Australian Government
Department of Health
Therapeutic Goods Administration

Overview of GMP Regulatory Activities

GMP Forum 2021

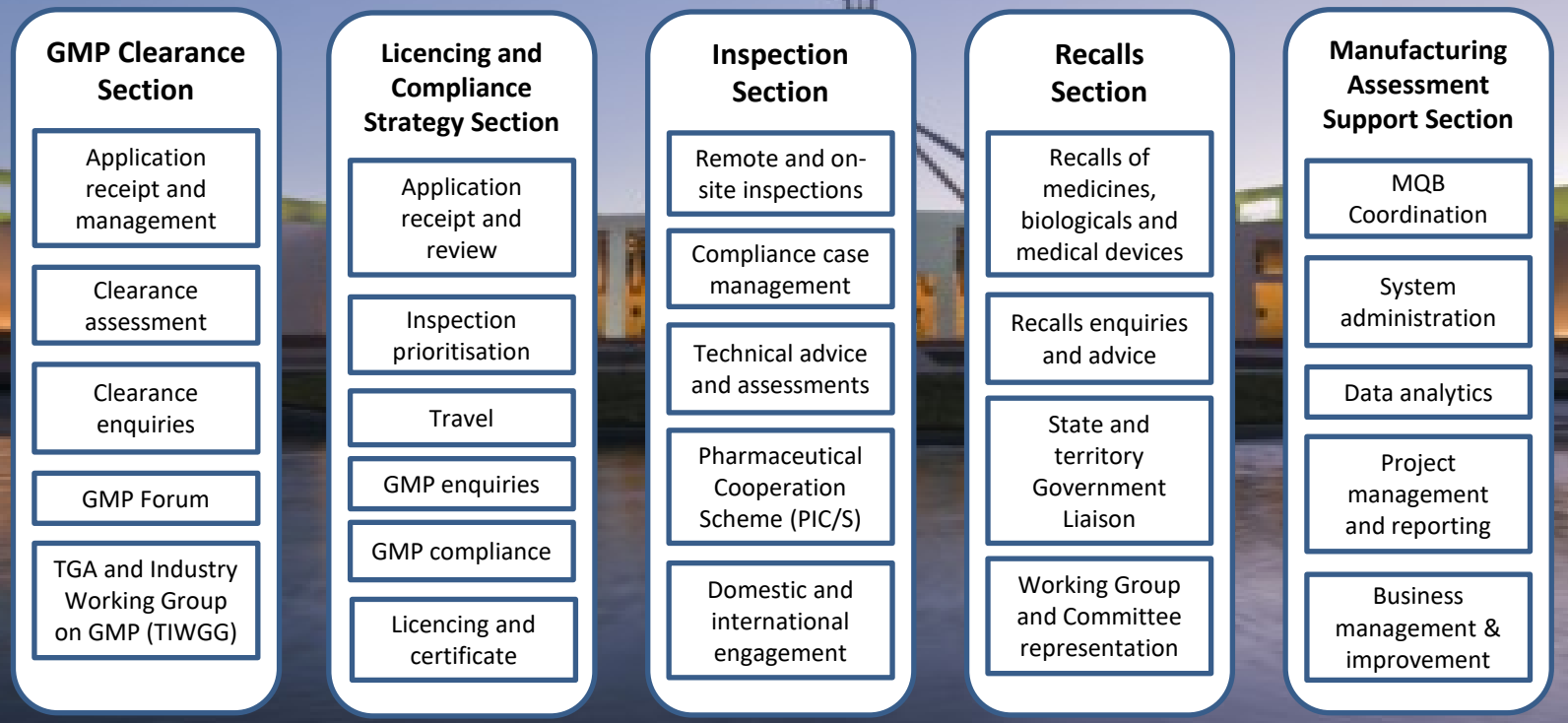
Ben Noyen

Assistant Secretary
Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
GMP Forum 2021

TGA Health Safety Regulation

12/05/2021

Manufacturing Quality Branch



Our Annual Reports

Three options for GMP clearance

1) GMP clearance through a MRA desktop assessment

Use this if:

- the manufacturing site is located within the borders of an MRA country **and**
- the site has been inspected by that country's regulatory authority

2) GMP clearance through a compliance verification (CV) desktop assessment

Use this if:

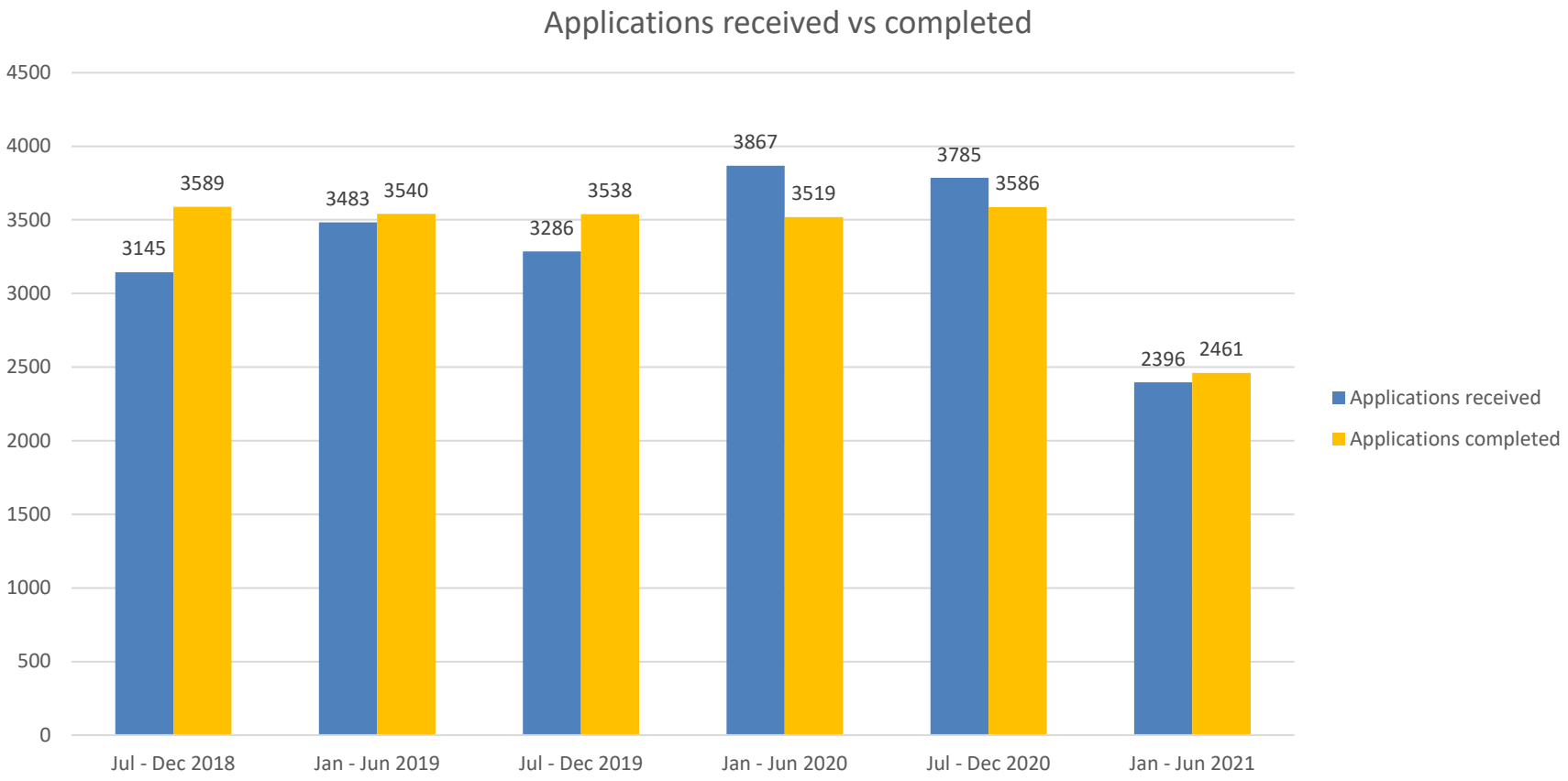
- the manufacturer does not meet the criteria for MRA **and**
- the site has been inspected by a regulatory authority that has an agreement or arrangement with TGA

3) GMP certification via a TGA on-site inspection

Use this if:

- MRA and CV pathways are not applicable **or**
- no acceptable evidence from a recognised regulatory authority is currently available

GMP Clearances



GMP clearances during COVID-19 pandemic

A number of our overseas regulatory partners faced disruptions to their on-site inspection programs for both domestic and overseas manufacturers. This created additional challenges for our reliance mechanisms requiring flexibility in our regulatory oversight.

TGA Inspections Approach

Licencing and Certification Section

Application receipt, compliance signal or re-inspection activates a review process.

Application review and pre-inspection questionnaire informs whether to undertake a GMP clearance or remote inspection.

Scheduling and assignment of inspection to Inspector following conflict of interest check.

Costing estimate determined and agreed with Australian sponsor and initial invoice sent.

Inspection Section

Inspector undertakes preliminary review and develops Inspection Plan.

Desktop evaluation only for reinspections where GMP Clearances have previously been granted.

Evaluation of evidence including electronic documents through secure platforms; live sharing of screens displaying computerised systems; teleconference and videoconferences with manufacturer personnel and SMEs**.** Video recordings supplied by manufacturer may be reviewed. Translation may be required.

Inspection Section

Live virtual inspection required at high risk or new international sites where there has been no or unreliable prior visits from other regulators. These may be undertaken by manufacturer personnel or third parties.

On-site limited time domestic inspection undertaken for all domestic sites unless WHS risks exist, travel restrictions apply or when manufacturers cannot accommodate inspection of COVID-19 reasons.

Live video (via smart glasses, mobile cameras, drones or cameras) meetings to review manufacturing operations, equipment, facilities and relevant documentation. Translators may be required.

Overseas regulator assistance may be sought as a last resort to undertake onsite components of international inspections. Existing MOUs will be used (if possible) to facilitate arrangements or re/developed if required.

PIL prepared and issued to manufacturer.

CAPA received then liaison with manufacturer prior to finalisation of Inspection Report and close out of inspection.

Review Panel may be convened when serious compliance issues identified.

All Sections

Invoicing of inspection reconciled.

GMP Certificates are issued only when a full desktop and virtual inspection process is undertaken or if an inspection by another regulator if deemed relevant and reliable.

GMP Clearance issued to Australian Sponsor for international inspections.

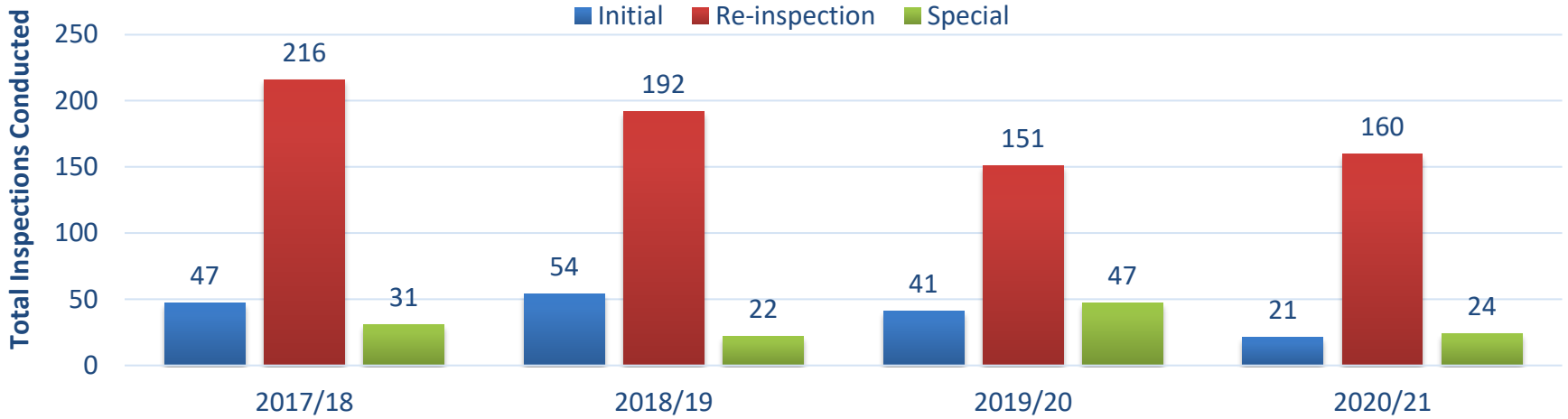
Licences may be issued with conditions.

Acronyms

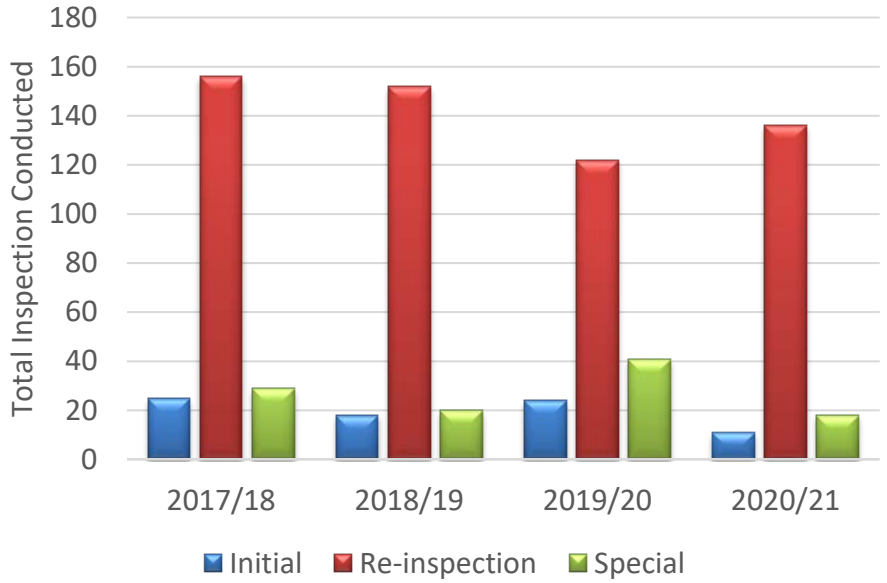
CAPA – Corrective and Preventative Action
GMP – Good Manufacturing Practice
MQB – Manufacturing Quality Branch
PIL – Post Inspection Report
SME – Subject Matter Expert

GMP Inspections
(at 20 April 2021)

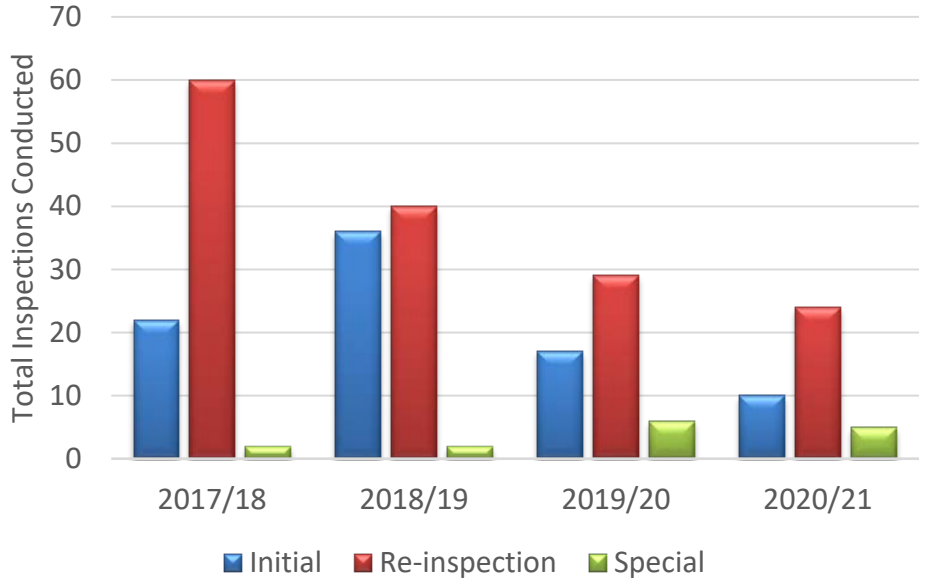
Overall



Domestic Inspections

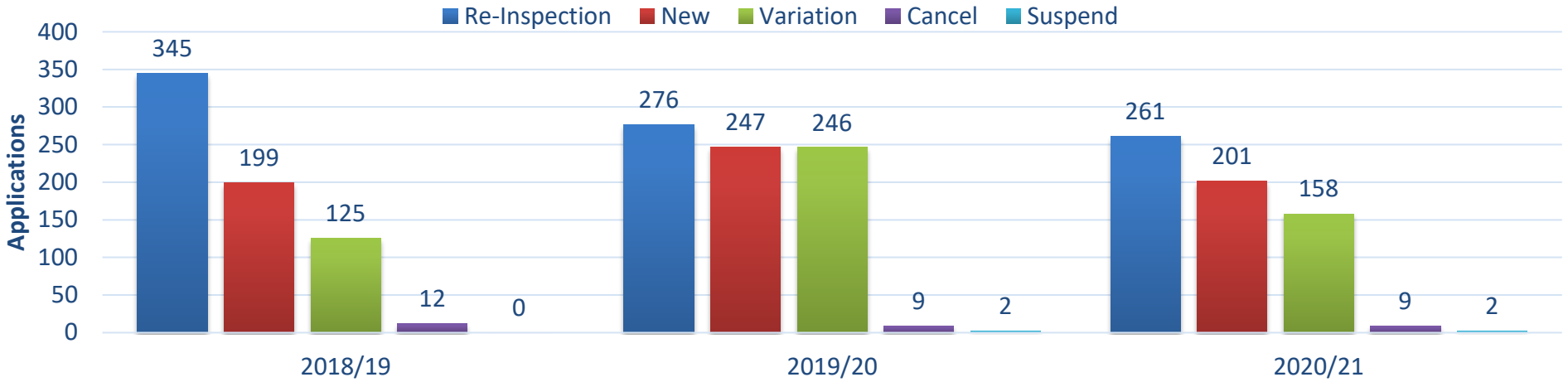


Overseas Inspections

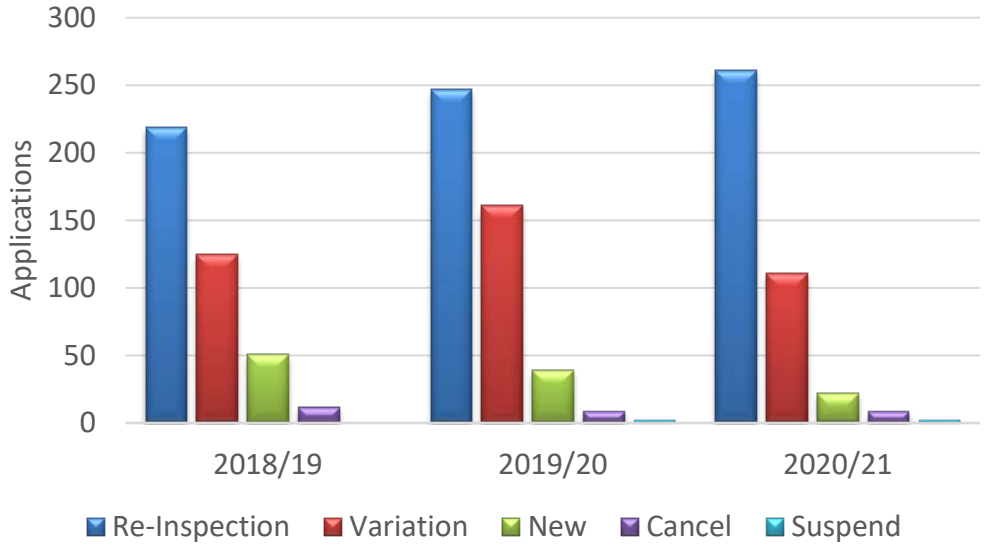


GMP Licence and Certificate Applications (at 20 April 2021)

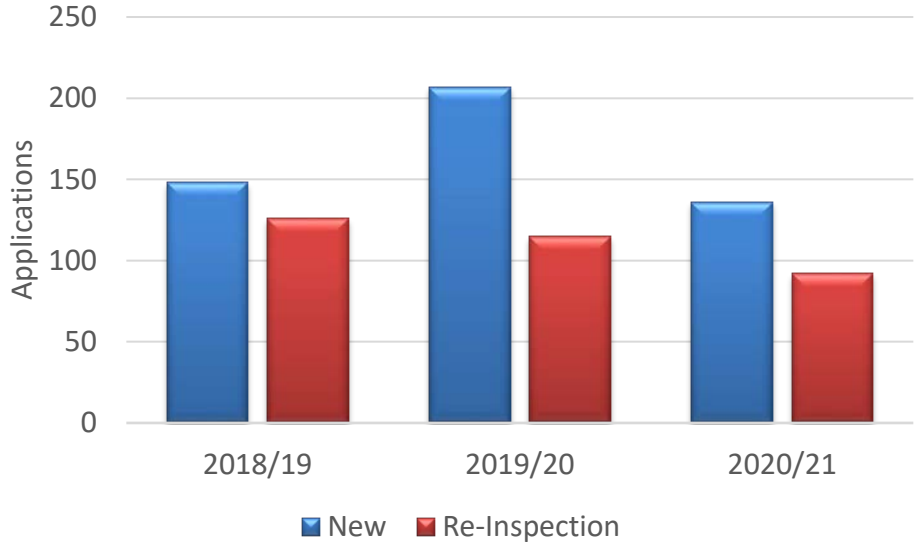
Total Licence and Certificate Applications



Domestic Licence Applications



Overseas Certificate Applications



Exemption to enable timely access to radiopharmaceuticals and RAI

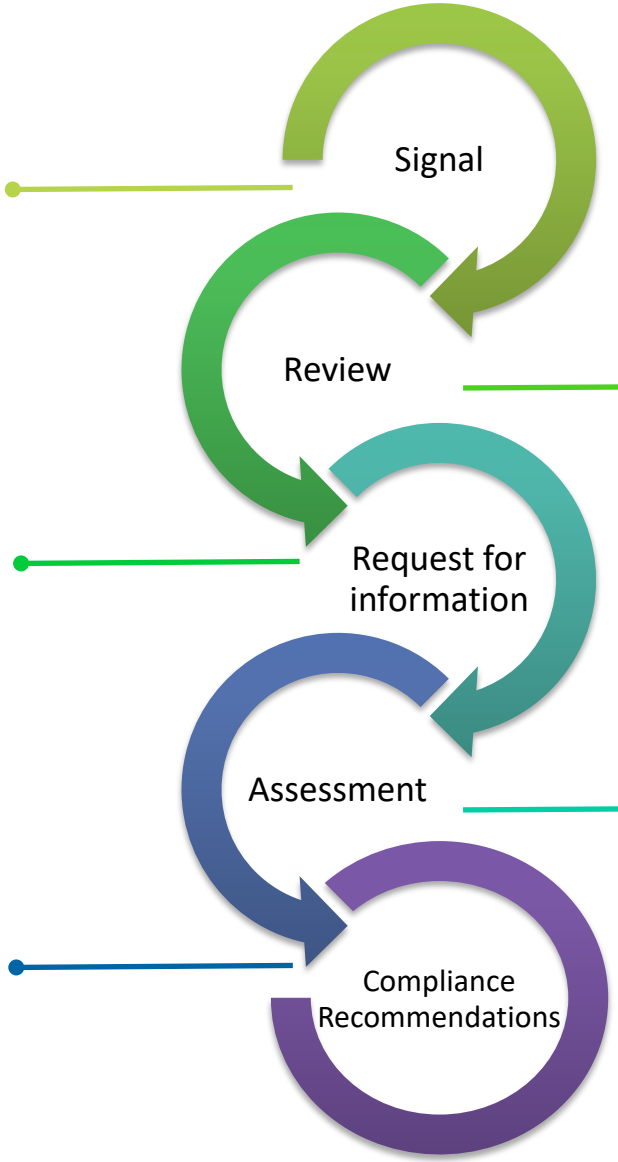
- Therapeutic Goods Amendment (Radiopharmaceuticals and Radiopharmaceutical Active Ingredients) Regulations 2020 amended the TG Regulations to provide an exemption, in Schedule 7 to the TG Regulations, from the operation of Part 3-3 of the Act for certain radiopharmaceuticals and RAI.
- The exemption enabled specified persons within public and private hospitals and public institutions that do not hold a manufacturing licence under the Act to manufacture radiopharmaceuticals or RAI for the treatment of a patient in another State or Territory,
- This enables radiopharmaceuticals or RAI can be transported to the patient in a timely manner.

Management of GMP compliance signals

Signal received by Compliance team and an investigation begins.

Sponsors are requested to provide risk assessments and other additional information relevant to the signal.

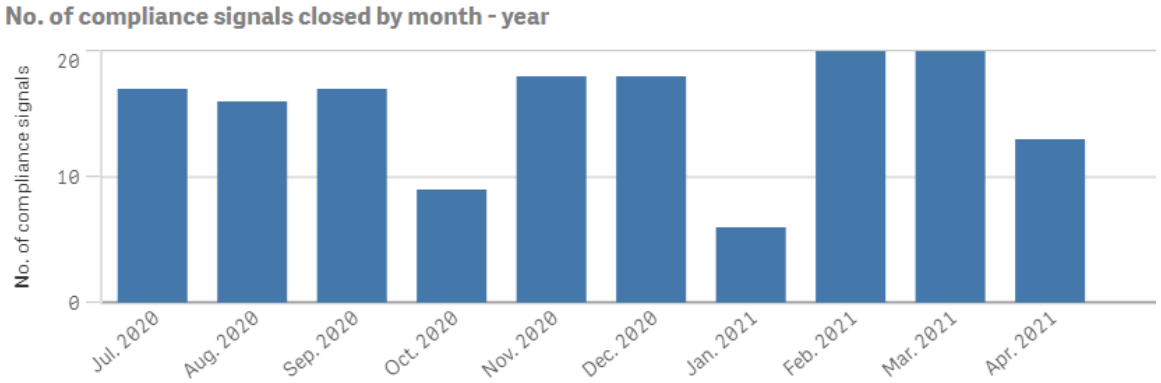
Sponsors are notified of the outcome of the compliance investigation and regulatory actions

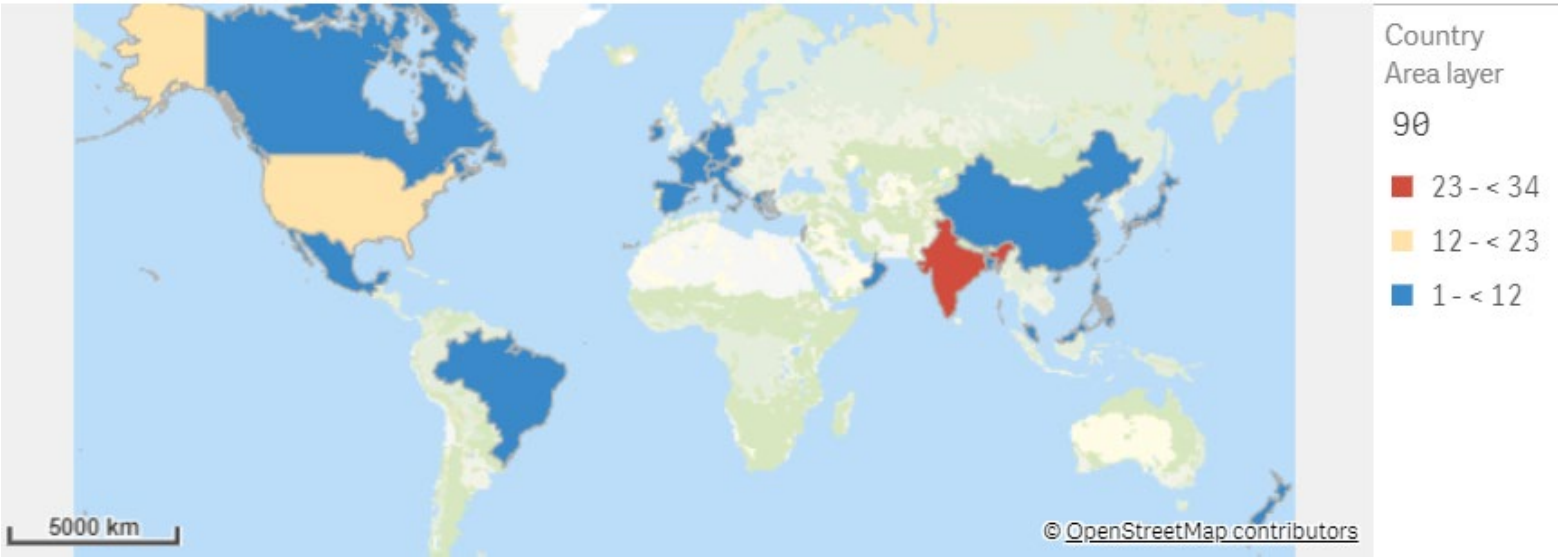


GMP clearance applications related to the site are placed on hold pending the outcome of the assessment.

Assessment of information and documentation from sponsor and manufacturer.

GMP Signals


No. of compliance signals closed by month - year
No. of compliance signals
20
10
0
Jul. 2020
Aug. 2020
Sep. 2020
Oct. 2020
Nov. 2020
Dec. 2020
Jan. 2021
Feb. 2021
Mar. 2021
Apr. 2021


Country
Area layer
90
23 - < 34
12 - < 23
1 - < 12
5000 km
© OpenStreetMap contributors

Recalls of therapeutic goods

For all therapeutic goods the TGA:

- coordinates recall and non-recall actions
- receives and assesses all new notifications – domestic & overseas
- agrees the type, depth and classification of recall actions and the sponsor's recall letter and communication strategy
- distributes the Commonwealth recall notice to all State & Territory recall coordinators for further jurisdictional action, as appropriate.

All notifications are actioned in accordance with the Uniform Recall Procedure for Therapeutic Goods (URPTG)

	2020	2021
	1 January – 31 December	1 January – 4 May (*)
Medicines	76 (10%)	31 (10%)
Medical devices	575 (76%)	264 (81%)
Biologicals	15 (2%)	5 (2%)
Bloods	89 (12%)	23 (7%)
Total recalls	**755 (100%)**	**323 (100%)**

(*) 2021 year to date

TGA Digital Transformation

To deliver a contemporary regulatory platform to allow the TGA to be more flexible, transparent and connected, to better safeguard the health and safety of all Australians.

TGA Transformation Program Vision

Reduce regulatory burden and costs for businesses

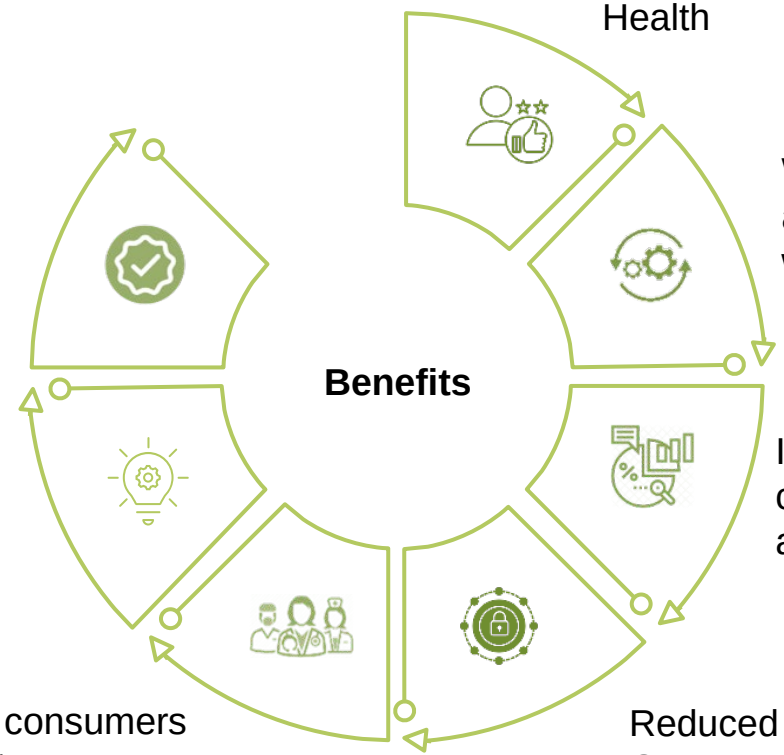
Improve responsiveness to the needs of industry, patients, consumers and healthcare professionals

Make faster, more consistent decisions

Better inform health consumers through greater data accuracy

Reduce risk to Government service delivery

TGA Digital Transformation Benefits



Improved customer experience for sponsors when interacting with TGA and Health

Workflow efficiencies through automation and reduction of manual workarounds

Improved data analytics capabilities to support the TGA and multiple stakeholders

Reduced cyber security risk to Government service delivery, through provision of modern platforms

Better informed health consumers through greater data accuracy

The TGA will be more responsive and make faster, more consistent decisions

Consumers feel more confident in how we regulate products

The TGA transformation will take a number of years and deliver various outcomes.

Which 3 outcomes are you most excited about?

TGA and Industry Working Group on GMP (TIWGG)

Accord Australasia
Active Pharmaceutical Ingredient Manufacturers' Association of Australia (APIMAA)
Association of Therapeutic Goods Consultants (ATGC)
Australia and New Zealand Region of International Society of Cell and Gene Therapy (ISCT)
Australia New Zealand Industrial Gas Association, (ANZIGA)
Australian Red Cross Lifeblood (Lifeblood)
Biotherapeutics Association of Australasia (BAA)
Complementary Medicines Australia (CMA)
Consumer Healthcare Products Australia (CHP)
Generic and Biosimilar Medicines Association (GBMA)
Medicinal Cannabis Industry Association (MCIA)
Medicines Australia (MA)

Focusing on education of industry professionals about GMP

The TIWGG has identified a need to improve access to education material and resources for members and industry, including documentation and webinars.

The TIWGG noted that some of their members lack base knowledge of GMP and manufacturing, legislation and regulatory requirements.

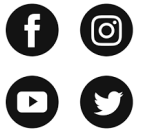
TGA Website

Webinars

Bilaternal meetings

Forums and conferences

Telephone
1800 020 080



Social media

Email
GMP@health.gov.au
GMPClearnace@health.gov.au
GMPCompliance@health.gov.au

What three areas relating to GMP are you most interested to learn about?

International update

International Coalition of Medicine Regulatory Authorities (ICMRA)

- PIC/S partnership proposal
- ICMRA Digital Transformation and Inspections Working Group

Pharmaceutical Inspection Cooperation Scheme (PIC/S)

We continue to have active participation in the international development, implementation and maintenance of harmonised Good Manufacturing Practice standards and quality systems of inspectorates for medicines, including direct participation in:

- Subcommittee on GM(D)P harmonisation
- Subcommittee on Compliance
- Subcommittee on Strategic Development
- PIC/S working group on Data Integrity
- PIC/S working group on classification of deficiencies
- PICS working groups on Blood, Tissues and Cell Therapies and ATMPs
- PIC/S working group on inspection reliance
- PIC/S working group on Good Clinical Practice and Pharmacovigilance
- PIC/S working group on Unique Facility Identifiers (UFI)
- Expert Circles for API and Cross Contamination in Shared Facilities

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Medicinal Cannabis

The TGA recently consulted on proposed reforms to the regulation of medicinal cannabis manufacturing, labelling and packaging. The reforms are principally intended to enhance the quality and safety of medicinal cannabis products by introducing equivalent GMP requirements for imported and domestic medicinal cannabis, introducing labelling requirements for imported medicinal cannabis, and requiring child-resistant closures to be used on products.

Development of a Good Clinical Practice (GCP) Inspection Program

Collecting and Verifying Information

• Legal and Administrative – examination of aspects related to the implementation, progress and termination of the clinical trial, including evidence of communication with the HREC and regulatory authorities

• Organisational – examination of the implementation of the trial at the site, including qualifications and experience of site personnel, delegation of authority, standard operating procedures, facilities and equipment, source of the investigational medicinal product, monitoring and auditing records

• Informed Consent – determine whether patient consent was obtained in accordance with GCP Guidelines and approving authority requirements

• Clinical Trial Data – review whether the trial was conducted according to the study protocol by source data verification (SDV), particularly inclusion/exclusion criteria

• Management of the Investigational Medicinal Product (IMP) used in the trial.

Operational Review

In mid 2020 Manufacturing Quality Branch undertook a review of its functions and work processes to identify and implement improvements to its core function of regulating the manufacturing quality of therapeutic goods supplied in Australia.

Looking ahead

Contact us

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GMPCompliance@health.gov.au

Australian Government

Department of Health

Therapeutic Goods Administration