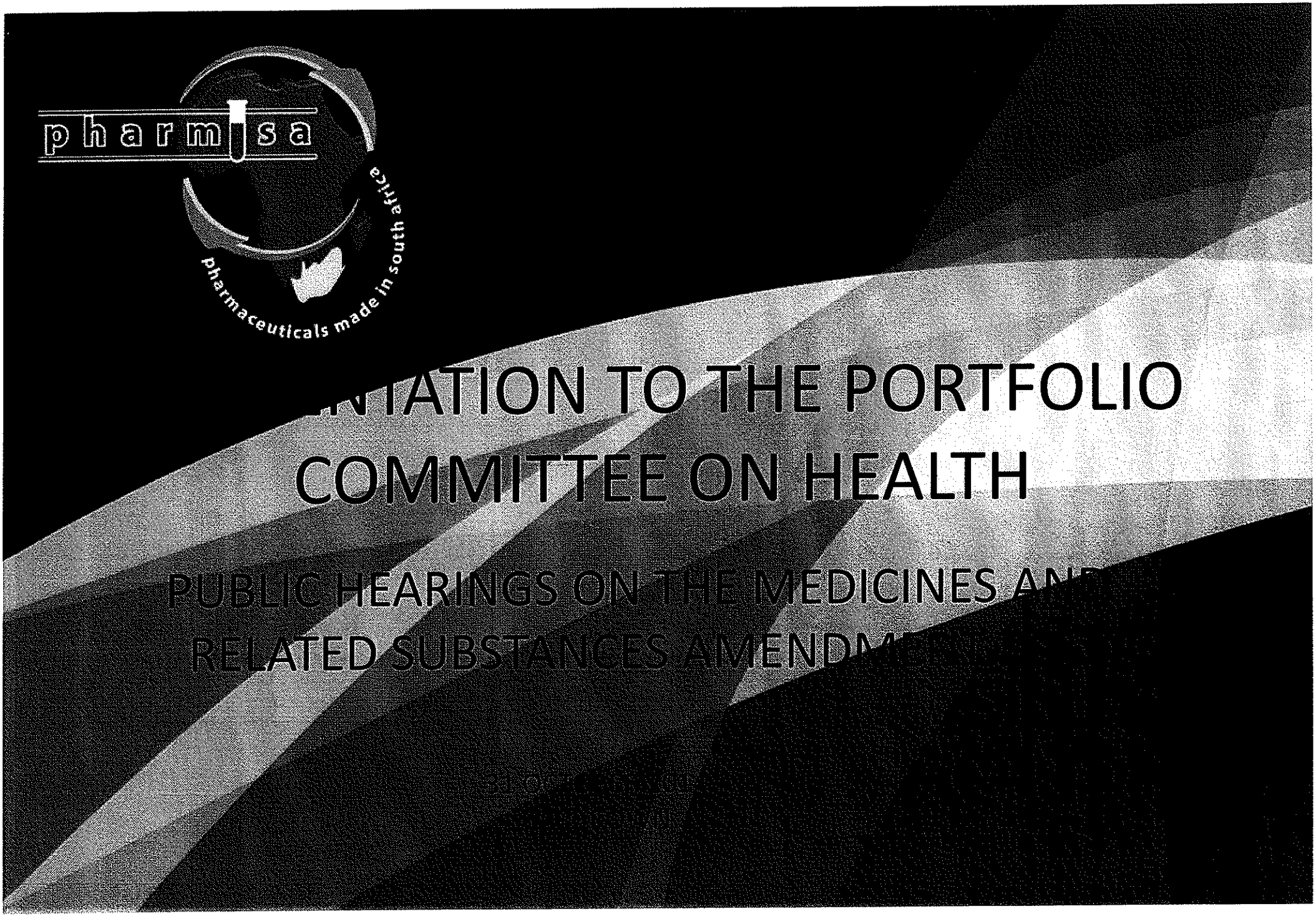


NTATION TO THE PORTFOLIO COMMITTEE ON HEALTH

PUBLIC HEARINGS ON THE MEDICINES AN
RELATED SUBSTANCES AMENDM

CREATING SUSTAINABLE VALUE

PRESENTATION OUTLINE

- Introduction to PHARMISA
- Prevailing MCC Landscape
- PHARMISA's Evaluation Of the Amendment Bill – Key issues.
- PHARMISA's Proposals
- Way Forward

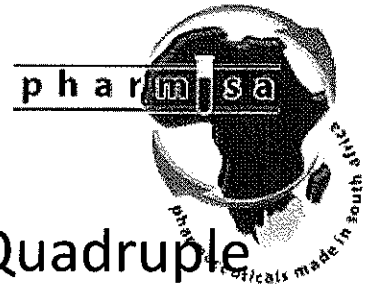
ABOUT PHARMISA....

- 1 of 4 South African Pharma Trade Associations
- Only Trade Association that is exclusively made up of local manufacturers.
- Represents over 30% of the total S.A pharma market in value and over 50% in volume.
- Largest supplier of medicines to the state.
- > 80% of SA's manufacturing capacity.
- Largest Exporter of Medicines

MCC MANDATE

- Registration and Approval of Meds, etc.
- Clinical Trials
- Continuous Vigilance and Risk Assessment
- Monitoring and Evaluation
- Public Safety and Protection

PREVAILING MCC LANDSCAPE



- One of the world's most challenging disease burdens – Quadruple Disease burden
- Epidemiologies a strong driver of social behaviour.
- > 1994 Deluge of applications
- Globalisation – Post Reg Amendments became an issue
- Underestimated the deluge and post reg amendments .
- Increase in applications and shortage of reviewers.
- Under resourced, Under staffed, Under Capacitated and Under Funded.
- Backlogs
- Staff committed, under trying circumstances.
- Constitutional right to meds – 527 Constitution.

IN A NUTSHELL.....

MCC HAS A BICYCLE, EVERYONE EXPECTS A JET... BUT A JET COSTS AND NEEDS PILOTS

A KEY IMPERATIVE IN OUR COUNTRY

- Radical Economic Transformation, Re-Industrialisation and Job Creation.
- Medicine Supply Security
- Investor and International Community. Perceptions.
- Pharma and IPAP priority sector.

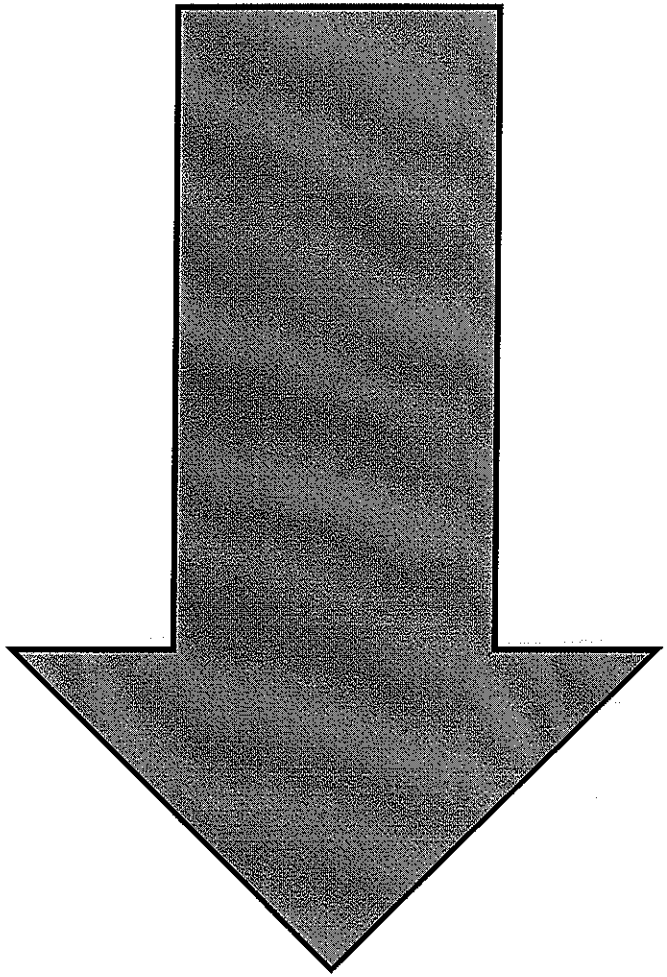
PHARMISA's EVALUATION OF THE AMENDMENT BILL AND KEY ISSUES IN THE BILL

- Exact model – Is it akin to a SOE, Agency or Commission or a hybrid of these?
- Minister – Board – CEO relationship
- Board Composition (2C (1) and 2C(3))
- Backlogs – Timelines – Accountability and Transparency
- Timeous Registration – How/When? (2B(1)(b))
- Mutual recognition and co-op (2B(2)(6))
- Duplication of work of other Regulators (Only accredited Regulators)
- Remuneration – Retention of skills and talent attraction/staff turnover.
- Electronic submission
- Enabling legislation for approved regs.
- S22G Exemption

OTHER KEY ISSUES

- Transitioning Plan – Existing applications
- Reasonable and Capacity base – Where will it come from.
- Evaluators
- Multiple Dossier Submissions
- Procurement objectives aligned to MCC activities.
- Local products should be granted registration priority – attract investment and consistent with re-industrialisation objectives.
- Plan to clear backlog.

REGULATORY SCIENCE INSTITUTE

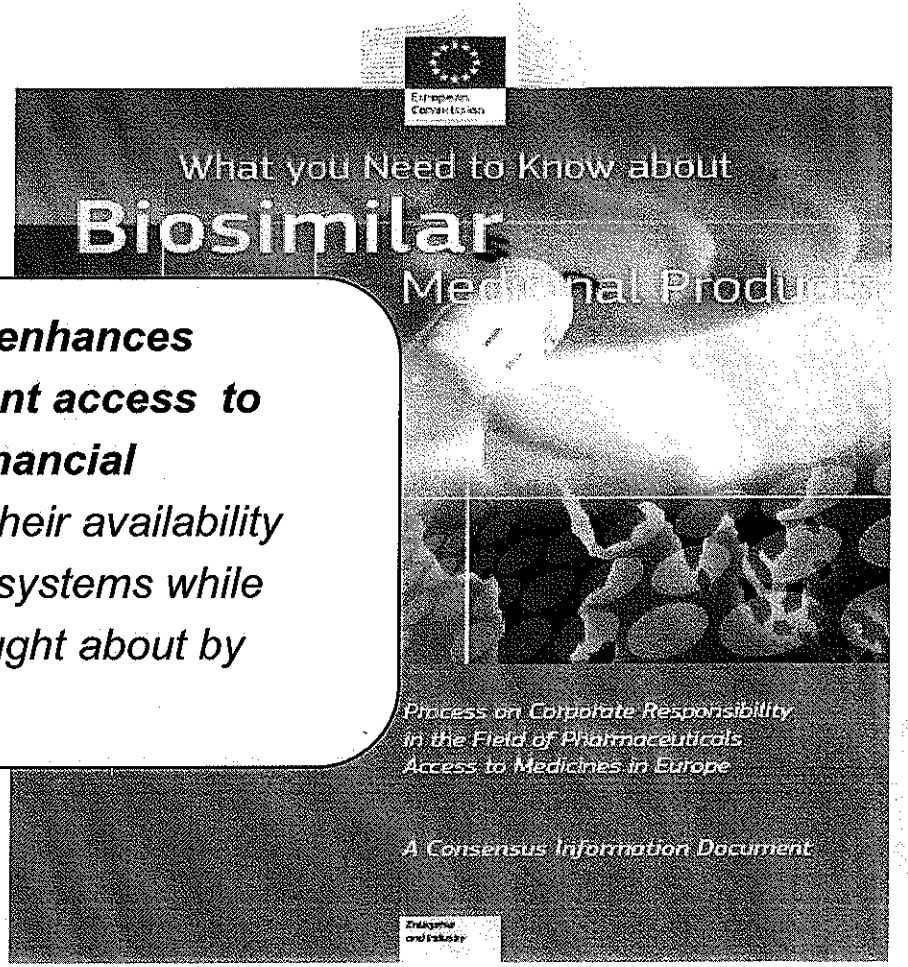


PHARMISA's PROPOSAL – WAY FORWARD

- Board – MoH Link.
- Authorised 3rd party Evaluators – pre-review
- Funding Model – Staff retention
- Local Producers preference
- Multiple Applications – Single review
- Reviewer Prioritisation programme
- Biologicals Pathway

European Commission endorses role of biosimilars in enhancing competition and improving patient access

*The **availability of Biosimilar** medicinal products **enhances competition, with the potential to improve patient access to biological medicines and to contribute to the financial sustainability of EU healthcare systems**. Thus, their availability offers potential economic benefit to EU healthcare systems while addressing the issue of new treatment options brought about by advances in medical science.*



Consensus Information Paper 2013.
What you need to know about
Biosimilar Medicinal Products

Sales of top biologicals1 in South Africa in 2013 (R1.1 bn) vs projected growths and sales in 2018 (+R1.8 bn)
10 Products contribute 5% of total private Healthcare rand sold and equates to 0.2% of total sold product in the private market

Rank Product	Originator	Type	*2018 Rev. (ZAR m)	2013 Rev. (ZAR m)
4. CLEXANE®	Sanofi	Biologic (LMWH)	217.5	181.3
7. NOVOMIX 30®	Novo Nordisk	Biologic (insulin)	219.6	153.6
10. MABTHERA®	Roche	Biologic (mAb)	225.2	136.7
12. LANTUS®	Sanofi	Biologic (insulin)	194.3	133.6
15. MIRCERA®	Roche	Biologic (Epo)	286.4	106.9
18. HERCEPTIN®	Roche	Biologic (mAb)	92.4	123.7
24. HUMIRA®	AbbVie	Biologic (mAb)	172.4	89.2
60. NOVORAPID®	Novo Nordisk	Biologic (insulin)	81.1	68.4
87. REVELLEX®	Johnson&Johnson	Biologic (mAb)	74.4	54.0
100.ENBREL®	Amgen	Biologic (mAb)	270.8	36.2

Source: South Africa IMS TPM June 2014 MAT Sales in Rand
Rank based on MAT value IMS TPM Dec 2013 – Top 100 Products
[1] Note: All trademarks are the property of their respective owners
Growth based on annual growth 2013 vs 2014 x years excluding a clone or generic entrant

ENABLING LEGISLATION

1. **Necessity**

   Regulations should be outcomes based. This will ensure regulations are only promulgated when necessary. Regulations should be focused or targeted on the problem they seek to address, in a manner that minimizes unintended consequences. In some instances, regulation may not be the best solution to a specific problem. Thus, alternatives to regulation must be considered first, in order to choose the best option.

   In order to ensure necessity and relevance, regulations should be reviewed on a regular basis to test whether they are still necessary and effective. If not, they should be modified or repealed. In certain instances, regulations could be built on existing regulations and influenced by available databases e.g. JSE data.

2. **Simplicity**

   All regulations should contain a clear statement of purpose, expressed in clear and plain language, to guarantee unequivocal understanding of the regulations and aid effective compliance. The complexity of some regulations can undermine their effectiveness. Regulations must be user friendly. The relationship between regulator and regulated persons should be enabling. A choice of methods of interaction with the regulator should be available.

ENABLING LEGISLATION.....

3. **Proportionality**

Government should only intervene where necessary and such intervention should be commensurate with the potential risk/harm posed, while the cost of regulation is identified and kept at a minimum. In order to achieve this, regulatory impact assessments become important. The costs and benefits of each alternative must be evaluated and the benefits must outweigh the costs. In instances of particular effects on certain subjects or cases, e.g. effect on smaller entities, accurately adapted regimes should be considered.

4. **Predictability**

Regulation should be predictable in order to give stability and certainty to the regulated. Wherever possible, a requirement should be rule rather than judgment based. This will create a context of predictability, and will facilitate effective compliance. Though rules may require mechanisms to deal with exceptions, they reduce uncertainty and help ensure fairness. Requirements and expectations from applicants must be stated upfront.

ENABLING LEGISLATION.....

5. Accessibility

Regulation must be accessible to anyone for whom it may be important. Authorities should strive to provide one location to access all necessary documentation and requirements. This will reduce the administrative burdens for regulated people and entities. Technology becomes useful in this respect.

6. Timeframes

Approval processes must be expeditious and efficient, and operate within appropriate and specified timelines. All regulatory processes must allow applicants to track progress of applications. Reasons should be provided to the regulated party when the specified time line cannot be achieved. Where regulatory approval for an activity is required from more than one regulator, wherever possible, provision should be made for regulatory processes to proceed in parallel in both time and process, so that a reasonable turnaround time can be maintained for the effective approval of the activity.

ENABLING LEGISLATION.....

7. Coordination and consistency

Government rules, standards and their intended objectives should not contradict each other. Harmonization of regulations with regional and international trading partners should be achieved wherever possible. The harmonisation of regulation is necessary for consistent legislation. Good regulation in itself, or juxtaposed with other regulations, does not result in redundancies and conflicts and is part of a consistent whole.

Mechanisms to achieve coordination are needed both horizontally between regulators operating in different institutions and within a single institution where regulatory steps are required at different vertical levels, for example from regional or provincial levels of the regulator.

8. Competitiveness

Regulations need to be competitive in respect of other countries. It will be important to establish if other countries regulate for a similar purpose. If yes, a question needs to be posed as to whether our system is comparable and harmonised. If not internationally comparable, a justification will be required as to why. In some instances such regulation could be for domestic reasons only e.g. BBEE (aimed at redressing past injustices)


THANK
YOU