



**MEDICAL DEVICE REGULATIONS STATUS**  
**LYDIA MOTLOGELWA**

## Vision

- An agile and responsive health products regulator that is globally recognized as an enabler of access to safe, effective and quality health products in South Africa.

## Mission

- To promote access to health products and protect human and animal health in South Africa through making science-based regulatory decisions.

## Values

- Ubuntu
- Responsiveness
- Integrity
- Transparency
- Efficiency
- Excellence

**Quality, Safety ,  
Efficacy/performance**

1

- April 2021 : publication of MD regulations
- August 2021: Comment closed
- September 2021: collation of comments

 **Comment**  
**23 respondents:**  
**12 Associations**  
**11 organizations**

2

- Internal team review
- Medical device committee review
- November 2021 Internal document updated
- ITG WG update
- Management recommendation & Legal WG
- Industry update on review status

**1<sup>st</sup> review**



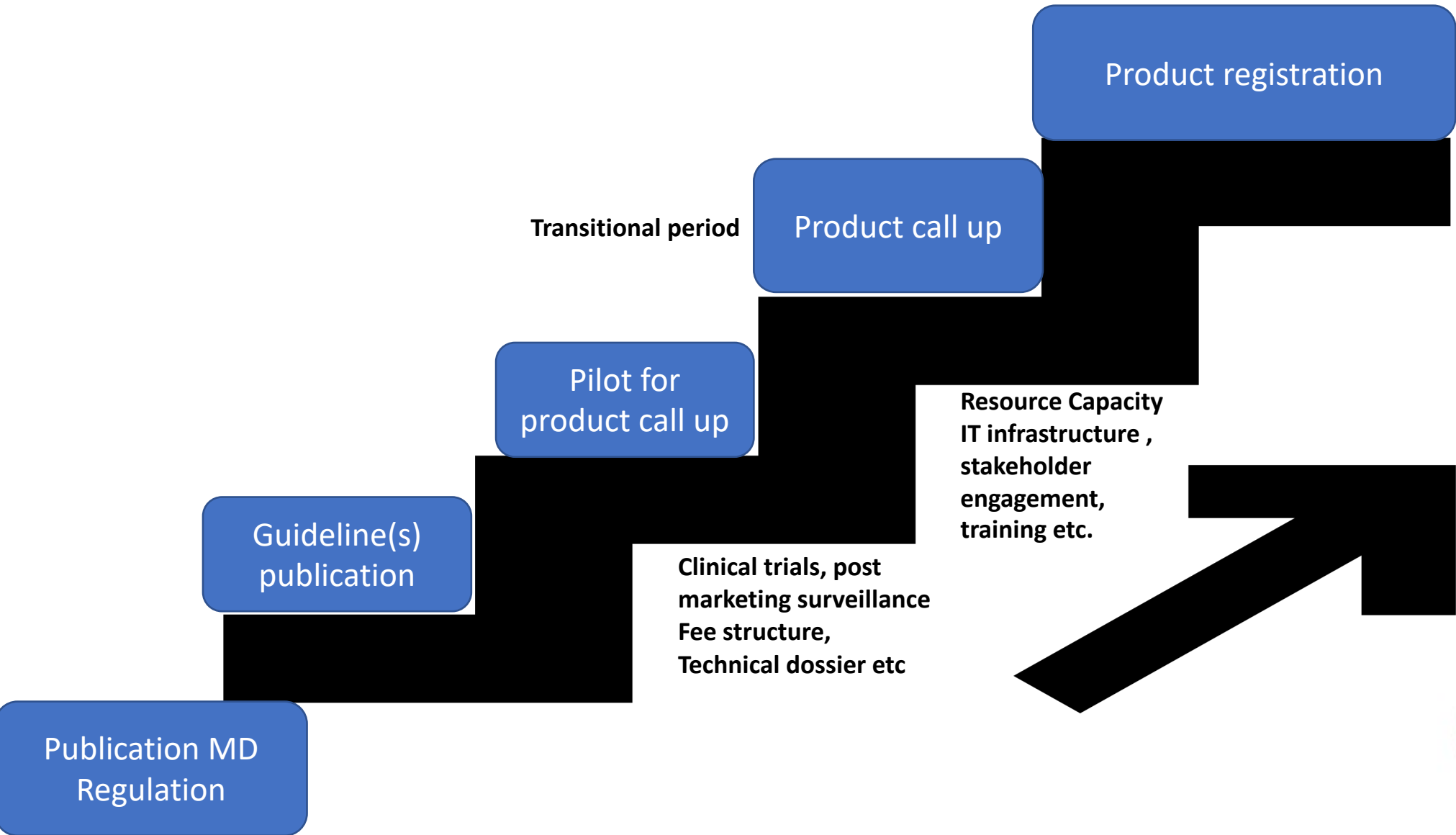
**2<sup>nd</sup> review**

3

- Exco submission
- Board submission
- Communication to be shared

**submission**

# INTENTION



**Thank you**