Johnson & Johnson

Presentation to Portfolio Committee on Health
29th October 2014

Johnson & Johnson

Presentation Outline

1. Introduction to Johnson & Johnson
2. J&J Interest in Bill 6
3. Comments and Recommendations on Bill 6

J&J – Global Reach and Local Footprint

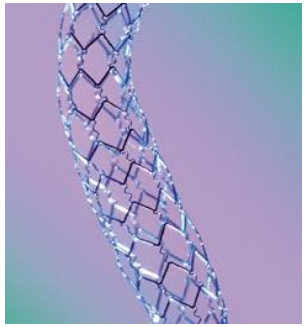
- Global Leader in Health Care
- World's **most comprehensive** manufacturer of healthcare products
- More than **250** Operating Companies
- Selling Products in more than **175 Countries**
- **128,000 Employees** Worldwide

- J&J established in South Africa in **1930**
- J&J consumer has **2 manufacturing plants**
- Janssen plant sold to **BEE partner**
- **± 1200** employees

Ethicon Employee, France
Quality Assurance checks on sutures

Pioneering Firsts





RhoGAM® to combat hemolytic disease of newborn (1968)

HALDOL® (1970)

Disposable contact lenses (1980s)

First coronary stents (1990s)

Orthopaedic products

Medicines for CNS disorders, anti-infectives, pain management, antivirals and more.

Pioneering firsts in public partnerships: Sisonke Mom – "Mom Connect"

Partnership with the Department of Health for TB Management

Johnson & Johnson manufactures, imports and sells medicines, medical devices, IVDs and cosmetic products in South Africa that all fall within the proposed scope of regulatory oversight of SAHPRA and other legislation, e.g. Cosmetics & Disinfectants Act

PHARMACEUTICALS

janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

CONSUMER

Johnson & Johnson
CONSUMER (PTY)LTD

MEDICAL DEVICES AND DIAGNOSTICS

Johnson & Johnson
MEDICAL (PTY) LTD
Caring for Life

DePuy Synthes
COMPANIES OF Johnson & Johnson

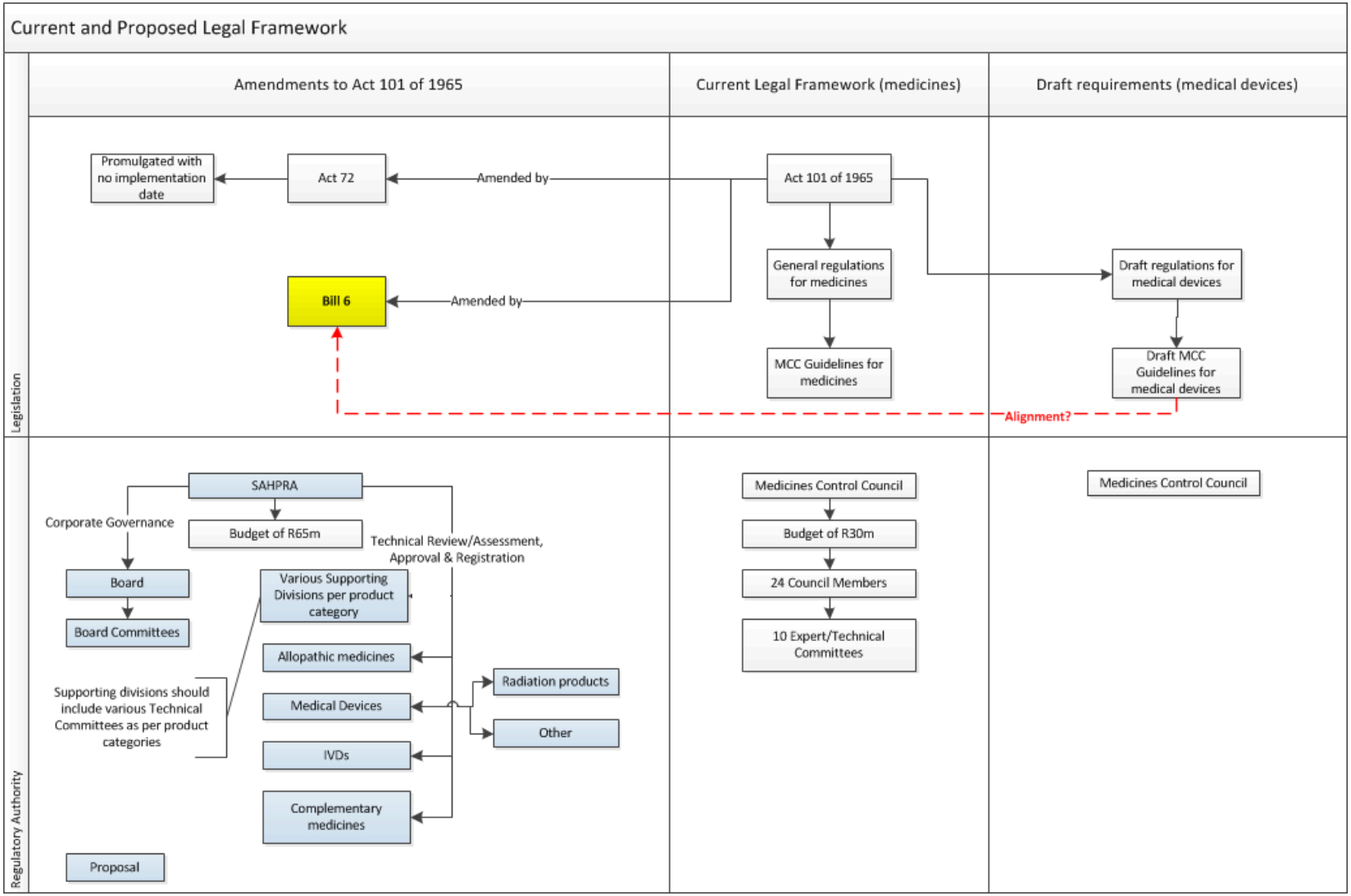
Johnson & Johnson
Vision Care, Inc.

LIFESCAN
PART OF THE Johnson & Johnson
DIABETES SOLUTIONS COMPANIES

General Comments

- J&J supports the **appropriate regulation of health products**
- Recommend **comprehensive regulatory impact assessment** to ensure that various categories of products are regulated appropriately prior to finalisation of Bill 6
- Deal with **overlapping legislation** specially those aspects which currently fall under different jurisdictions so that a pragmatic approach be taken in dealing with the transition from the MCC to SAHPRA (i.e. consider Foodstuffs, Cosmetics and Disinfectants Act, etc.)
- Differences in **supply chain and licensing requirements** between medical devices and other products must be considered
    - ***(i.e. amend s22C and s22H – page 9 of Bill to reflect device-specific supply chain and criteria on licensing)***

Legislative Context of Bill 6



J&J Recommendations on Bill 6

1. Recognition Agreements with Stringent Regulatory Authorities
2. Establishment of Regulatory Science Institute
3. Agreement on Regulatory Timelines
4. Abbreviated and Expedited Reviews
5. Diversity of Regulatory Pathways for different product categories
6. Transition Planning

1 Recognition Agreements with Stringent Regulatory Authorities

- In order to ensure resource optimization and availability of key therapies to patients, it is important that the new authority (SAHPRA) is mandated (compelled) to enter into **co-operation and recognition agreements with other stringent regulatory authorities**, as a key efficiency measure.
- Currently the Bill makes this optional, as per Section 2B(2)(a)-(b) (page 4) and although the introduction of the concept is welcomed, this should not be discretionary power but rather **a matter of normal operations to ensure the sustainability of the Authority**.
    - ***[Amend section 2B(2) to read "must" and not "may"]***

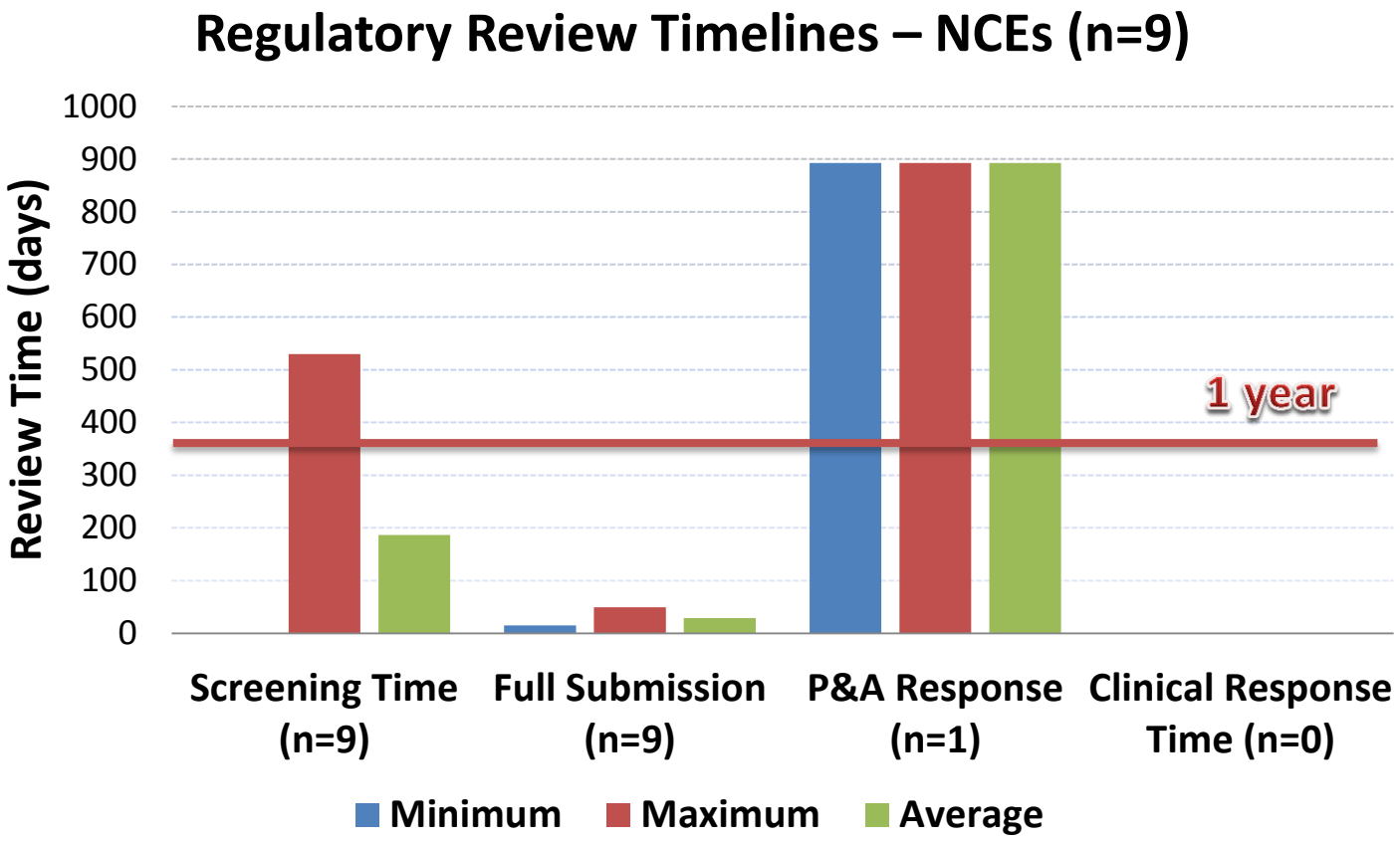
2 Establishment of Regulatory Science Institute

- Broad proposed scope of SAHPRA means that **various types and levels of technical skills will be required** to ensure that SAHPRA is able to fulfil its mandate and duties. Board composition **[Section 2C]** current reflect predominance of pharmaceutical skills
- Proposal to establish a regulatory institute is **welcomed** since it is critical to the success and sustainability of SAHPRA
- Recommended that **requirements for Institute be included in the Bill** so as to ensure technical capacity building of various types of regulatory staff necessary for the operations and sustainability of SAHPRA
    - ***New subsections to be added to section 3, page 6, to establish functional divisions, separate technical committees, Registrars and the Regulatory Institute, with amendments to Board powers – s2B as is necessary as the body to which Registrars will be accountable***

3 Agreement of Regulatory Timelines

- Proposed broadened scope to include medical devices and IVD's, could potentially **exacerbate lengthy registration timelines** situation.
- Recommend a system that ensures that **timelines are published in regulations** (i.e. become binding), and creating a remedy where those are not adhered to
  - we propose a stop-clock system, so that SAHPRA is not held to timelines where the company is creating delays) is proposed
  - ***[amend s2B(1)(b) to ensure "concluding timeously in accordance with prescribed timelines"]***
- This will ensure **regulatory certainty** through predictable timelines which is also of specific importance as the Department of Trade and Industry has identified the medical devices and pharmaceutical sectors as a IPAP priority sectors.
  - [E.g. a J&J combination medical device, Vicryl Plus (sutures) although erroneously required to be registered as a medicine, spent five years in the registration process of the MCC, whereas it takes 6 weeks to 3 months to register such products in other jurisdictions]

The importance of different regulatory pathways – to ensure the medicines registration backlog can be effectively addressed



9 submission for NCEs submitted between 2nd September 2008 and 5th March 2013, of which all 9 had outstanding resolutions from the MCC as at 20th December 2013

4 Abbreviated and Expedited Reviews

- Provision must be made *[in amendments to 15 – page 7]* for
  - **abbreviated reviews**, i.e. recognition of registrations elsewhere, or recognition of regulatory reports
  - **expedited reviews**, where in the interest of patient health (i.e. the old "fast-track" system in Act 101 of 1965, but which has been removed in Act 72 of 2008), and
  - **listing / notification** for products that do not pose significant risks and/or are of a low risk class in the case of medical devices and IVDs – such systems also exist in other jurisdictions for complementary medicines and low-risk medical devices.

5 Diversity of Regulatory Pathways for different product categories

- It is important that there is recognition of the **fundamentally different regulatory pathways** for different product categories and criteria to be applied when regulating each requiring a specific and in many respects unique regulatory approach, specific staff and specific systems.
- Ensuring therefore that in, e.g:
  - ***section 15 (page 7) terminology is device-appropriate (e.g. not efficacy, but performance),***
  - ***labeling requirements section 18 (page 8) (in many instances patient don't even see the device or is not the user of the device)***
  - ***section 35 (page 11ff) create separate empowering provisions for regulations on medical devices and IVDs – do not just include everywhere as for medicines. For example, the classification of medicines in section 35(1)(iii) fulfills a totally different purpose than the classification of medicines – device classification shows the regulatory rigour to be applied prior to registration (due to use an risk), medicines classification shows categories that has no bearing on use and risk***
  - ***Etc.***

Medical Devices

Diagnostics & Borderline Devices

Medicines Act as well as Hazardous Substances Act, SANAS (on IVDs)?

Pharmaceuticals

Consumer

Cosmetics, Foodstuffs AND Medicines Acts? As well as NRCS?

6 Transition Planning

- **Transitioning products**
  - A clear **plan of action for the current MCC to address legacy issues**, such as the existing registration backlog and inclusion of complementary systems into the same regulatory entry-point, is necessary.
- **Transitioning staff**
  - The transitional measures in Bill 6 state that other staff from the DoH (Foodstuffs and Radiation Control) must move into SAHPRA – however, these two Acts do not and did not create the change of regulatory powers. It would only be possible to move such staff if those laws are amended.

6 Transition Planning

- **Premises, infrastructure**
  - It must be noted that the set-up costs of a schedule 3A public entity requires operational independence in terms of a premises, movable assets (currently all within the Department of Health), etc. would require significant set-up costs.
  - The set-up costs of an entity such as the NHLS may be illustrative, as well as the time taken to make up those costs in fees charged for services, bearing in mind that fees levied for device and IVD registration will be significantly lower, as the actual regulatory compliance assessments will be made by third party entities, such as TuV, SABS, etc. who will also be inspection bodies for the section 22C licenses, and not by SAHPRA

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Thank you

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