BD NHI Presentation to Parliamentary Portfolio Committee

13 July 2021

Agenda

01 Introduction to BD

02 The BD NHI Submission

03 Closing Remarks

Who is BD?

We are united in our purpose: ***Advancing the world of health***

Employees:
70,000

Global reach:
Serving
190+
countries

Global position:
One of the largest medical technology companies in the world with ~**$17 billion annual revenues**

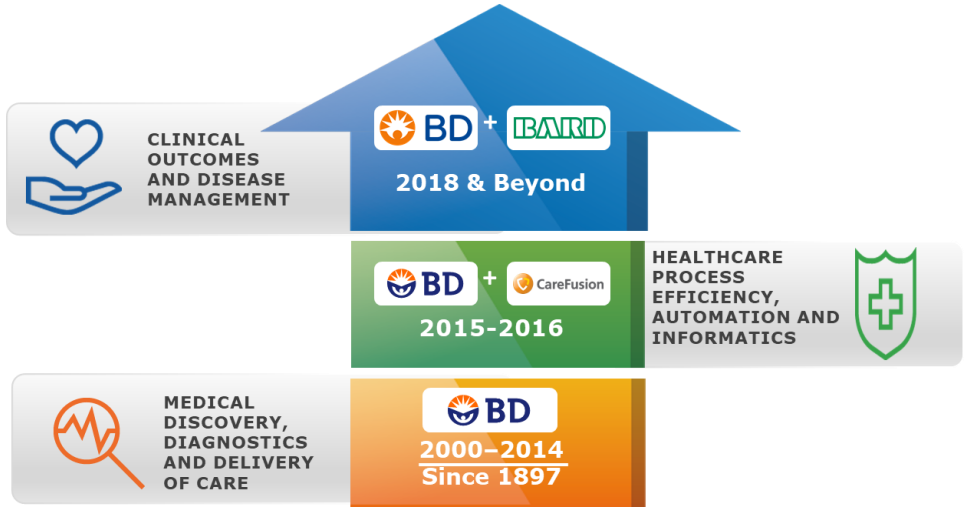
Founded in 1897:
A legacy of health impact

Annual investment in innovation:
$1+ billion

Fortune
500
#195

Fortune Change the World List
#15

Fortune The World's Most Admired Companies
#5



Becoming a provider of complete healthcare solutions with a strong foundation

BD South Africa supports Transformation towards inclusive growth

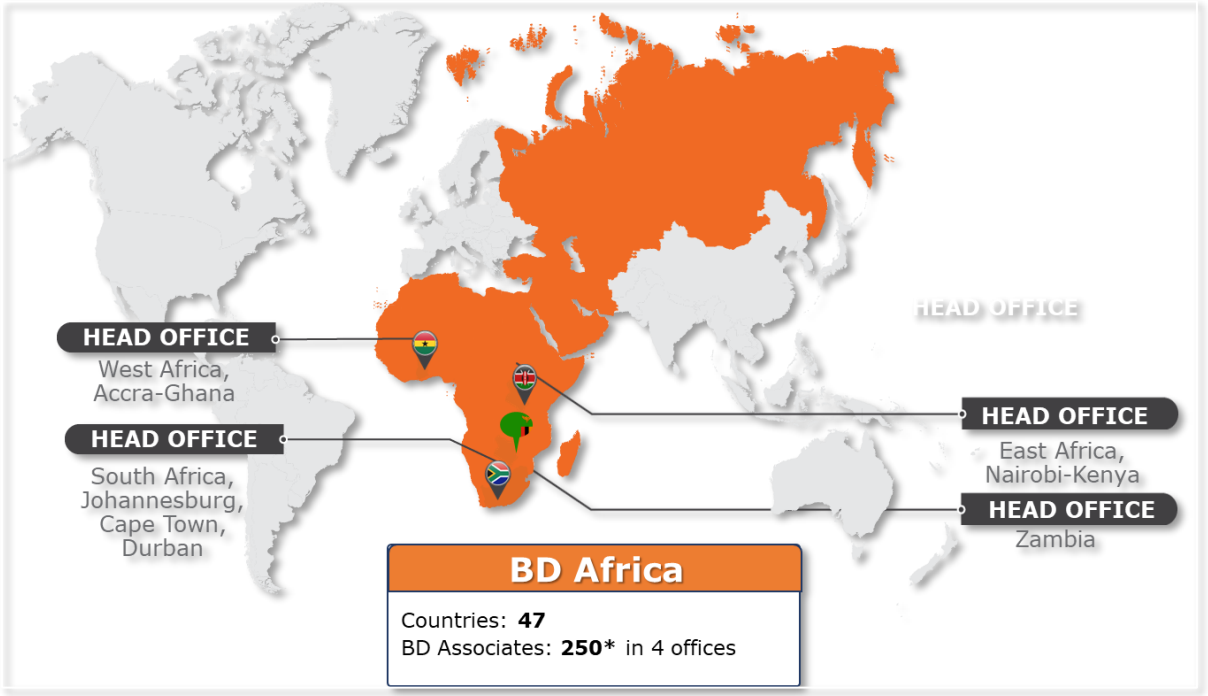
Diverse and Inclusive workforce

- 75 % black board members
- 25% black female board members

Commitment to Skills Development

- Work Integrated Learning Programme
  - Vaal University of Technology- students in 4th Semester
  - 18 months programme in-service programme
  - Employment on permanent basis: Workshop Technicians & Field Service Engineers.
- Sales Representative Learnership
  - Science degree graduates
  - 12 months programme: theory & practical training.
  - learners are awarded with the NQF5 – Pharmaceutical Sales Representation qualification,
  - Employment on permanent basis: qualified Sales Representatives.
- Project Management NQF4 learnership
  - aimed disabled individuals:
  - theory and practical training
  - assists in obtaining employment opportunities.

Strong Presence in Africa



Our innovative solutions help to address some of healthcare's most pressing challenges

LIFE SCIENCES

Discovery | **Diagnostics**

Enabling research inside and outside the cell

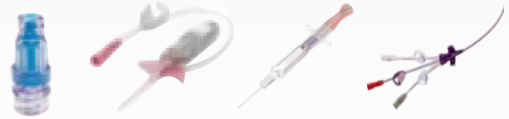
Improving diagnostic accuracy & efficiency

MEDICAL

Medication management

Integrating medication management across the care continuum

Optimizing medication delivery

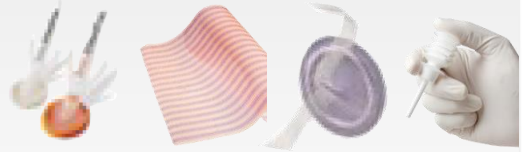


Integrating diabetes management

INTERVENTIONAL

Therapy management

Maximizing outcomes for surgical processes



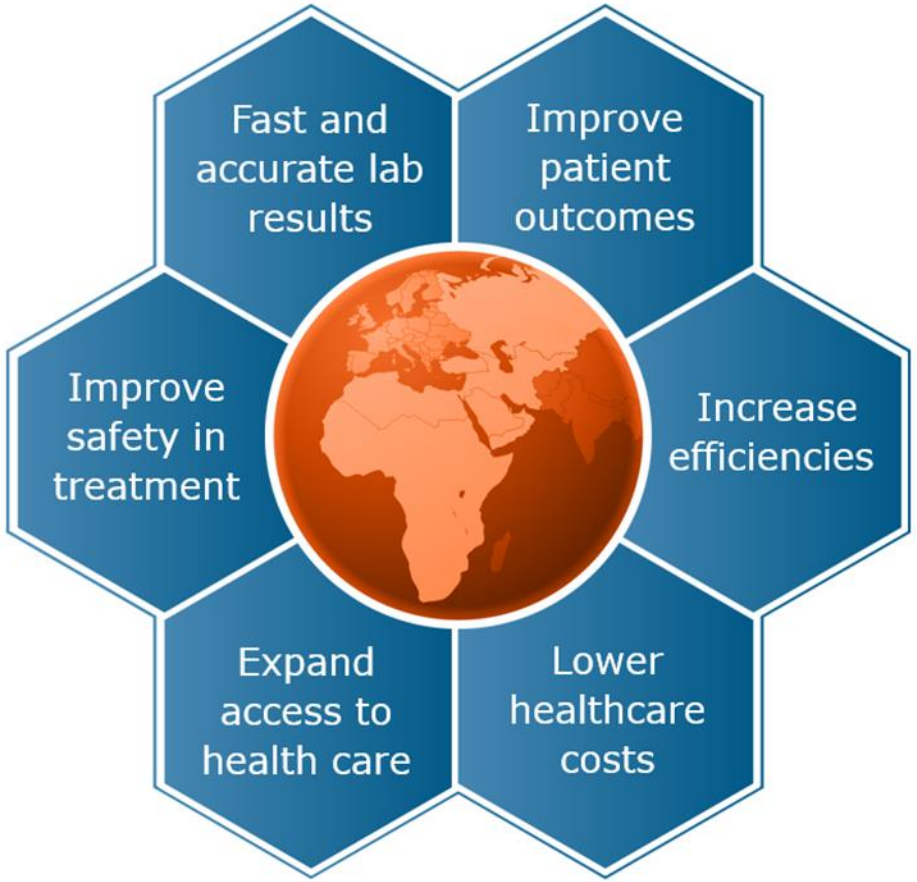
Advancing urology & critical care

Enhancing outcomes for peripheral intervention

Informatics: integrated workflow management and data analytics

BD collaborates around the world to address some of the most challenging global health issues

- HIV / AIDS
- TB
- Diabetes
- Cervical Cancer



- Antimicrobial Resistance
- HCW & Patient Safety
- Immunization
- Health Systems Strengthening

Bill & Melinda Gates foundation · The Partnership for Maternal, Newborn & Child Health · PATH A catalyst for global health · Direct Relief Deliver a world of good. · Clinton Health Access Initiative · APIC · National Association of Community Health Centers · PEPFAR The United States President's Emergency Plan for AIDS Relief · unicef · Project HOPE · American Red Cross · World Health Organization · CDC Centers for Disease Control and Prevention · BD

BD Submission on NHI

BD supports the principles & objectives of NHI

BD recognises the inequalities of current healthcare system and is keen to support the achievement of UHC in South Africa under NHI:

- To achieve universal access to quality health care services
- To provide for the equitable, effective and efficient utilisation of the resources of the Fund to meet the health needs of the population
- Through its global and African efforts BD supports Goal 3.8 of the Sustainable Development Goals (SDGs)
  - *universal health coverage*
  - *financial risk protection,*
  - *access to quality essential health-care services and*
  - *access to safe, effective, quality and affordable essential medicines and vaccines for all*

BD will make comment on the following aspects of the NHI Bill:

1. The role of the Private Sector in the delivery of a quality healthcare system
2. The MedTech sector and the role that it plays within the healthcare system
3. Procurement of medical technology
4. Health technology assessment and reimbursement of medical technology
5. The accreditation process
6. The benefits package & the rights of users
7. Legal concerns

Role of private sector

Collaboration with the private healthcare sector affords the opportunity for more rapid, innovative and constructive progress towards NHI objectives:

- Leverage existing current best practices amongst private healthcare stakeholders
- Resources, capabilities and systems can be provided

BD examples include:

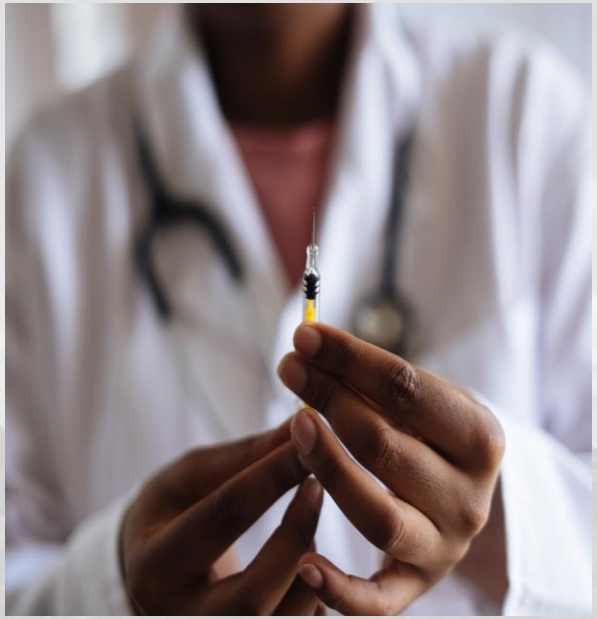
1. R&D to support Covid- 19response –POC antigen testing & customised devices for vaccine delivery
2. Collaboration with public sector to advance “Safety in Healthcare”
3. Training on brachytherapy technology for prostate cancer in the public sector
4. Surgical skills cadaver training – Hernia Repair
5. Labs for Life – programme to strengthen and capacitate healthcare and laboratories in Africa
6. Digital diabetes patient education programmes

Recognition & distinction of the MedTech industry

	MedTech	Pharmaceutical
Industry Composition	• Over 80% small and medium-sized companies	• Very large multinationals dominate
Active Components	• Generally based on **mechanical, electrical and materials engineering**	• Based on pharmacology and chemistry; now encompassing biotechnology, genetiengineering etc. • Pharmacologic properties and action of active ingredients are known, based on pre-clinical and clinical studies • Standardised batch sizes, manufacturing processes and starting materials • Products stable/generally stored at room temperature with a long shelf life
Product Development	• **Wide variety** of products and applications – from thermometers to x-rays • Designed to perform specific functions and approved on the basis of safety and performance • Often developed by health professionals	• Products are usually in the form of pills, solutions, aerosols, or ointments • Product development by discovery, trial, and approved on basis of safety and efficacy • Products developed in laboratories by chemists and pharmacologists
How Products work	• Most act through **physical interaction with the body** or body part	• Products are administered by mouth, skin, eyes, inhalation, or injection and are biologically active; effective when absorbed into the human body. Often act systemically on the entire body
Intellectual Property Concerns	• **Continuous innovation** and iterative improvements based on new science, new technology, and new materials	• Extensive research and development of a specific compound or molecule; takes several years for a new drug to enter the product pipeline
Product Life Cycle	• **Short product life cycle** and investment recovery period (~18 months on market)	• Little patent linkage possible. Data exclusivity is important Intensive patent protection, including data exclusivity and patent linkage, needed due to extensive product life cycle and long investment recovery period
Innovation	• Majority of new products bring added functions and clinical value based on **incremental improvements**	• Usually large step innovation
Support Provided	• **Large investment** in manufacturing, distribution, and training/education; plus need to provide service and maintenance (for many high tech devices)	• Low manufacturing and distribution cost, and, in most cases, no training, service or maintenance costs

Ref: https://www.mtaa.org.au/devices-vs-drugs

Recognition and distinction of the medical technology industry



BD requests recognition and distinction of the medical technology industry:

- Medical devices and IVDs play a vital role across the continuum of patient care (prevention, screening, diagnosis, treatment and rehabilitation)
- Consumes only a small percentage of healthcare expenditure:
  - MedTech value: $20B vs Pharma Value $60B
- MedTech could play a significant role in providing effective and efficient healthcare for all South Africans under NHI
- Has distinct characteristics which impact procurement and practices vs medicines and other health goods or services

Recommendations:

1. Difference between medicines and medical devices & diagnostics * diagnostics to be recognised in the definitions of NHI Bill
2. The terms “medical device” and “IVD” as defined in the Medicines and Related Substances Act (“Medicines Act”) should be used as opposed to “health goods”
3. Expertise in medical devices & diagnostics to be included in decision making bodies e.g. Benefits Advisory Committee, Health Care Benefits Pricing Committee, Stakeholder Advisory Committee (Chapter 7)
4. An Essential Devices List be included on the formulary developed by the Office of Health Products Procurement (Chapter 8 Section 38(4))

Ensuring Access to Quality MedTech Solutions under NHI

The following are important considerations for equitable access to MedTech Solutions under NHI and is our key focus:

- Procurement
- HTA
- Accreditation

Procurement of medical technology:

Procurement should support and recognize the value of innovation in medical technology to patients, clinicians and the healthcare system:

- Medical technology often relates to integrated solutions: e.g.
  - software with data management,
  - medical equipment plus consumables, after sales service, maintenance and training.
  - capital equipment and consumables are not always interchangeable.
- Cycle of innovation is rapid (updates 6 to 24 months) – can be both evolutionary & incremental
- A centralised mechanism of procurement by the Office of Health Products Procurement will have practical implications for medical technology :
  - unmet patient needs –clinical variation amongst patients impact MedTech solutions required,
  - lack of innovation – fast pace of change in MedTech
  - exclusive contracts - - prevents multiple models and types required to meet specific needs
- Value added services is critical and cannot be separated from capital purchase
  - maintenance of equipment
  - servicing & technical support
  - education
- A value-based approach should take into account:
  - life-cycle cost of healthcare delivery
  - wider outcomes of care for the patient and society

Procurement of medical technology:

Recommendations

- The NHI Procurement System should recognize the complexity of medical technology and
- Review of international **best practice on the procurement of medical technology** encouraged e.g., MEAT.
- **Decentralised procurement (where applicable) as opposed to a centralised system** (Chapter 8(38)) - considering specific patient needs and full life cycle value, including servicing & maintenance requirements, training needs etc
- **Agility** in procurement process – cater for MedTech **improvement cycles**
- **Tailored approach** & multiple suppliers for specialised devices - clinical choice based on patient need
- Establishment of a substantive Essential Equipment and Diagnostics List(**EEL) to support standardisation** in access and standards of care – informed by HTA

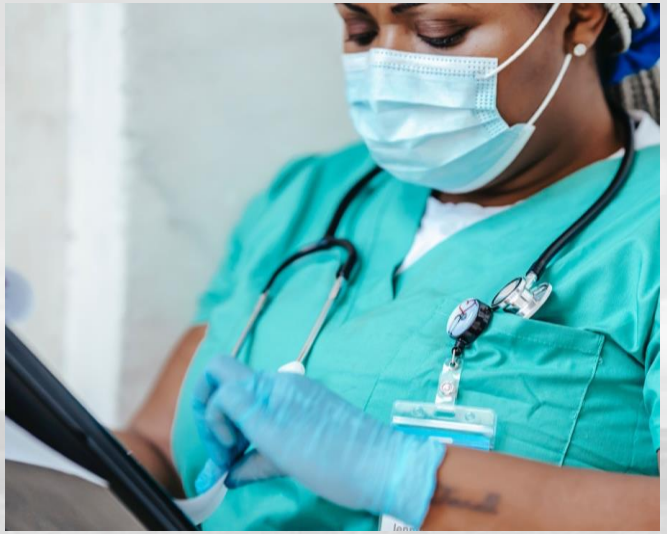
Best Practice Example: Value Based Procurement in EU (MEAT):

- Value-based purchasing is facilitated in accordance with the “most economically advantageous tender” (MEAT) approach
- Adopts a broad definition of value,
  - the benefits of a particular product/service/solution in terms of improved outcomes for patients,
  - cost of care efficiencies
  - benefits for other stakeholders
- The sum of which is the most economically advantageous purchase

Health technology assessment and reimbursement of medical technology

BD supports the establishment of an independent, effective and sustainable Health Technology Assessment (HTA) agency:

- The bill makes provision the establishment of a Ministerial Advisory Committee on Health Technology Assessment for NHI
- A Ministerial Advisory Committee on HTA will serve as a precursor to the HTA agency
- An HTA process based on the principles of regularly reviewed, evidenced-based assessment of cost-effectiveness is a sound objective
- However, currently in SA there is a shortage of HTA skills



Recommendations

1. An HTA agency should be independent to the NHI (Chapter 11 section 58(3)(d).
2. Further information is required on the composition and decision-making processes of the HTA agency
3. The HTA process should not become an administrative bottleneck that limits patient access (as evidenced by National Health Laboratory Services' initial HTA process, which led to its subsequent discontinuation)
4. We recommend the development of an independent agency to conduct an expert, efficient and uniform HTA process in SA that is patient-focused and seeks to achieve best value

Multiple accreditation steps could lead to administrative bureaucracy and duplication

The need to ensure quality goods, suppliers, service providers and the achievement of acceptable standards in the delivery of goods and services to the Fund are recognised.

- Registration, certification and accreditation must be supported by efficient processes
- Delays in the contracting of sufficient and appropriate providers and suppliers could impact negatively on patient access to appropriate and necessary care.

Recommendations:

1. SA Health Products Regulatory Authority ("SAHPRA") remains only regulator for medical devices and in-vitro diagnostics
2. Independence of SAHPRA maintained
3. Adoption and inclusion of a quality management system operating on a clear set of SOPs and incorporating recognised standards (SABS / ISO accreditation)
4. Clear strengthening required in the assessment skills for Medical devices

Benefits Package and Rights of Users

BD is supportive that all levels of care will be considered; primary, secondary, tertiary and quaternary care.

- The Fund via the Benefits Advisory Committee will determine the health care services benefits due to users (Chapter 3)
- A significant number of details are outstanding, e.g., the financing model, contents of the benefits package, details of the procurement process.
- Only complementary benefits can be purchased from Medical Schemes - greater clarification of complementary services
- The Medical Schemes amendment Bill (MSAB) allows the Minister of Health and Registrar to prohibit schemes from providing NHI benefits.

Recommendations

1. Freedoms of choice in access to health care services covered under NHI should be maintained as is international practice (Chapter 2, Chapter 8 section 33).
2. Benefit design and services should be reviewed at least annually (Chapter 7 section 25(5).
3. BD supports the Bill statement that the emergence of new technologies - this must be considered in determining treatment guidelines (Chapter 7)
4. Decisions should be based on sound medical evidence
5. The approach to drive cost-effectiveness should not mean cheapest (Chapter 7)
6. The governance processes in the selection and functioning of the Benefits Advisory Committee and Health Services Pricing Committee should be adequately defined (Chapter 7)
7. There should be adequate representation of MedTech expertise on these committees.

Legal Concerns

The constitutional impact of some of the provisions in the Bill is of concern with reference to the rights to freedom of association and access to health care services.

- Governance and decision-making are to a large degree centralised in the office of the Minister of Health
- Centralised decision-making process poses a risk & is not in accordance with good governance principles.
- The Minister will establish and appoint the BAC, the HPC, the SAC and all technical committees (Chapter 7, Sections 25 to 28).
- This creates concerns about the independence of the board

Recommendations

1. Any limitation of existing rights must meet the criteria set out in Section 36 of the Constitution.
2. The separation of legislative and executive power needs to be maintained
3. Greater inclusivity in terms of decision making
4. Appropriate representatives with requisite expertise of MedTech should be included to provide input on the Stakeholder Advisory Committee.

Concluding Remarks

In conclusion BD looks forward to contributing positively to the attainment to Universal Healthcare Coverage for all South African. We highlight the following concerns and recommendations for NHI as we move towards this goal:

- Phased implementation with milestones as opposed to being time-based
  - Consideration given to time and investment required to improve existing health infra-structure especially in public sector through collaborative approach
- Access of all South African patients to “best” Standard of Care
- The continued existence of a private healthcare sector which provides for choice and creates a competitive landscape
- A procurements system which allows for Alignment with the National Department of Health's’ Strategic Plan
- Strong governance structures which are representative of all sectors
- Transparency and information on the financing of and flow of money within NH