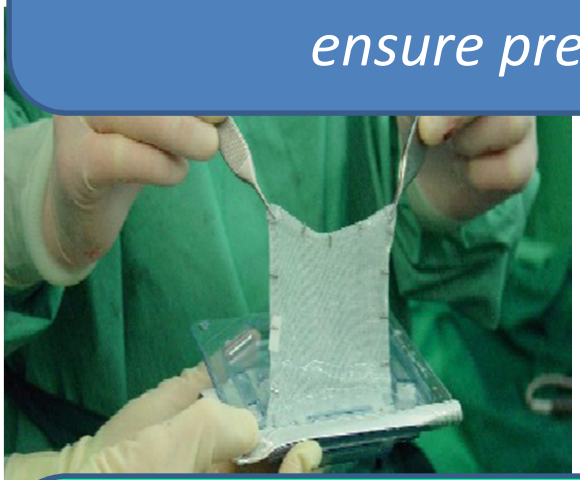


Bill 6 of 2014: Main Concerns

#1. Replacement of “products” with “medicines and scheduled substances” throughout the Bill - **s1 and throughout the Bill**
#2. Erroneous inclusion of Medical Devices and IVD’s under clauses that previously only pertained to Medicines-**s2B (f); s16; s18; s22As22B; s22C; s22H; s28; s29; s21; s35**
#3. Criteria for evaluation of medical devices and IVD’s remain aligned with medicines (Conformity Assessment Bodies, Essential Principles of Safety and Performance, labeling, use of scheduling, and supply chain differences are not taken into account) -**s2B, s15; s16; s 22H**
#4. Medical devices registered via other local regulatory bodies are not accommodated
#5. Overlap and conflicts with existing legislation not taken into account
#6. Grandfathering/sunsetting clauses and transitional period not provided for
#7. Health Economic Policy and Registration do not belong in the same Act - **s36**

Concern # 1: Registration of Scheduled Substances

From the Department of Health's presentation to Parliament, 3rd September 2014: *Bill 6 is necessary to replace the word "products" with "medicines and scheduled substances" to ensure precision and technical correctness.*



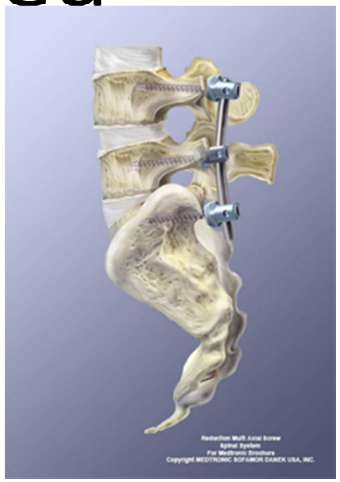
It is SAMED's view that inclusion of "scheduled substances", which appears throughout the Bill, is inappropriate in certain sections and will create confusion.
The result will be the opposite of precision and technical correctness.

Concern # 1: Registration of Scheduled Substances

Scheduled substances should not be subject to separate registration because:

- they are ingredients /components of products and are not sold as stand-alone items
- medicines, medical devices, *in-vitro* diagnostics, etc.. that contain scheduled substances are sold to appropriate users (not directly to the patient)
- the reference to “scheduled substances” will drag medical devices, *in-vitro* diagnostics, etc. into inappropriate medicine registration and regulatory requirements
- The quantity, purpose and effect of scheduled substances on a medical device is not the same as a therapeutic dose found in a medicine

Proposed registration of Scheduled Substances will result in:



- The opposite of precision and technical correctness
- Double registration for some products
- Inefficiencies, backlogs in registrations
- Categories of products other than medicines will:
  - Need a responsible dispensing pharmacist
  - Be subject to single exit pricing
  - Require special labelling
  - Require licensing of premises as a pharmacy

Stand-alone registration of scheduled substances -regulated as what? Medicine? Medical Device?

The changes to Bill 6 have not been thought through.
The only remedy is for industry stakeholders and the DoH to review the law line by line and have open discussions about the effects of the changes to the law on the supply of medical devices.
Parliamentary approval of the Bill as it stands should not be considered.

Concern # 1

Concern #2: Erroneous inclusion of Medical Devices under clauses that previously only pertained to Medicines

Unintended consequences

- Need a responsible dispensing pharmacist for devices

(imagine a Pharmacist ‘dispensing’ an x-Ray machine)

- Be subject to single exit pricing
- Require special labelling, package inserts, etc.
- Require licensing of premises as a pharmacy
- Be subject to medicine supply chain requirements for wholesalers

- Review sections 18, 22A, 22C, 22H, 35

Proposals for Control of Medicines, Medical Devices

- Separate the control of MDs & IVDs from Medicines
- Supply Chain is very different from Medicines
- Medical Devices are distributed to Health Care Establishments / Professionals except for low risk classes as is the case with Medicines.
- Medical Devices should not be subject to Pharmacist control
- Medical Devices are out of scope of practice/training of Pharmacists
- Combination Medical Devices are sufficiently controlled under HCP
- Unlike Medicines, majority of Medical Devices are used under the care of a HCP in a “clinical setting”.
- Medicines on the other hand are taken at home under self administration.
- Make provision for those products that sit on the fence where dual registration may be required

Concern #3: Criteria for evaluation of medical devices and IVD's remain aligned with medicines

International Best Practices

Evaluation of medical devices makes use of accredited Conformity Assessment Bodies

- Reduces the need for costly government bureaucracy
- Flexible, to accommodate rapidly changing technologies
- Harmonised internationally

Medical Devices are checked against Essential Principles of Safety and Performance, not medicines criteria

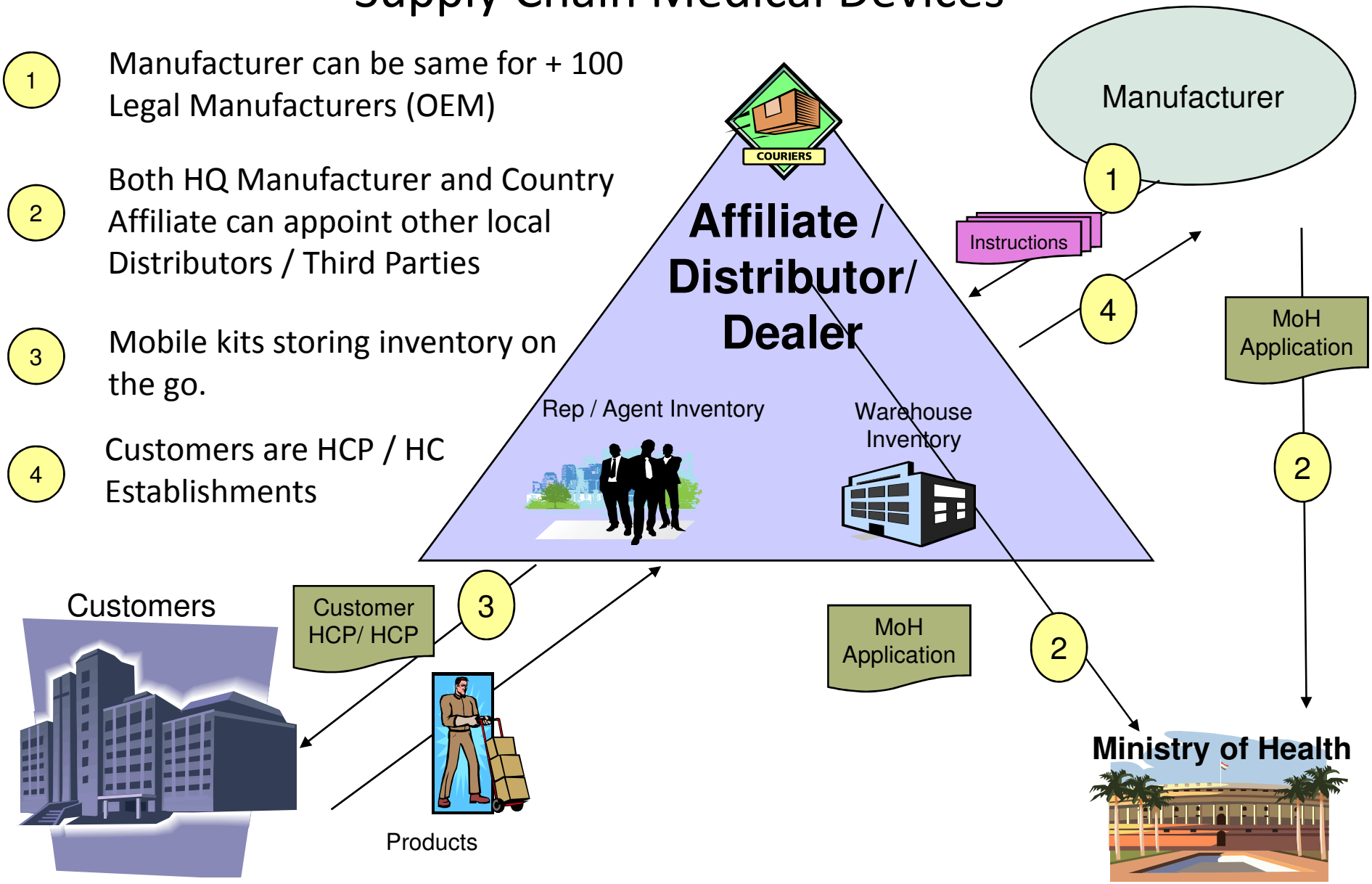
Medical Devices have international standards for labelling and Instructions for Use, which differ from requirements for medicines

Medical Devices are not scheduled, **nor should their components be scheduled** – this does not occur anywhere else in the world

Medical devices are not supplied via wholesalers and do not follow the typical medicines supply chain, therefore cannot be regulated similarly

Supply Chain Medical Devices

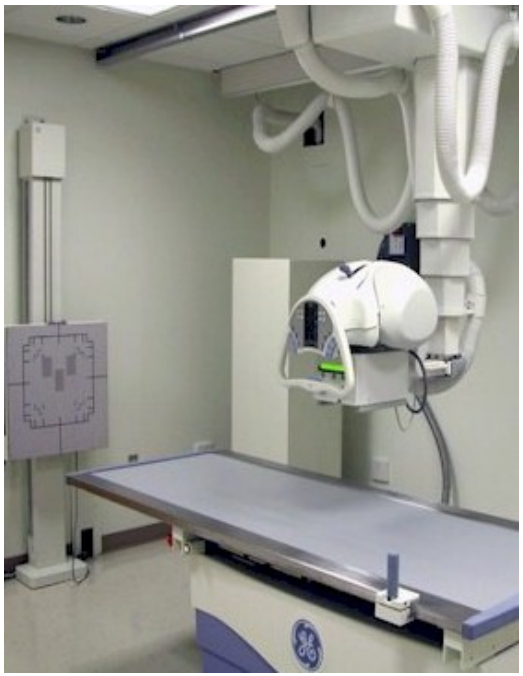
1. Manufacturer can be same for + 100 Legal Manufacturers (OEM)
2. Both HQ Manufacturer and Country Affiliate can appoint other local Distributors / Third Parties
3. Mobile kits storing inventory on the go.
4. Customers are HCP / HC Establishments



Concern #4: Medical devices registered via other local regulatory bodies are not accommodated

RADIATION CONTROL, DEPARTMENT OF HEALTH, SOUTH AFRICA

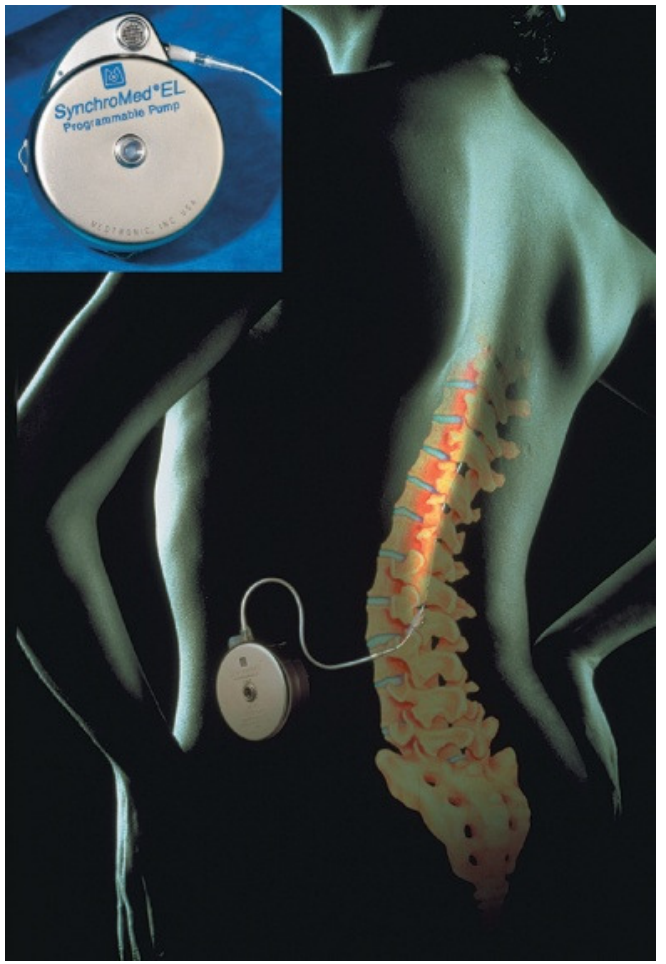
ICASA



Concern #5: Overlap with existing legislation

- National Health Act
- Consumer Protection Act
- Hazardous Substances Act
- Human Tissue Act
- Health Professions Act
- Medical Schemes Act

etc.



Concern # 6: Grandfathering/Sunsetting clauses and transitional period not provided for

- Enact transitional measures in a **phased manner** – learn from the Complimentary Medicines implementation!
- Enact and clarify lawfulness of products already on the market

Concern #7: Health Economic Policy and Registration do not belong in the same Act

- Regulation in Act 101 is for the purpose of assuring Safety, Quality and Performance

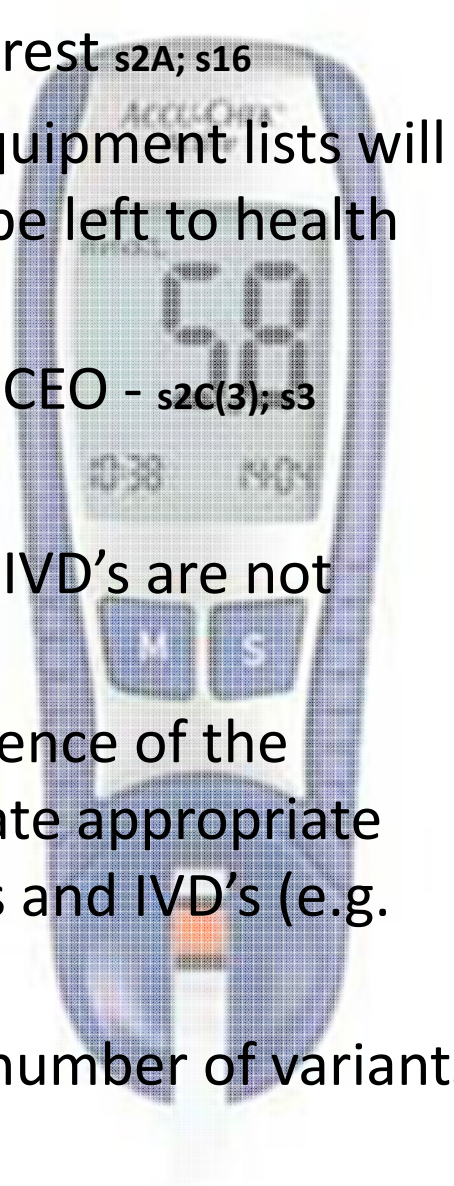
- Section 16 (1) C refers to barring products from registration *"if ….not in the public interest"*

- This is a catch-all clause to empower the Regulator to prevent access to products **for reasons which go beyond safety and effectiveness/performance**

- Amendments in the proposed Bill could mean that all pricing, tendering, procurement, essential equipment lists will fall under registration legislation – does not belong in Act 101

Bill 6 of 2014: Other Concerns

1. Registration denied if not in the public interest **s2A; s16**
2. Pricing, tenders, procurement, essential equipment lists will fall under registration legislation – should be left to health policy - **s36**
3. Replacement of the Registrar with a single CEO - **s2C(3); s3**
4. Independence of SAHPRA is crucial
5. Current definitions of medical devices and IVD's are not internationally harmonised – **Act 101**
6. Proposed structure, funding and independence of the Regulatory Authority does not accommodate appropriate and efficient regulation of medical devices and IVD's (e.g. appeals process)
7. Naming rules too aligned with medicines, number of variants in devices not taken into account - **s15**



Successful Introduction of Medical Device Regulation

- Policy formulation in the Department of Health is good.
- However, excellence in implementation is key.
- Previously DoH has not been able implement regulation effectively. Backlogs, delays and confusion have affected health care delivery to South African patients.
- Unless DoH has clear measurables, project plans with deadlines that they are obliged to meet, there will be no improvement.
- Parliament must hold the DoH accountable.
- Implementation model and option appraisal for the proposed Regulatory Institute should be presented to the committee for Review
- Important because this is where training and capacity building will originate
- NDOH to present clear project plans with timelines and measurable outputs for implementation of SAHPRA and Regulatory Institute

DOH needs to be part of international regulatory working groups

- Memoranda of Understanding with other Regulatory Authorities is important – so far only one has been initiated
- Local *ad –hoc* regulation does not work in a globalised world.
  - DoH should participate in the working groups of international regulatory harmonisation organisations, who take on board the best expertise and provide training [AHWP/ IMDRF/WHO]
- Specific plans are required for training regulatory staff, building appropriate infrastructure and IT systems
- The regulator must have control of own budget.

IMDRF International Medical Device Regulators Forum

AHWP Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

SAMED Recommendations

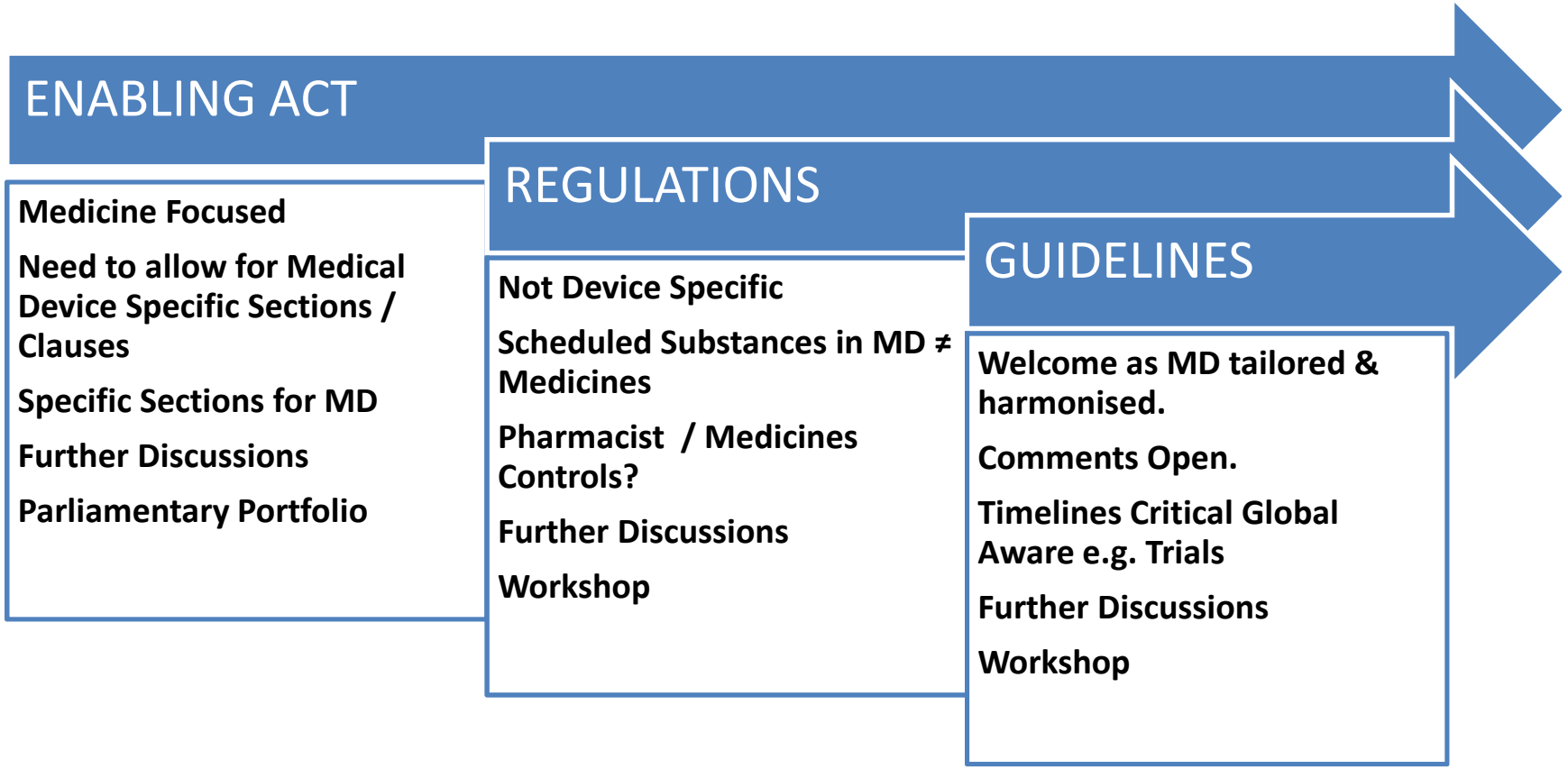
We ask the Portfolio Committee on Health to:

- Take heed of the concerns of people supplying medical devices
- Be concerned that the Bill, as is, may result in delay of access to medical devices for South African patients and other unintended consequences
- Request the Department of Health to workshop with the industry to adjust the proposed legislation taking industry's comments into account – **to provide a solid, legally sound foundation from which Regulations and Guidelines can flow**

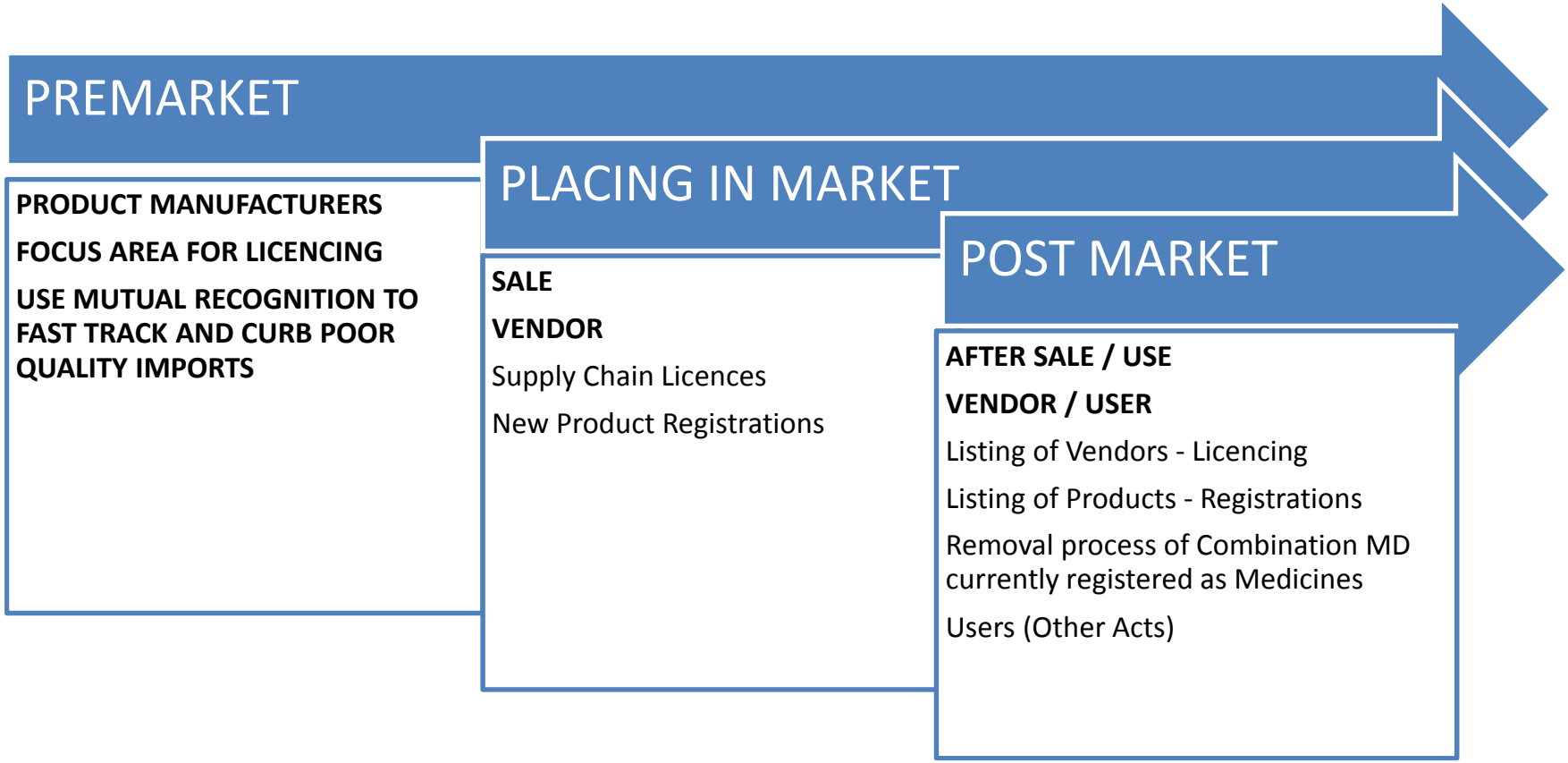
Workshop Focus Areas

- Include additional definitions
- Provide for Divisional Heads (Registrars)
- Separate Sections for different Control & Sale
- Provision committing to Mutual Recognition
- Provision to commit to timelines via Regs
- Abbreviated reviews
- Amendments /Conflicts to other legislation
- Commit to an Implementation Plan / Phased Road Map
- Capacity Building
- Alignment of Legal Framework
- Scheduled Substances in context of Medical Devices

Align & Balance (Remove Medicine Bias)



Road Map Proposals



RISK BASED APPROACH