

Optimizing Reliance Pathways Across the Product Lifecycle: Exploring Best Practices to Enhance Predictability and Consistency

Singapore's Perspective

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- Overview of HSA
- Singapore's experience with best practices on regulatory reliance
- A multiprong approach to optimize regulatory reliance

1. OVERVIEW OF HSA

Health Sciences Authority (HSA): National Health Products Regulator

Ensure that health products meet safety, quality and efficacy throughout product life cycle

Ensure timely access to patients

Support development of biomedical sciences industry

Risk based, fit-for purpose regulations with least regulatory burden possible

Reliance/Confidence based approach

Adoption/judicious adaption of international standards & best practices

Forging strategic international partnership

Our Regulatory Approach

Medicines Approvals Statistics



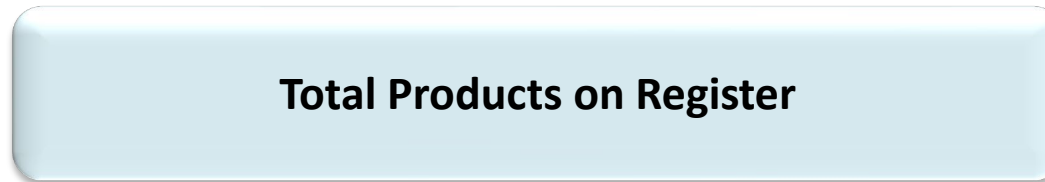
31

New Chemical/Biological Entities Approved in FY 2025



5,131

Products Variation Application Approved



Total Products on Register

210

Total Therapeutic Products Registrations Approved (New Drug Application & Generic Drug Application)



5,098



Statistics for the period
Apr 2025 to Mar 2026
(Figures shown extracted as at end March 2026)

2. SINGAPORE'S EXPERIENCE WITH BEST PRACTICES ON REGULATORY RELIANCE

- Adherence to published turnaround time (TAT) by HSA and stakeholders through:
 - Internal guidance for officers to ensure that review meets application milestones and TAT
 - Self-help tool ([Application timeline calculator](#)) for applicants to estimate key milestone timelines

Application Timeline Calculator

Estimate the key milestone timelines of your therapeutic product registration and major variation applications.

This calculator enables you to estimate the first evaluation input request (IR) and regulatory outcome dates of new product and major variation applications to facilitate submission planning and management. These key milestone dates are calculated based on working days (WD) and the respective application target turnaround times (see [HSA | Fees and turnaround time for therapeutic products](#)). This tool estimates the evaluation timeline and **does not include** the screening process.

Acceptance date

dd/mm/yyyy

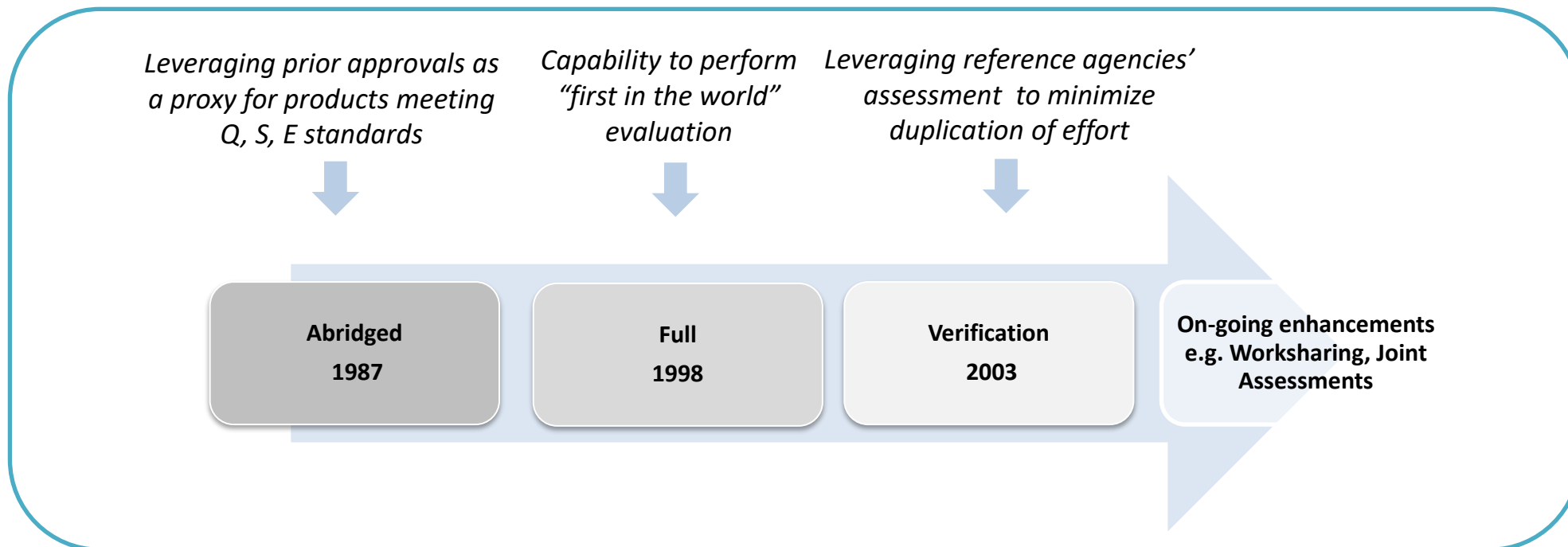


Application type

Select an option ▾

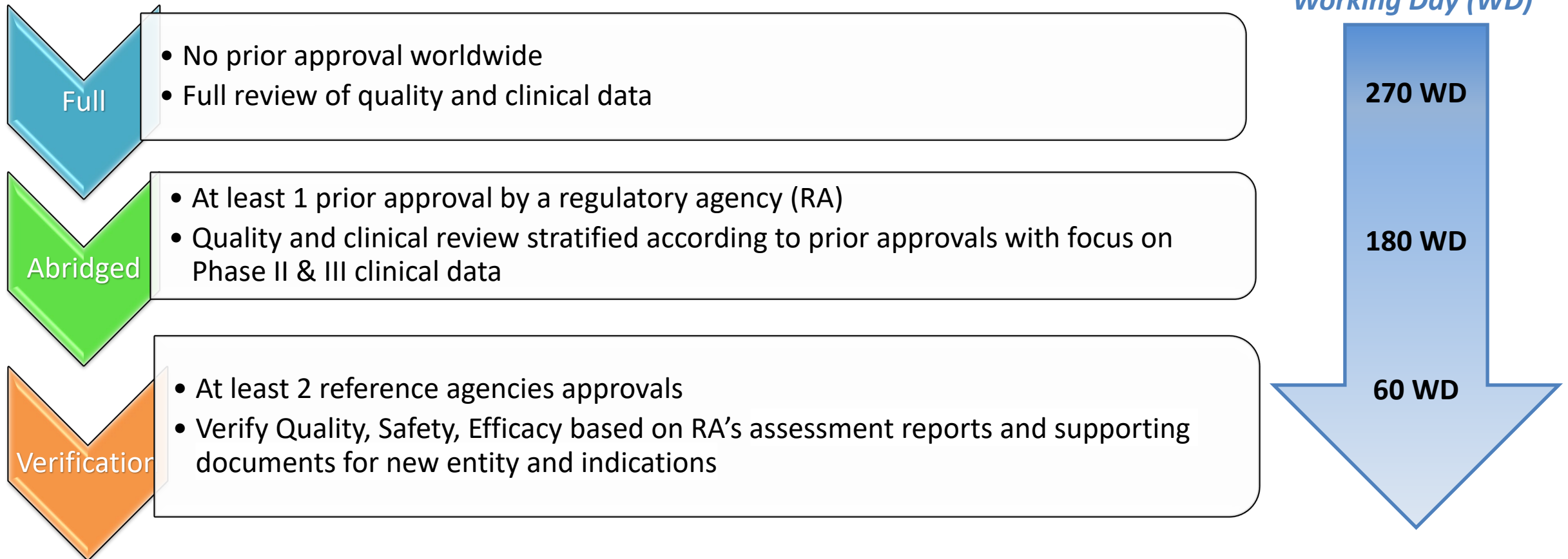
HSA's Medicines Evaluation: A Journey of Pragmatism & Agility

- Drug Registration first implemented in 1987 based on regulatory reliance
- Balance of regulatory efficiency and ensuring access to good quality, safe, and effective therapies
- Continued capability building for independent review
- Refinements to further enhance efficiency e.g., worksharing, joint assessments



Reducing Duplicative Effort

- Confidence-based approach for calibrated depth of evaluation across the product lifecycle to avoid reinventing the wheel
- Focus on value-adding/ contextualizing the assessment e.g., examining differing opinions by between RAs



*RAs: Australia TGA, Health Canada, Europe EMA, UK MHRA, US FDA, Switzerland Swissmedic

Facilitating Confidential Information Sharing – International Partners

HSA engages actively in multilateral and bilateral initiatives and cooperations

North America

- Federal Commission for the Protection Against Sanitary Risk (COFEPRIS), Mexico
- Food and Drug Administration, United States*
- Health Canada

South America

- Brazilian Health Regulatory Agency (ANVISA), Brazil*

Europe

- Health Products Regulatory Authority, Ireland
- Dutch Health Inspectorate, Netherlands
- European Directorate for the Quality of Medicines and Healthcare of the Council of Europe*
- European Medicines Agency*
- European Commission*
- Medicines Evaluation Board, Netherlands
- Medicines and Healthcare Products Regulatory Agency, United Kingdom
- Ministry of Health, State of Israel*
- Office for registration, medical devices and biocidal products (URPL), Poland
- Paul Ehrlich Institute, Germany
- Swedish Medical Products Agency (LV), Sweden
- Swissmedic, Switzerland

Africa

- South Africa Health Products Regulatory Authority, South Africa

Asia

- Thai Food and Drug Administration, Thailand*
- Ministry of Food and Drug Safety (MFDS), South Korea
- Ministry of Health, Labour and Welfare (MHLW), Japan
- Ministry of Health, Brunei*
- Ministry of Health, State of Israel*
- National Medical Products Administration (NMPA), China
- National Pharmaceutical Regulatory Agency (NPRA), Malaysia
- Pharmaceutical and Medical Devices Agency (PMDA), Japan

Australia

- Medsafe, New Zealand
- Therapeutic Goods Administration, Australia*

- World Health Organisation*
- WHO National Control Laboratory (NCL) Network for Biologicals (WHO-NNB)*

3. CONCLUSION

A MULTIPRONG APPROACH

A Multiprong Approach



Enhancing predictability through internal and external guidance and self-help tool



Reducing duplicative effort via a confidence-based approach for calibrated depth of evaluation across the product lifecycle and focused efforts to **value-add/ contextualize assessment**



Facilitating confidential information through multilateral and bilateral initiatives and cooperations with international partners

Thank You!

