Australian Government
Department of Health
Therapeutic Goods Administration

Regulatory aspects of vaccine development

COVID-19 vaccines

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TGA Health Safety Regulation

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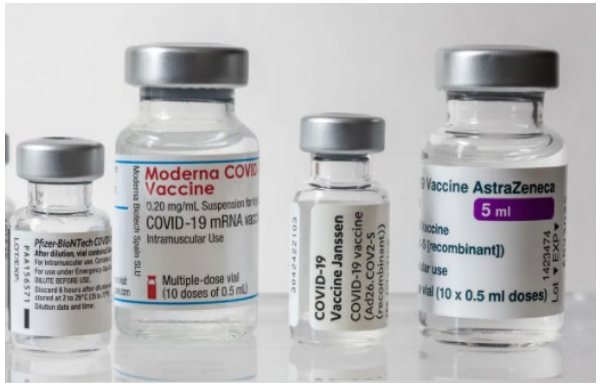
Agenda

- Introduction
- COVID-19 vaccines: Challenges for the medicines regulator
- TGA strategies and response
- Questions

Therapeutic goods in a pandemic



Learnings from COVID

Continue to consider ways to leverage current processes and networks for future health emergencies

To be pragmatic, flexible and adaptive for the priority situations

Increase communications and planning to support the decreased timeframes

Proactively engage with sponsors to assist with decreasing timeframes noting the global pressures due to submitting to multiple regulators in parallel

Regulation in a global pandemic (2020-2022)

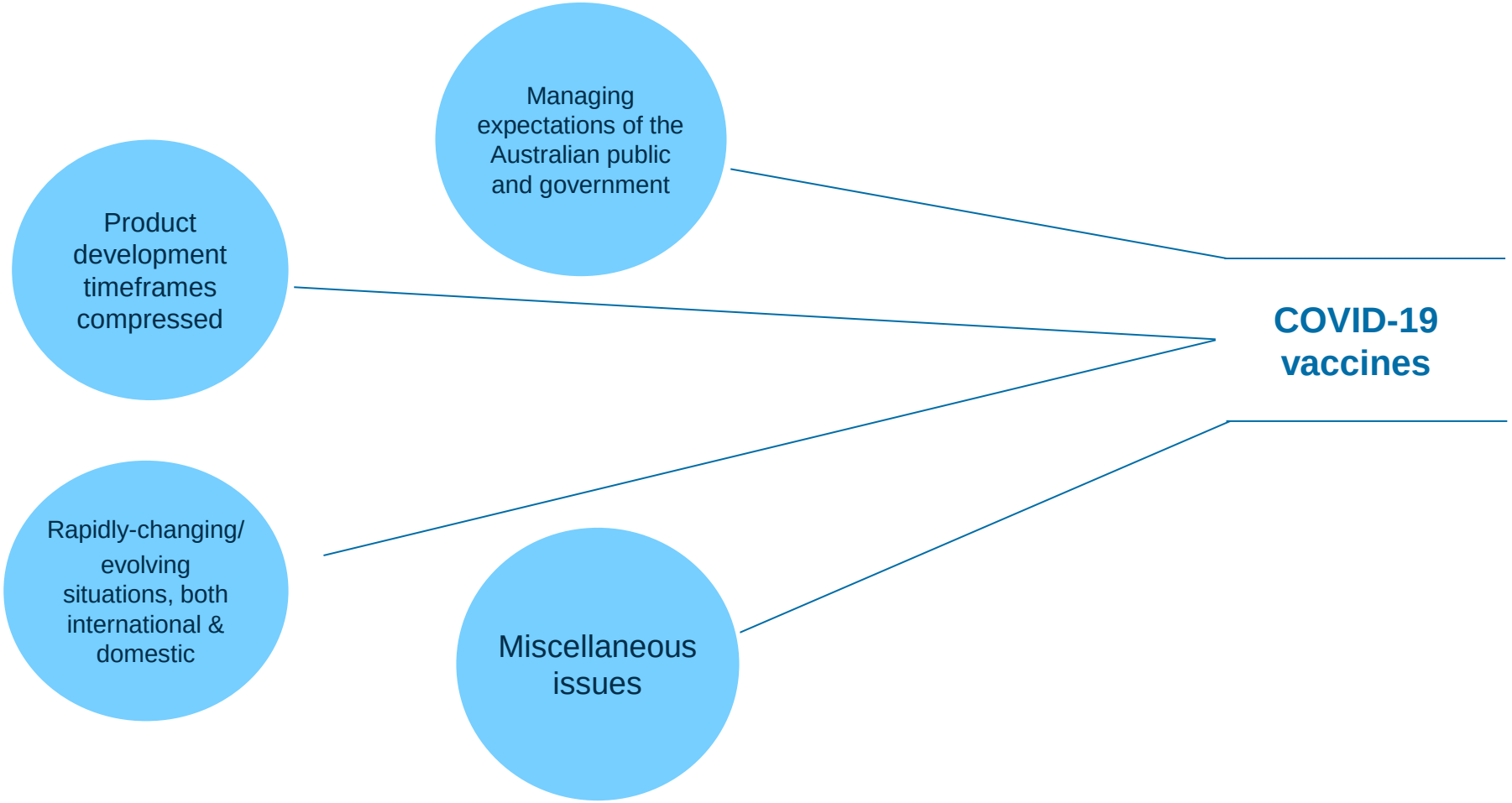
Parallels in pandemics – Spanish flu & COVID-19

- Similarities: quarantine, hygiene
- Differences: rate of global spread of disease & information, product development

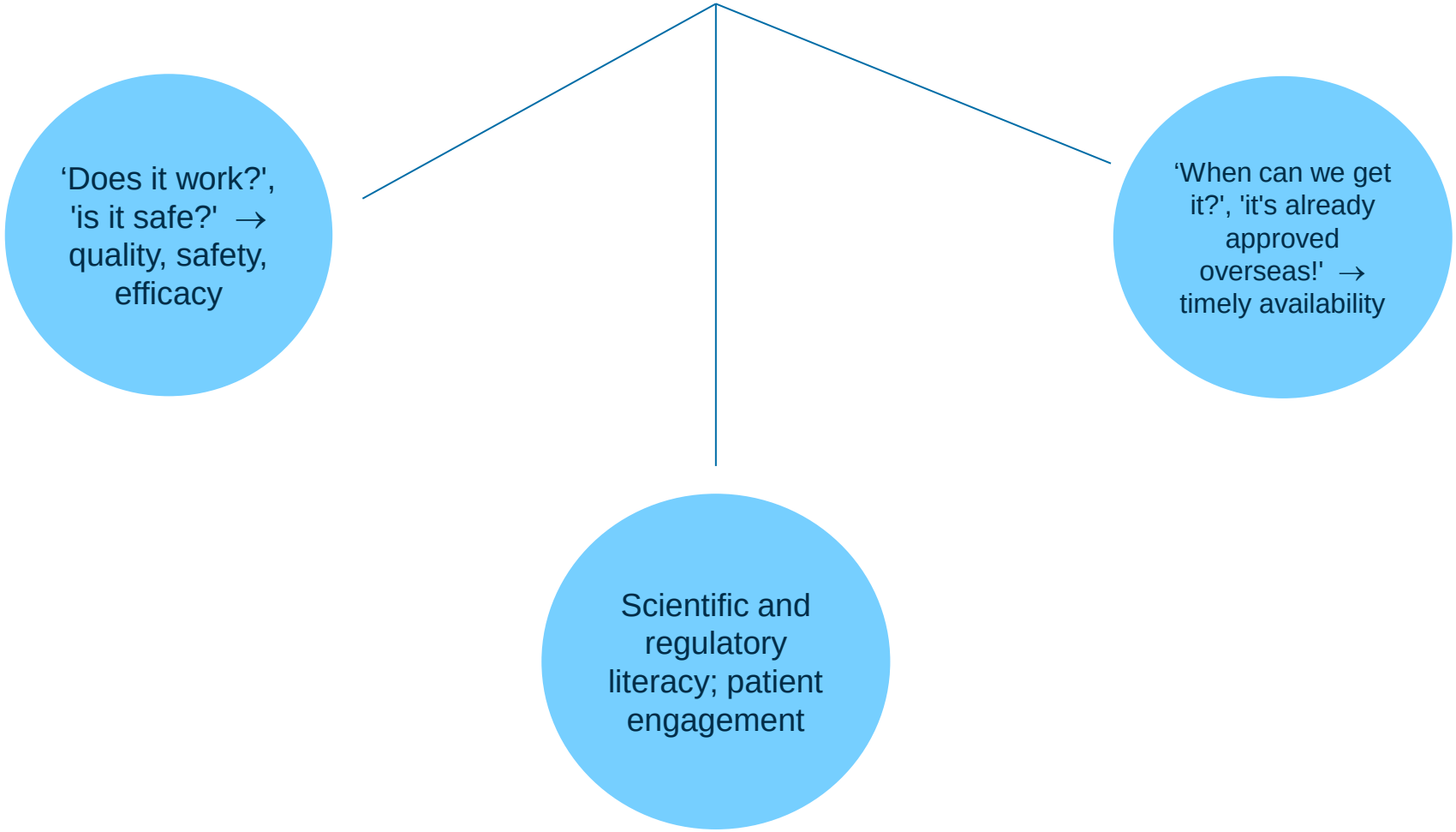
Role of the regulator – Therapeutic Goods Administration

- Therapeutic Goods Act 1989
  - establishment and maintenance of a national system of controls relating to the **quality, safety, efficacy and timely availability of therapeutic goods**

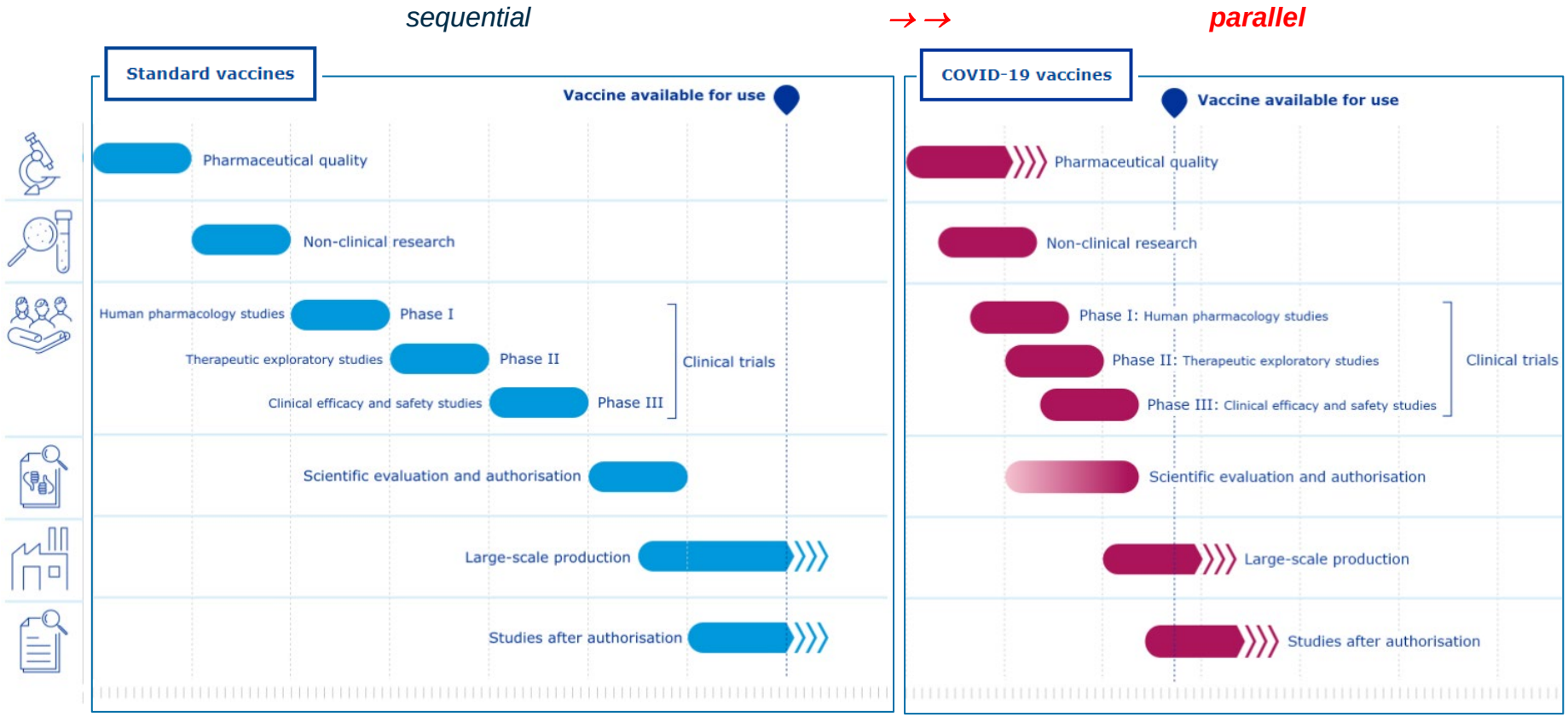
Challenges for the medicines regulator



Managing expectations of the Australian public and government



Product development timeframes compressed



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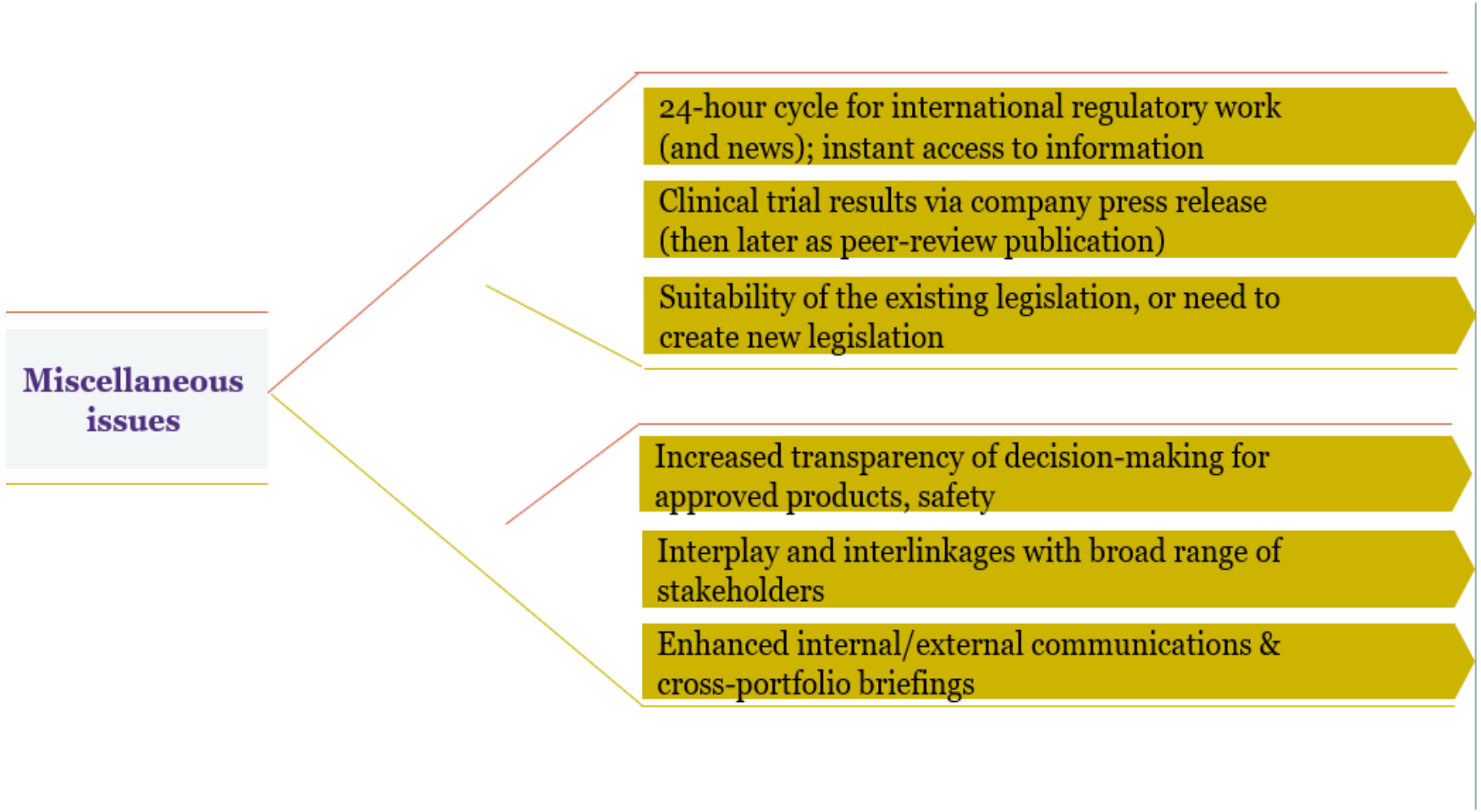
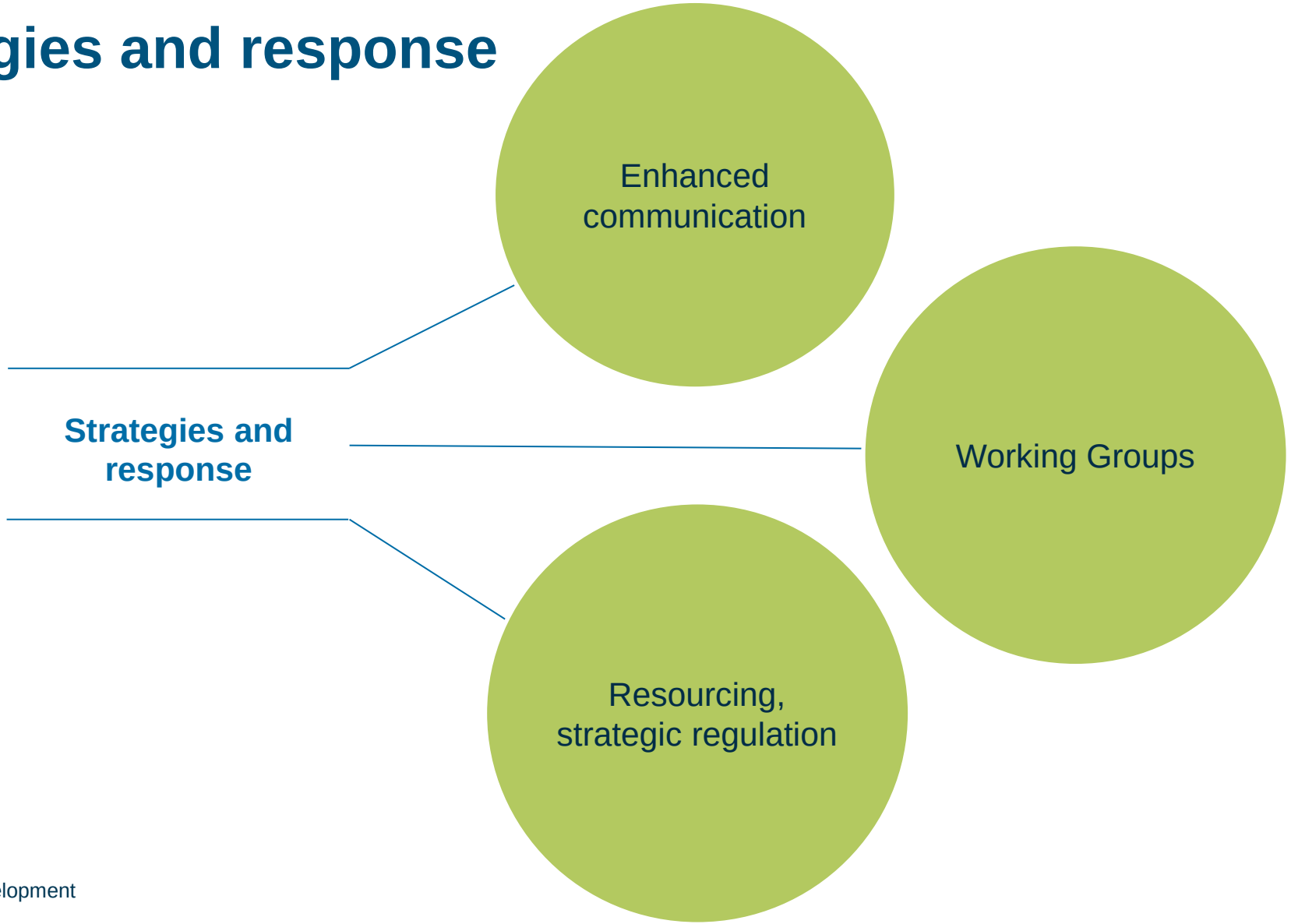
Rapidly-changing/evolving situations, both international & domestic

Outbreaks/waves in different countries (or within a country)

Miscellaneous issues



TGA strategies and response



Enhanced communication

Internal

Department & internal status updates

Broader government engagement

Cross portfolio meetings & State and Territory Government engagement

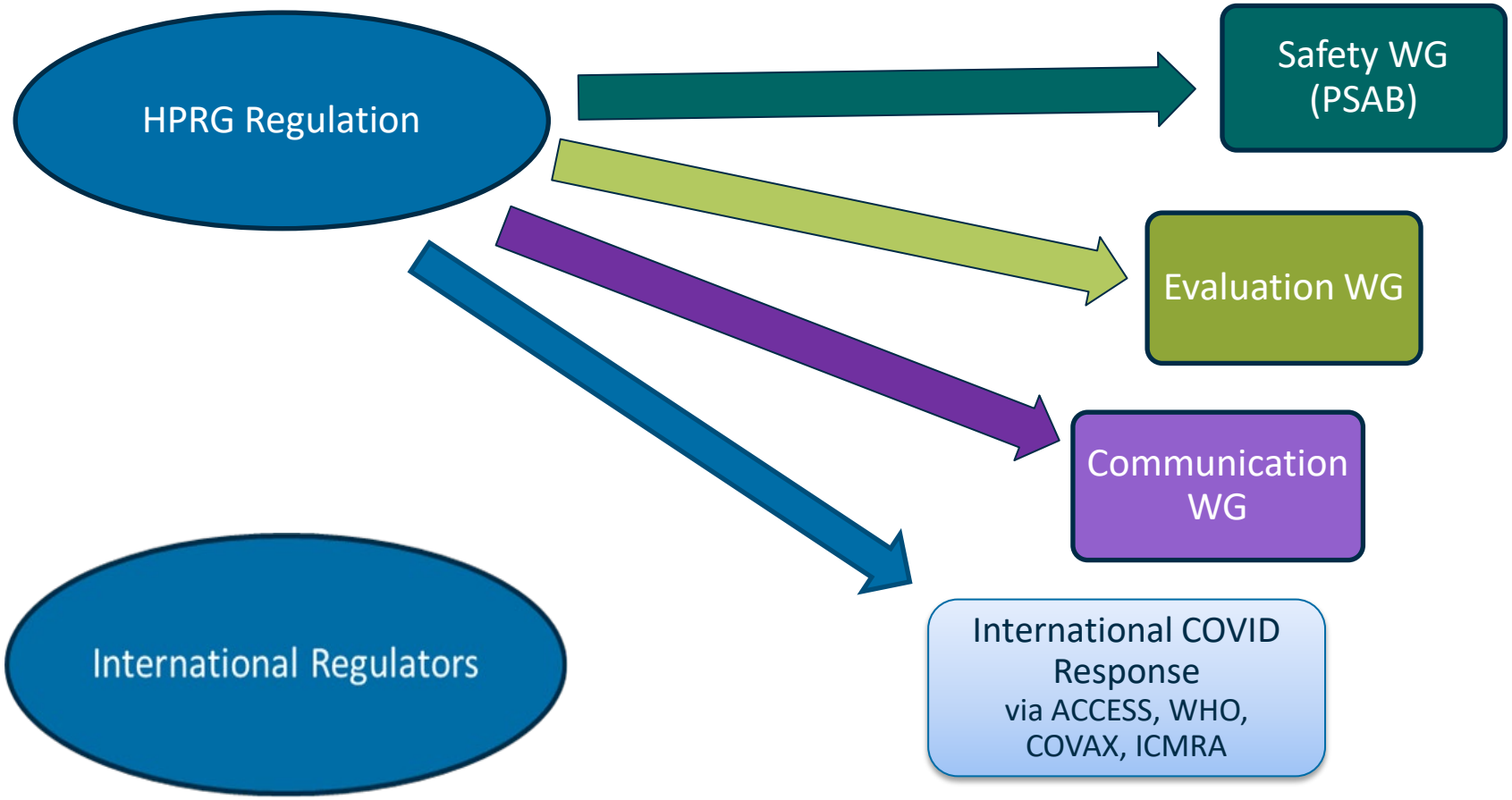
International Regulators

Share research and information supporting new COVID-19 vaccines

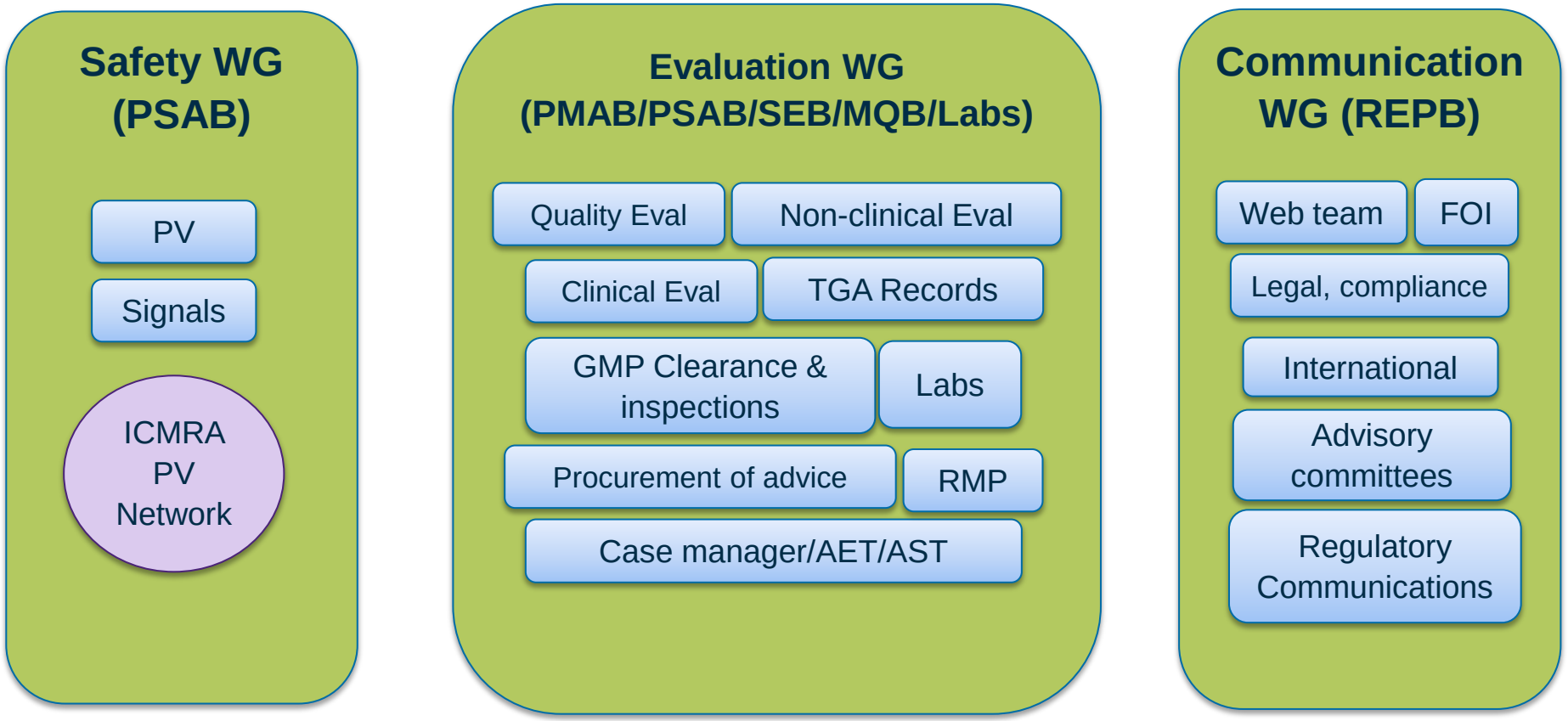
Sponsors (companies)

Manage rolling data

Working groups

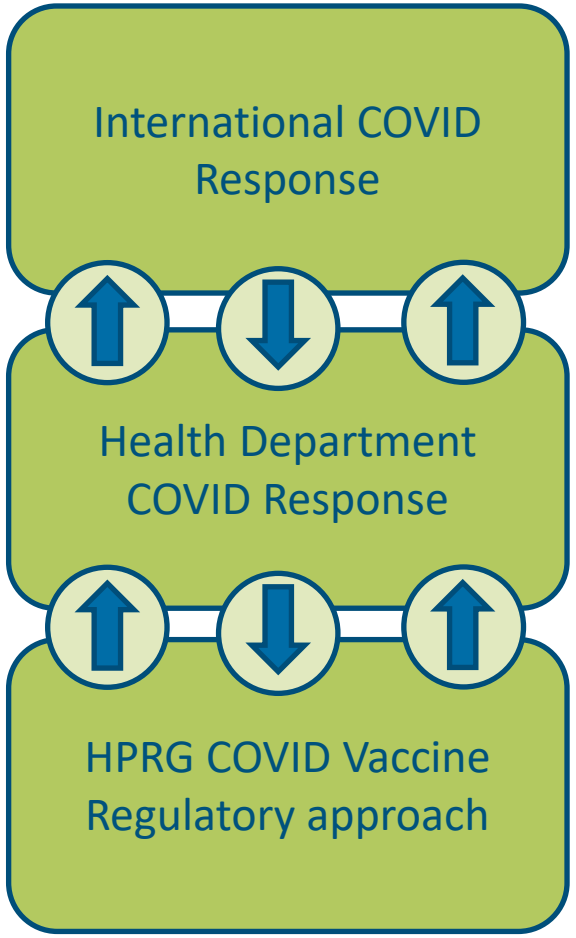


HPRG's regulatory response



Global COVID response & interlinkages

- **TGA involvement with International COVID Response**
  - via WHO, COVAX, ICMRA & subgroups, ACCESS consortium
- **Health Department COVID response**
  - Multi-faceted - various programs mental health, immunisation, testing, Aged Care
  - National COVID vaccine strategy taskforce (5 teams)
  - ATAGI, OGTR, Communications
- **HPRG COVID regulatory approach**
  - Evaluation WG, Safety WG & Communications WG



Resourcing, strategic regulation

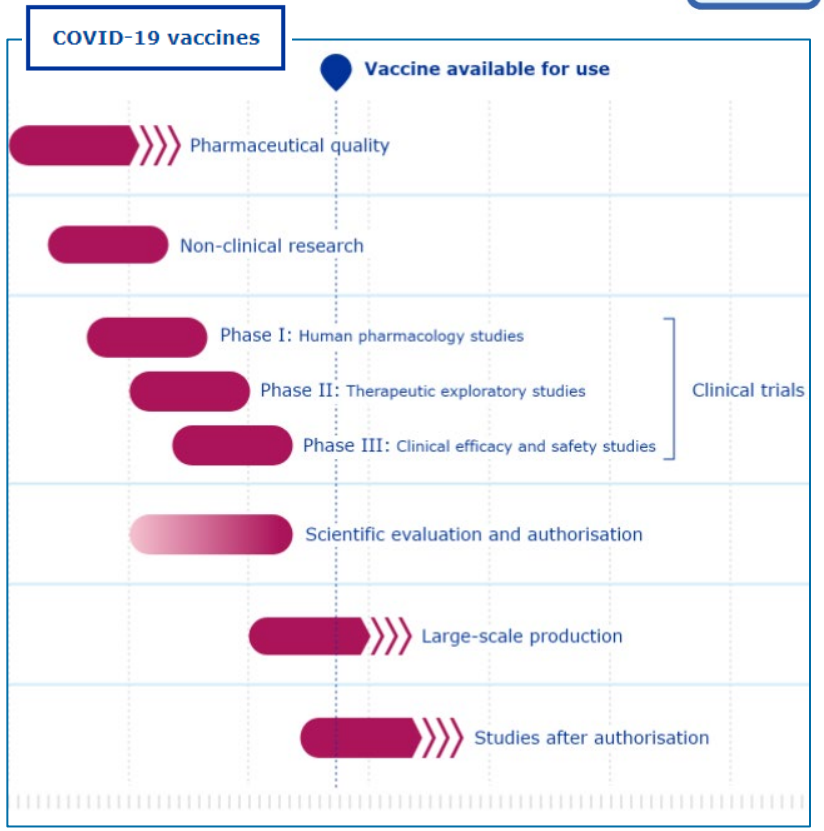
- Additional layer of support to regulatory scientists/medical officers & Executive
- Liaison & coordination with internal/ external (companies, evaluators, broader Dept., Intl regulators)
- Communications, updates, queries (Minister, Senate Estimates, consumers)
- Strategic options, legislation (pathways, flexibilities in a pandemic)

Expedited evaluation process – COVID-19 vaccine

- Managing expectations: 'does it work?', 'is it safe?', 'when can we get it?'
- Maintain strict regulatory standards for: quality, safety, efficacy

Product development and regulatory evaluation timeframes compressed:

- Enhanced communication and planning:
  - weekly t/c with companies during evaluation
- Provisional approval pathway (with post-approval commitments)
- Rolling data & 'informal' format
- Rapid and rolling review by evaluators:
  - highest priority work
  - additional hours
- Ad-hoc meetings of expert advisory committees
- International collaboration with other regulators



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Mechanism for international regulatory collaboration

Confidence-building = gaining comfort/confidence in processes and regulatory framework

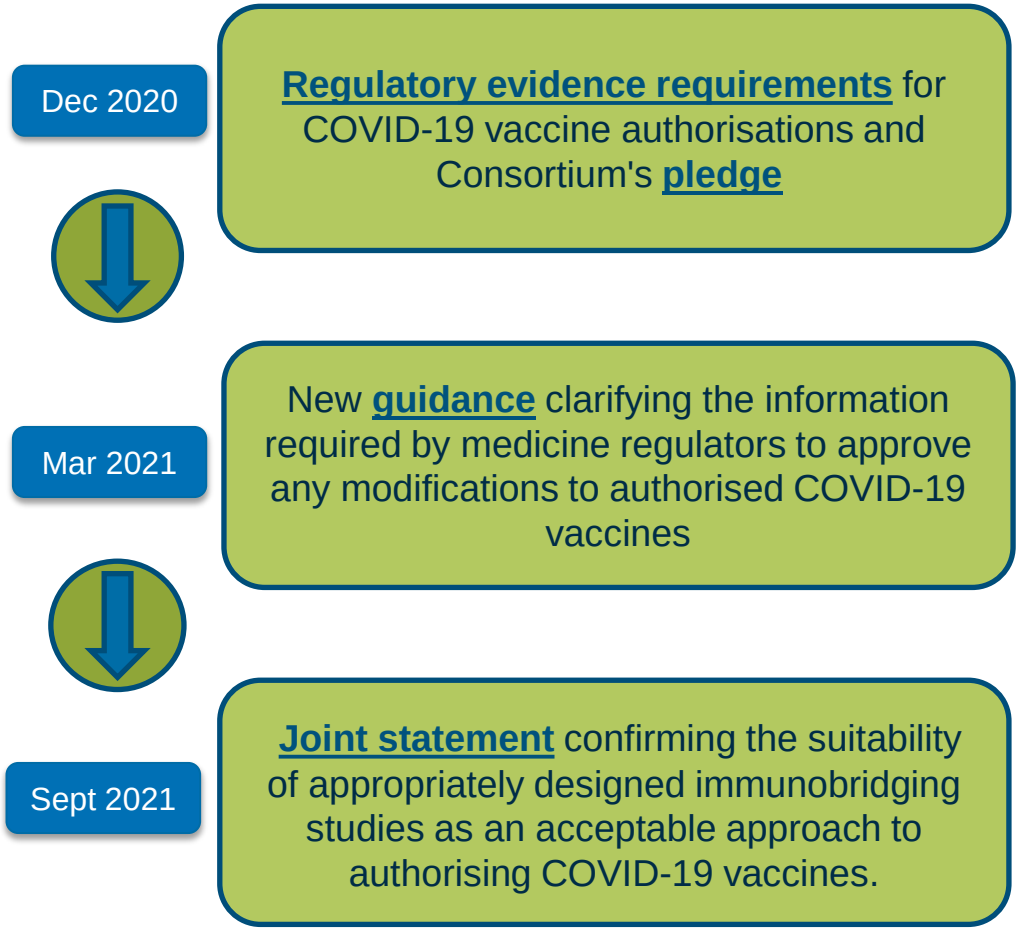
Information-sharing = regulators share completed evaluation reports for a given product; real-time discussions on specific issues (written, teleconferences)

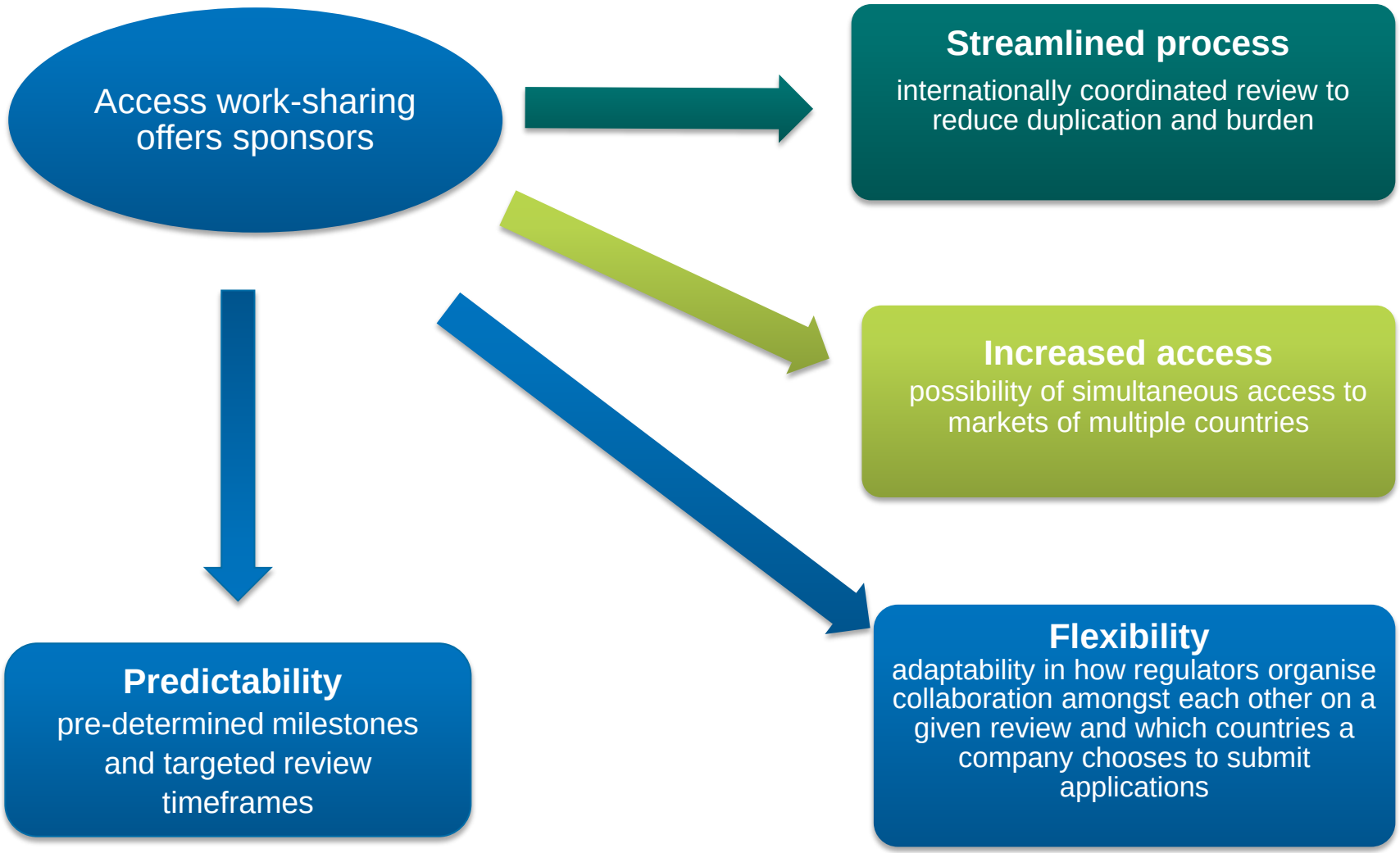
- Access Consortium, Medsafe (NZ), EMA (Europe)
- WHO Emergency Use Listing - TGA as National Regulatory Authority for AZ vaccine: provide TGA evaluation reports to WHO for Australian & Thai manufacturing sites
  - supports donations to Indo-Pacific

Work-sharing = division of evaluation labour across regulators for a given product (evaluation of quality, safety, efficacy)

- Access Consortium

Australia-Canada-Singapore-Switzerland-United Kingdom (Access) Consortium




Access work-sharing offers sponsors
Streamlined process
internationally coordinated review to reduce duplication and burden
Increased access
possibility of simultaneous access to markets of multiple countries
Predictability
pre-determined milestones and targeted review timeframes
Flexibility
adaptability in how regulators organise collaboration amongst each other on a given review and which countries a company chooses to submit applications

COVID-19 vaccine: Provisional registrations

Following a thorough and independent review, the TGA has decided that the following vaccines meet the high safety, efficacy and quality standards required for use in Australia. Learn more about the COVID-19 vaccine approval process.

Effective date	Sponsor	Name	Type
19 January 2022	Biocelect Pty Ltd on behalf of Novavax Inc	NUVAXOVID (NVX-CoV2373) For individuals aged 18 years and over	Protein vaccine
a. 9 August 2021 b. 3 September 2021 c. 7 December 2021 d. 17 February 2022	Moderna Australia Pty Ltd	SPIKEVAX (elasomeran) a. For individuals aged 18 years and over b. For individuals aged 12 years and over c. Booster dose for individuals aged 18 years and over d. For individuals aged 6 years and over	mRNA
25 June 2021	Janssen-Cilag Pty Ltd	COVID-19 Vaccine Janssen For individuals aged 18 years and over	Viral vector
a. 15 February 2021 b. 8 February 2022	AstraZeneca Pty Ltd	VAXZEVRIA (previously COVID-19 Vaccine AstraZeneca) a. For individuals aged 18 years and over b. Booster dose for individuals aged 18 years and over	Viral vector
a. 25 January 2021 b. 22 July 2021 c. 26 October 2021 d. 3 December 2021 e. 27 January 2022 f. 7 April 2022	Pfizer Australia Pty Ltd	COMIRNATY (tozinameran) a. For individuals aged 16 years and over b. For individuals aged 12 years and over c. Booster dose for individuals aged 18 years and over d. For individuals aged 5 years and over e. Booster dose for individuals aged 16-17 years old f. Booster dose for individuals aged 12-15 years old	mRNA

https://www.tga.gov.au/covid-19-vaccine-information-consumers-and-health-professionals#provisional
COVID-19 vaccine: Provisional registrations | Therapeutic Goods Administration (TGA) as of 27 April 2022

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THANK YOU.....

DO YOU HAVE ANY QUESTIONS ?

Australian Government

Department of Health

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