



Sanofi South Africa

Empowering the lives
of all South Africans,
through healthcare
solutions and partnerships

SANOFI 

Agenda : NATIONAL HEALTH INSURANCE BILL [B11 -2019] SUBMISSIONS TO THE PORTFOLIO COMMITTEE ON HEALTH



TCL

Presenters:

Mr Thibault Crosnier-Leconte
SANOFI General Manager
GENMED SOUTH AFRICA
Country Lead



Mrs Prudence Selani
Communications Head SANOFI



Mr Gavin Bauer
Market Access Head SANOFI



①

SANOFI Opening Statements

②

Substantive Proposals On Medicine Related NHI Topics

③

SANOFI Closing Statements



Sanofi South Africa: Key facts and figures addressing Healthcare Needs in all Health Sectors



Over 600 employees



Diverse product portfolio across 15 key therapeutic areas including innovative and generic medicine



One of the few multinational companies with an industrial site: **Waltloo**



Local industrial site, a **global center of excellence** aligned to South African burden of disease

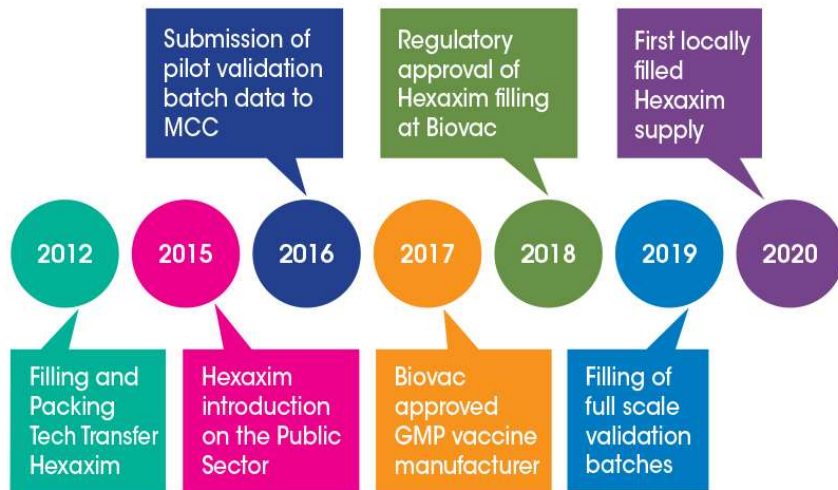




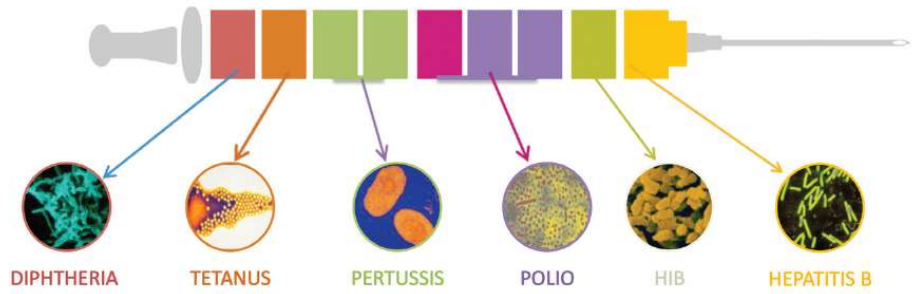
Partnership Sanofi Pasteur & Biovac

Relations with Biovac started in the 1900s

Tech transfer signed in 2012, milestone reached in 2017 with Biovac approved GMP vaccine manufacturer



Our Paediatric Vaccine protects against Several Diseases



1 Vaccine Injection	9 Antigens	50 Manufacturing steps	223 Analytical Methods	1277 Individuals tests
----------------------------	-------------------	-------------------------------	-------------------------------	-------------------------------

Sanofi Pasteur future opportunity with Biovac

- Biovac to become a fully fledged local vaccine manufacturer and supplier



1. SANOFI Opening Statements:

SANOFI NHI Submission Affiliations

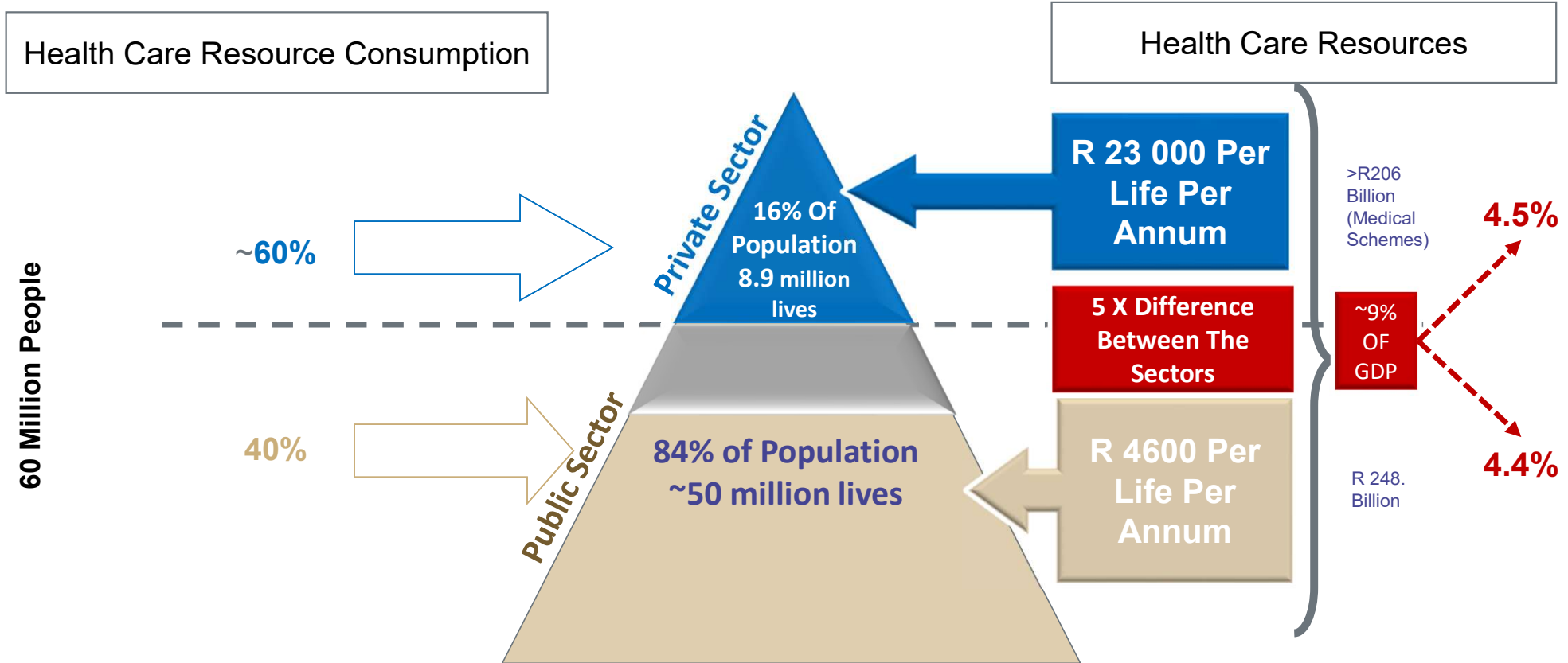
PS

- **SANOFI is a member of three pharmaceutical industry associations:**
 - The Innovative Pharmaceutical Association South Africa (IPASA)
 - Pharmaceuticals Made in South Africa (PHARMISA)
 - Self-Care Association of South Africa (SCASA)
- **As such SANOFI supports the NHI submissions of these trade associations.**
- **SANOFI additionally supports the NHI Submission of the Pharmaceutical Task Group (PTG)**



1.Sanofi Opening Statements :The Need For NHI

PS



Need To Address This Inequity Through Universal Access Regardless Of Ability To Pay

2. Substantive Proposals On Medicine Related NHI Topics

Proposals on The National Health Insurance Fund:



GB

- SANOFI proposes that the NHI Fund be subject to schedule 3A of the PFMA regulations like other entities such as SARS, RAF, UIF, Council for Medical Schemes, The Competition Commission etc.
- SANOFI proposes that “**affordable**” **universal access be defined within the legal mandate of the Fund.**
- SANOFI proposes an **explicit description of the process to be followed in establishing the Comprehensive Benefit Package**, in order to ensure that the package is all inclusive and factors the current Burden of Disease that exists within our current SA environment and at the same time does not limit the number of benefits that qualify for cover by the additional complementary insurance cover (offered by private insurers).



NHI Fund Should Be A 3A Entity To Ensure Governance And Oversight



Affordability Should Be Specifically Defined In Bill If It IS To Be Used To Define Or Limit A Patient Right



The Process Of Providing For Or Limiting Patients Benefits And Entitlements Under NHI Will Need An Explicit Process Linked To SA's Burden Of Disease And Health Priorities



2.Substantive Proposals On Medicine Related NHI Topics

Proposals on The National Health Insurance Fund Procurement:

GB We accept that the Fund, as a schedule 3A public entity, will be bound to procuring healthcare services and medicines in accordance with the provisions of the Constitution, and that it must do so in terms of a procurement process that is equitable, fair, transparent, cost-effective and competitive. **It is our concern that the procurement process set out in the PFMA, NT Regulations and the PPPFA Regulations, being an exclusionary tender-based system, may be inappropriate to the procurement of medicines by the Fund**, as it may undermine (not only the achievement of value for money), but the long-term goals of the Bill. As such, we advocate for National Treasury to: **(i) exempt the Fund from procuring medicines in terms of this system**; and (ii) to set out in regulations a procurement system applicable to the procurement of medicines by the Fund, which is not only compliant with section 217 of the Constitution, but which seeks to support the sustainability of the pharmaceutical industry.

4

NHI Procurement Of Goods And Services Should Not Solely Be Based On A Winner Takes All Tender System Based On Price Alone

- **The NHI Bill should not close the door on PPPs.** SANOFI proposes that the NHIF be empowered, through the addition of a sub-section under clause 5(1), as subsection (1)(t): “enter into any public-private partnership, within applicable legal and policy frameworks, which partnership assists in the achievement of the objectives, duties and/or functions of the Fund.

5

Inclusion Of PPP's Should Be A Cornerstone OF NHI Development And Implementation

- **SANOFI believes that the NIPP, may make participation at the “lowest possible price”, as is required by clause 6(2)(e), difficult.**

6

NIPP Obligations And Criteria Should Be Revised For NHI Procurement

2.Substantive Proposals On Medicine Related NHI Topics



Proposals on The National Health Insurance Implementation:

GB

- In order to be successful, **it is essential that the universal healthcare coverage system contemplated in the Bill is backed by a sustainable healthcare sector**, i.e. the businesses involved in the provision of medical and related goods and services. As such, many of the queries and recommendations raised in this submission seek to address the common goals of improved universal access to healthcare while allowing a robust and sustainable supply chain.
- We respectfully submit that the **implementation of the NHI scheme should be linked to the completion of the interventions set out in the Health Compact**, in respect of each Pillar, and not the dates specified in the bill. As such, the Bill should not make use of the aforesaid dates as hallmarks for the implementation of the NHI; **but, instead should make use of the achievement of these interventions as implementation milestones**.
- **SANOFI proposes that the proposals made by the HMI be included into the development and implementation of NHI.** Specifically, SANOFI supports the HMI proposals be adopted to enable NHI in a way that addresses the current system issues in the healthcare sector



NHI Should Ensure A Sustainable Healthcare Sector Based On Current Sector Strengths, While Addressing Sector Challenges



NHI Development And Implementation Should Be Milestone Based And Informed By Current Processes Like The Health Compact



NHI Development And Implementation Should Be Based On Completed Processes Like The Health Market Inquiry AND Its Outcomes

2. Substantive Proposals On Medicine Related NHI Topics

Policy Alignment With The HMI Findings And Outcomes:



SANOFI supports the following HMI proposals be adopted to enable NHI in a manner in which address the current system issues in the healthcare sector :

- “49. For effective and efficient regulatory oversight of the supply-side of the healthcare market, we recommend the establishment of a dedicated healthcare regulatory authority, referred to here as the **Supply Side Regulator for Healthcare (SSRH)**. The role of the SSRH will include regulation of suppliers of healthcare services, which includes health facilities and practitioners. The SSRH will have four main functions: healthcare facility planning (which includes licensing); economic value assessments; health services monitoring; and health services pricing.
- 50.6 Conduct or contract out **health technology assessments to guide cost-effective practice.**
- 50.7 Liaise with the proposed **Outcomes Measurement and Reporting Organisation** to ensure that practitioners report on health outcomes and use these data for **HTA assessments where appropriate**
- 52. We recommend the creation of an **Outcomes Monitoring and Reporting Organisation (OMRO) as a platform for providers, patients and all other stakeholders in the provision of healthcare to generate patient-centred and scientifically robust information on outcomes of healthcare.** The OMRO will be an independent, private organisation in which key actors such as providers (doctors and hospitals) and patients co-operate to generate relevant and standardised outcome information for two purposes: to provide practitioners and hospitals with relevant outcome information and ways to improve clinical quality, and, secondly, to provide patients and funders with relevant choice information on health outcomes
- 58. To increase comparability between schemes and to increase competition in the funders market, we recommend, the introduction of a **single, comprehensive, standardised base benefit option, which must be offered by all schemes.** It will enable consumers to compare products, reward those funders which are able to innovate to offer lower prices and/or higher quality, and, thereby, both discipline and reward the market.
- 59 We recommend the introduction of a **risk adjustment mechanism linked to the single, comprehensive, standardised base benefit option to remove any incentive by schemes to compete on risk.** Schemes should compete on metrics designed to attract new members, irrespective of their age, health, or risk profile. Regionally-based medical schemes should be allowed through a temporary reinsurance facility to mitigate their exposure to demographic and claims risk”

11

SANOFI proposes that the proposals made by the HMI be included into the development and implementation of NHI

12

Risk Equalization Is Supported To Balance National/Provincial/ District Health Based Risks

13

HTA Is Supported Through A Defined Explicit Process Linked To Fund Procurement

14

Outcomes Monitoring and Reporting Organisation (OMRO) Is Supported

2. Substantive Proposals On Medicine Related NHI Topics

Proposals on The National Health Insurance Fund: HTA



GB

- SANOFI proposes that the use of HTA be specifically defined in terms of who will conduct the assessment, what will be assessed in the HTA, at what level will be the HTA be conducted and how will the outcomes of the assessment will be binding on the Fund.



HTA Is Supported Through A Defined Explicit Process Linked To Fund Procurement

- The goal and scope of the HTA should be explicit and relevant to its use. HTA should be an unbiased and transparent exercise. HTA should include all relevant technologies (Medicines/devices/machines/interventions etc). **A clear system for setting priorities for HTA should exist.** HTA should incorporate appropriate methods for assessing costs and benefits. The HTA agency should consider a **wide range of evidence and outcomes.** A full societal perspective should be considered when undertaking HTAs. HTAs should **explicitly characterize uncertainty surrounding estimates.** HTAs should consider and address issues of generalizability and transferability. The HTA agency should actively engage **all key stakeholder groups.** The HTA agency should actively seek all available information. The implementation of HTA findings needs to be monitored. **HTA should be timely.** HTA findings need to be communicated appropriately to different decision makers. **The link between HTA findings and all other decision-making processes needs to be transparent and clearly defined.**



An Explicit Independent Defined HTA Process Is Supported



2. Substantive Proposals On Medicine Related NHI Topics

Proposals on The National Health Insurance Fund:



GB

- SANOFI proposes a centralised authority within the NHI Fund which would be responsible for **coordinating all functions related to the procurement of health-related products** including medicines, devices, and equipment within the NHI environment in a transparent predictable manner.
- SANOFI proposes that multiple **medicine purchasing models and pricing mechanism be adopted by the NHI Fund in line with the type of medicine being procured including price negotiation with the fund based on a specific classification of medicines identified for NHI Fund procurement.** SANOFI would like to jointly develop and implement these purchasing models in a transparent process that ensures patient access, value for money for the NHI fund while balancing the long term sustainability of the pharmaceutical industry in South Africa.
- SANOFI proposes that the **price of a medicine not be the exclusive determinant of medicine purchases by the FUND** but that outcomes and evidenced based medicine be included in the decision making process leading to procurement.

17

NHI Fund Should Have A Central Co-Ordination Function For All Health Products

18

The NHI Fund Should Procure Specified Medicines Via a Hybrid Of Purchasing Models

19

The NHI Fund Should Not Use Medicine Price As The Sole Determinant Of Procurement. EBM Should Be A Explicit Procurement Consideration

2. Substantive Proposals On Medicine Related NHI Topics

NHI Medicine Procurement And Supply Process:



GB• In general, the **model of procurement and supply should ensure that the pharmaceutical industry remains viable, sustainable, and competitive.** In line with South African industrial and trade policies, smaller- and niche-market players should also be able to participate and remain viable. **For this reason, SANOFI does not support a centralized “winner takes all” procurement system and believes that the same efficiencies and better responsiveness to local and geographical needs, can be achieved through a range of procurement models**

- Pricing of medicines should not be pre-determined by the NHI Fund.
- The price offered to a health establishment or group of health establishments, should depend on such as the specific geographical area, volume uptake (the details of which should be available on the basis of the Diagnoses-Related Group (DRGs) or global budget calculations made by the NHIF), or value offered. **Prices should therefore be negotiated with the District Health Management Offices (DHMOs), or the management of a facility DRG funding, global budgets and/or being paid an “all-inclusive” fee by the NHI Fund.** If medicines are provided to the private sector as part of a capitated fee, or as part of a global fee, such medicines, when used for the NHI, should be exempted from the Single Exit Price (SEP), so as to allow the pharmaceutical industry to also participate in the risk-sharing nature of such funding models.

20

The NHI Fund Should Procure Specified Medicines Via a Hybrid Of Purchasing Models

21

The NHI Fund Should Use Medicine Price As The Sole Determinant Of Procurement. EBM Should Be A Explicit Consideration

22

An Ability To Negotiate Medicine Prices Should Be Build Into The Hybrid NHI Purchasing Model

2. Substantive Proposals On Medicine Related NHI Topics

Proposals on Ministerial Committees :



GB

- SANOFI proposes that the Benefit Advisory Committee must develop a transparent public participation process to determine the inclusion of OR exclusion of benefits from the comprehensive health services benefit package.
- SANOFI proposes that BAC be explicit and transparent in the decision criteria for inclusion in the benefits package based on potential funds available in terms of process followed and outcome determined.
- SANOFI proposes that the BAC develop a definition and criteria for deeming a service or medicine as medically unnecessary.
- SANOFI proposes the inclusion of one representative from the Pharmaceutical industry to be a member of the Benefits Advisory Committee.

23

NHI BAC Needs Structured Public Participation

24

BAC To Have Explicit Decision Criteria For Inclusion/Exclusion Of Benefits

25

Medical Necessity Is Patient Specific And Therefore Needs Explicit Definitions

26

BAC Needs To Be Representative Of All Stakeholders Including The Pharmaceutical Industry

2. Substantive Proposals On Medicine Related NHI Topics



Benefits and treatment guidelines:

GB

SANOFI recommends that the following criteria be inserted under the mandate of the BAC in clause 25, namely:

- Benefits must be set on the basis of evidence-based medicine, **considering also the care required by non-responders to various lines of care, adverse events, co-morbidities and patient profiles (e.g. ease of administration).**
- Regular reviews of these benefits at legislated time intervals, is necessary.
- Providers and facilities should be able to give effect to benefits in a manner that makes sense from the point of view of their resources (whether a DRG, a budget, a global fee or capitation), **while treatment guidelines should remain “guidelines”.**
- **Cost-effectiveness should not taint what would be treatment guidelines set on the principle of evidence-based medicine.** Each facility or provider should address what would be effective and efficient in their sphere of influence, utilizing treatment guidelines and HTA results, should they become available.

27

EBM Must Be Applied To All Patient Benefit Decision By The BAC

2. Substantive Proposals On Medicine Related NHI Topics

NHI Medicine Procurement And Supply Process:



GB• Although the Essential Medicines List (EML) may inform the selection of medicines that should be available at all entities offering NHI services, **these cannot be the only medicines available, as is stipulated by the National Drug Policy, 1995.** SANOFI would urge the adoption of a regulatory framework, as is envisaged by regulation 90(1)(d)6 in relation to the setting of the EML. Regular review of the list thereafter will be necessary.

- **There is a need for recognition of the level of inter-dependence of the public and private sectors to deliver a sustainable and secure supply of affordable medicines, inclusive of innovative, generic as well as the “core” Essential Medicines List (EDL) medicines.**

28

Procurement Of EML Only Medicine By The NHI Fund Will Not Meet All Patients Needs

29

Supply Of Medicine For NHI Needs To Recognise The Price Inter-dependance Of The Current Healthcare Sectors

2. Substantive Proposals On Medicine Related NHI Topics

NHI Benefits:

GB



- SANOFI proposes that the BAC develop a definition for the **inclusion of Orphan Diseases and Treatments** which will inform the comprehensive services benefit package to include the Orphan Disease that meet the inclusion criteria to ensure patient access and treatment.
- **Orphan medicines** are medicines or vaccines intended to prevent, diagnose or treat a rare disease. Examples of rare diseases include genetic diseases, rare cancers, infectious tropical diseases and degenerative diseases. The definition of rare diseases varies across jurisdictions but typically considers disease prevalence, severity and existence of alternative therapeutic options. In the United States (US) rare diseases are defined as a disease or a condition which affects fewer than 200,000 patients in the country (that is, 6.4 in 10,000 people) while the European Union (EU) identifies a rare disease as a life-threatening or chronically debilitating condition affecting no more than 5 in 10,000 people. 6000–8000 rare diseases are estimated to exist today, affecting approximately 6–8% of the world's population.
- Despite the need for, and importance of availability and access to orphan drugs, there is a paucity of available treatments for rare diseases. **Less than one in ten patients with a rare disease receives disease-specific treatment.**

30

The Specific Inclusion Of Orphan Diseases In The Benefit Package IS Required Support By Clear Definitions Thereof

31

The Specific Inclusion Of Orphan Diseases In The Benefit Package IS Required Support By Clear Definitions Thereof

2. Substantive Proposals On Medicine Related NHI Topics



Medicine Procurement

- GB• SANOFI accepts that a pricing mechanism needs to be in place that promotes accessibility to medicines; however, it is **equally important that this mechanism promote and support the viability of the medicines industry, if we are to sustain accessibility to medicines in the long-term.**
- To this end, we recommend that a medicine pricing system, which achieves the following, as opposed to simply the lowest possible price, be adopted, a system that:
 - enables the widest patient access possible while ensuring market access for all types of medicines (originator/generic and over the counter);
 - promotes and supports broad market access for a wide range of medicines;
 - does not threaten manufacturer sustainability through exclusionary medicines tenders; and
 - does not threaten manufacturer sustainability through the inadvertent imposition of 'lowest' prices', based on volume-based negotiations, through the SEP system, to buyers other than the Fund.
 - facilitates the access and entry of new innovative medicines in the market;



A Sustainable Hybrid Medicine Pricing Models Needs To Incorporated Into The NHI Procurement Process

2. Substantive Proposals On Medicine Related NHI Topics

NHI Alignment And Definitions:



GB

- SANOFI recommends that the definitions relating to “**health product**” and “**health related products**”, be **reviewed and redrafted**, so as to align with the definitions afforded to such goods in applicable legislation, namely the Medicines and Related Substances Act, 1965, on the definitions of medicines, medical devices and IVDs; the Hazardous Substances Act 1973, and the Foodstuffs, Cosmetics and Disinfectants Act, 1972, where there is reference to such products.
- SANOFI proposes that the definition causes, and the other laws to be amended, be reviewed for relevance. The review should also consider whether there are no further amendments required to such laws. **Some of these amendments or implementations must precede the NHI, and cannot be done in conjunction with and/or as part of the NHI Bill.**
- SANOFI proposes that an assessment of other public entities fulfilling social security functions, such as SASSA, the Compensation Fund and the RAF, be undertaken to inform policy and legislation on the NHI.



Clear Explicit Definitions Of Health Products And Services Must Underpin NHI Benefits And Procurement



Alignment Between Existing Legislation Needs To Precede NHI Introduction To Enable NHI Implementation



Alignment And Integration Of Existing Social Security Net Institutions Is Required To Enable NHI

2. Substantive Proposals On Medicine Related NHI Topics

Proposals on The Right To Healthcare: :



GB• SANOFI proposes that any proposal to establish and operationalize the NHI Fund **does not impede on South Africa patients' rights to access healthcare in a manner in which denies the patient choice of provider, treatment or ability to purchase additional healthcare coverage and does not ration access to care to below the current level of the patients existing treatment.**

36

NHI Should Enable Broad Patient Access Without Rationing Or Limiting Patient Rights Of Choice Versus Current Level Of Care

• SANOFI supports the **right of a user to purchase complementary benefits through a voluntary medical insurance scheme and allowing out of pockets payments for specific healthcare benefits including medicines.**

37

Complementary Health Insurance Should Be A Patient Choice As NHI Cannot Cover All Treatments



3. SANOFI Closing Statements

TCL

- SANOFI has offered a **number of substantive recommendations** on the content of the NHI Bill and made specific proposals which are **intended to assist** in the finalisation of the legislation which **are aligned to the pharmaceutical industries submissions**.
- SANOFI suggests the need for a **tiered or multi-layered healthcare system**, as proposed in the parliamentary high-level report, which advocates the **complementary role of the private medical schemes alongside the public sector and an NHI fund for the unemployed**.
- Whatever NHI model is chosen, the importance of recognising **the delicate balance between the different funding pools and the supply of medicines into those – which is the only example of UHC in the current system - is vital**. Medicines are supplied to the state sector on the basis of differential pricing, with investment and overhead costs covered in the private sector. This ensures **sustainability of supply** and across the board access to medicines of current research, while allowing the state sector to enjoy **internationally competitive pricing for medicines**.

3.SANOFI Closing Statements



TCL

- The pharmaceutical sector is a well-established partner to government as a supplier of medicines and other health products and **is one of a few industries that currently provides goods and services to both the public and private healthcare** sectors of South Africa.
- **SANOFI looks forward to partnering with Government** to create sustainable NHI business models that can appropriately support and assist efforts to ensure a secure, affordable and accessible medicines supply as part of a viable, sustainable and workable National Health Insurance (“NHI”) system.