Australian Government
Department of Health
Therapeutic Goods Administration

2015 - Achievements and challenges

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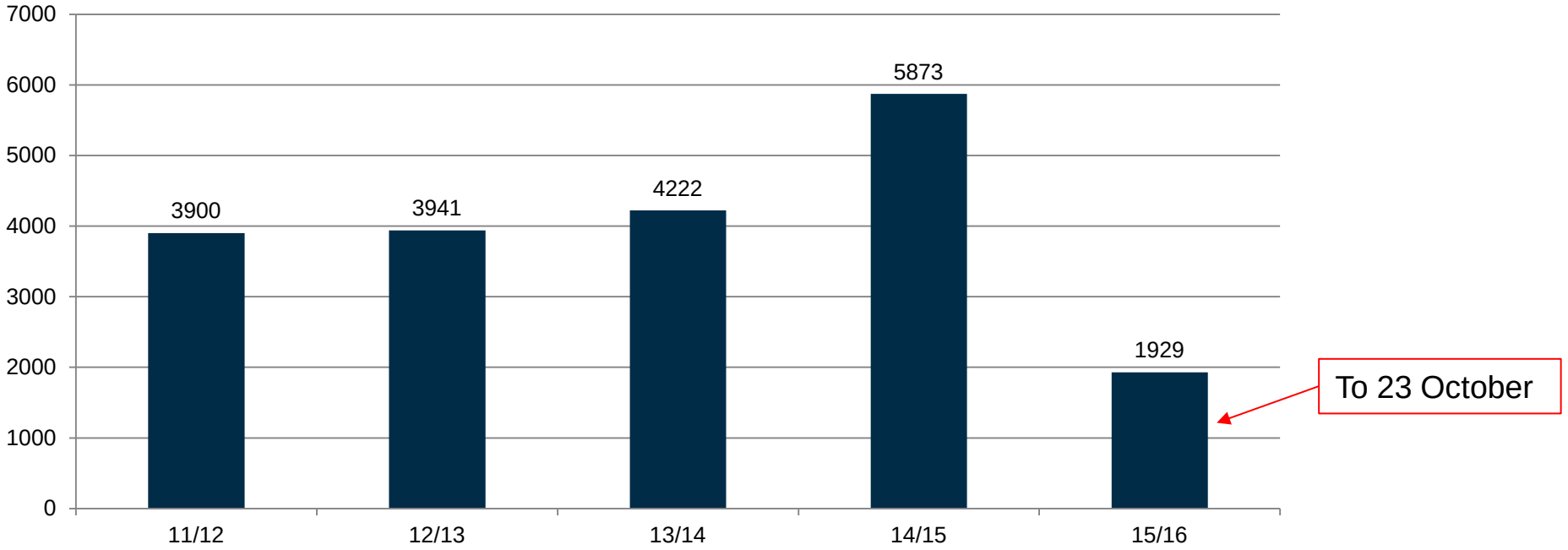
Overview

- 2015: Achievements and challenges
  - GMP clearances
  - Inspections performance data
- Looking ahead to 2016
  - Inspection close out process improvement
  - Rewarding consistent high levels of compliance

GMP clearances

GMP clearance applications



What are we doing to reduce clearance times?

Improving our ability to meet demand

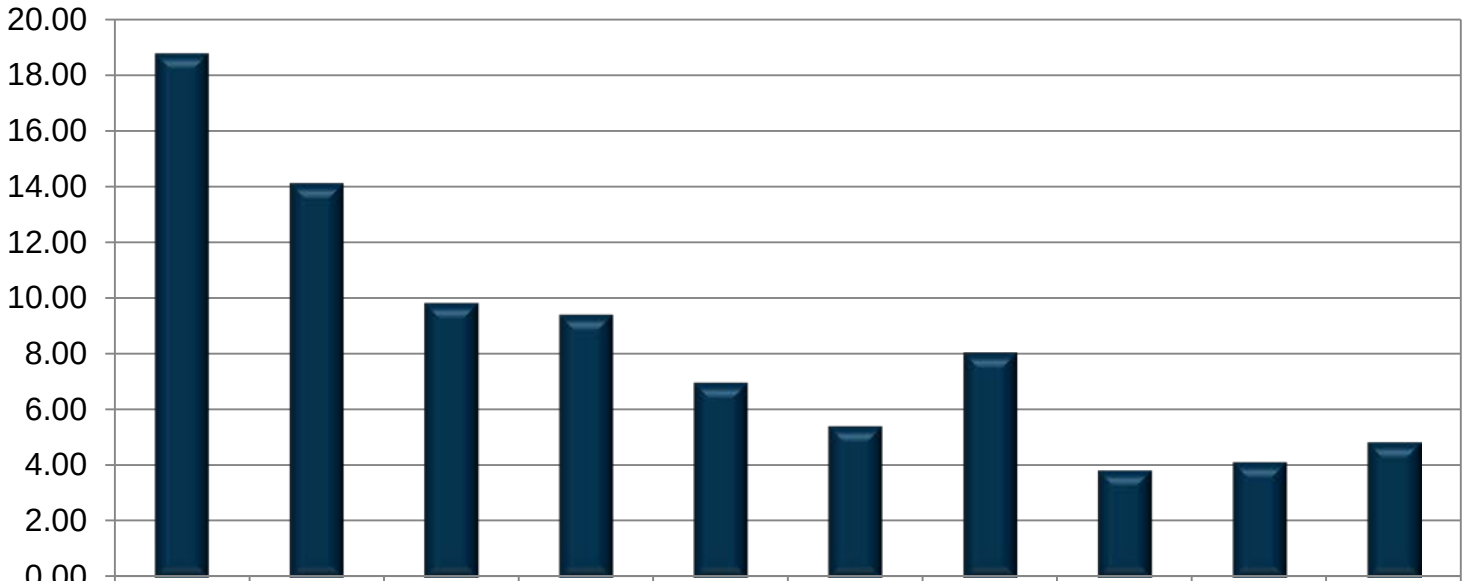
- OMQ restructure: aligning structure with function
- Improved application triaging
- Improved information management

Communication

- Updates on TGA website
- PDA presentations!
- TGA - Industry Working Group on Manufacturing Quality

GMP clearances

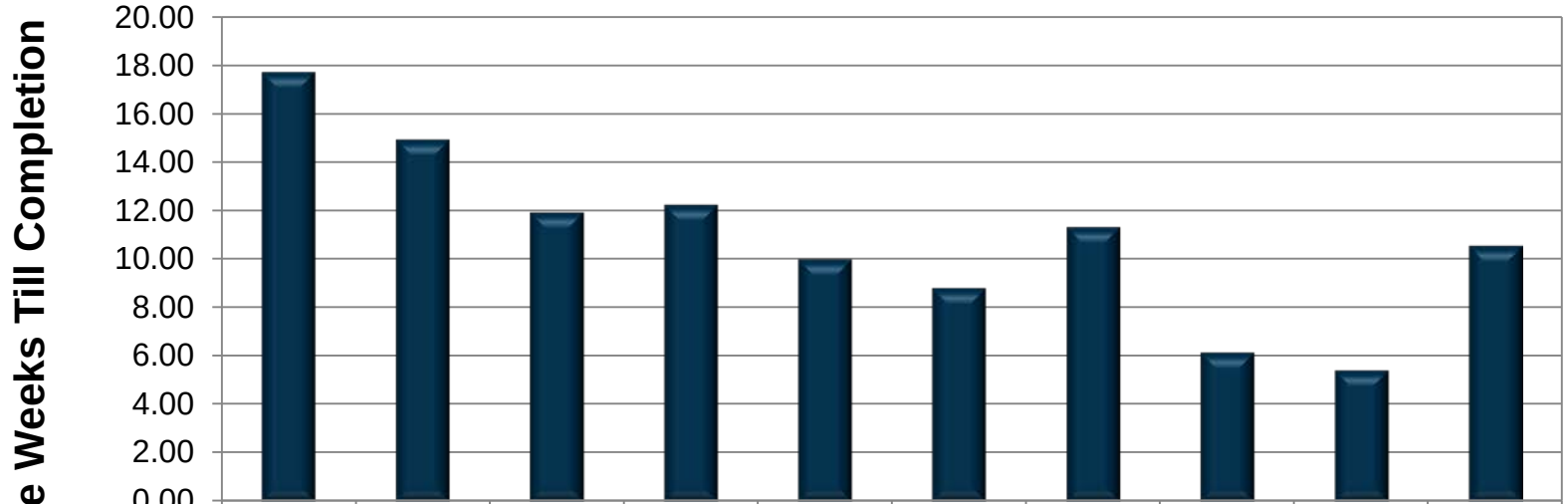
GMP clearance processing times - median



	08-19 June	22-03 June-July	06-17 July	20-31 July	03-14 August	17-28 August	31-11 August-September	14-25 September	28-09 September-October	12-23 October
Median	18.80	14.14	9.86	9.43	7.00	5.43	8.07	3.86	4.14	4.86
Number of Applications	153	257	161	182	183	170	106	111	94	101

GMP clearances

GMP clearance processing times - average



	08-19 June	22-03 June-July	06-17 July	20-31 July	03-14 August	17-28 August	31-11 August-September	14-25 September	28-09 September-October	12-23 October
Average	17.71	14.92	11.93	12.25	9.99	8.81	11.32	6.16	5.42	10.55
Number of Applications	153	257	161	182	183	170	106	111	94	101

What's in store for 2016?

Helping sponsors understand their role

- GMP clearance application tool
- GMP clearance guideline revision

Reducing impact of poor quality applications

- Decisions will be made based on information provided by the sponsor in the application

Inspection performance

2014 - 15

- 92% of domestic initial inspections conducted within target timelines (3 months)

2015 – 16 to end October

- 94% of domestic reinspections (44/47) conducted within target timelines (6 months)

What's in store for 2016?

Revised inspection close out process

- Objective:
  - Predictable inspection close out times for manufacturers who comply with requirements
- How:
  - No objective evidence required if acceptable CAPAs
  - Next inspection will include assessment of CAPAs
  - Limited rounds of additional information requests

What's in store for 2016?

Rewarding consistent high levels of compliance.

- Objective:
  - Reduced regulatory burden for manufacturers with repeat A1 rating
- How:
  - 3 year reinspection frequency for A1 manufacturers of high risk products (currently 2 years)
  - Second and subsequent A1 ratings: reduced scope inspection

Questions?