



Australian Government
Department of Health
Therapeutic Goods Administration

How do listed medicines shape up in the post-market compliance space?

An update from the Complementary and Over-the-counter Medicines Branch of the TGA

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TGA Health Safety
Regulation

Overview

- What is our post-market compliance program?
- 2015-16 Compliance data
- Breaking down the data
- Compliance projects
- Our goals
- What's in store for the future

What is our post-market compliance program?

- Random reviews
- Targeted reviews
- Investigations (complaints and referrals)
- Project work
- Business improvement



2015-16 Compliance data

Investigations and outcomes

	2014-15	2015-16
	Jul-Jun	Jul-Jun
Initiated investigations	86	114
Completed investigations		
Medicines prioritised for targeted review	24 ^a	69
Referred to another TGA area or government organisation	5 ^a	14
No further action taken	24 ^a	32
Total completed investigations	99	115



60% of all investigations became targeted reviews



^a Data collection commenced Jan 2015.

2015-16 Compliance data

Reviews by type

80% of all reviews had verified compliance breaches

	2014-15	2015-16
	Jul-Jun	Jul-Jun
Initiated reviews		
Targeted reviews	41	173
Random reviews	89	340
Total	130	513
Reviews on hand	188	151
Completed reviews		
Targeted reviews	156	158
Random reviews	56	315
Total	212	473

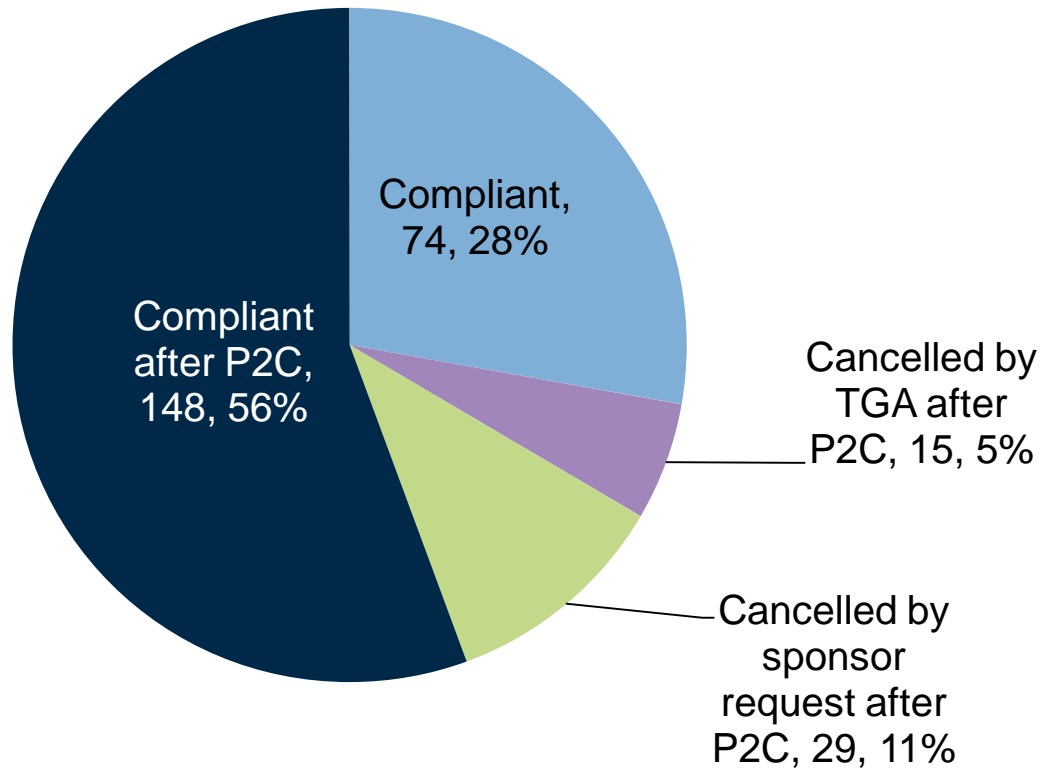


Random up by 560%

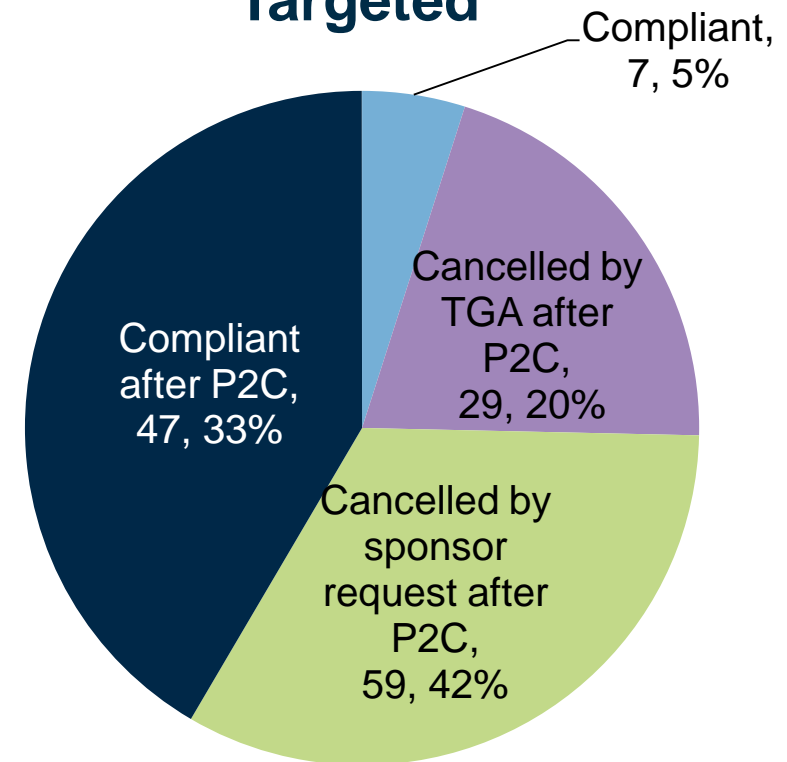
Total up by 220%

Outcomes of completed reviews

Random



Targeted



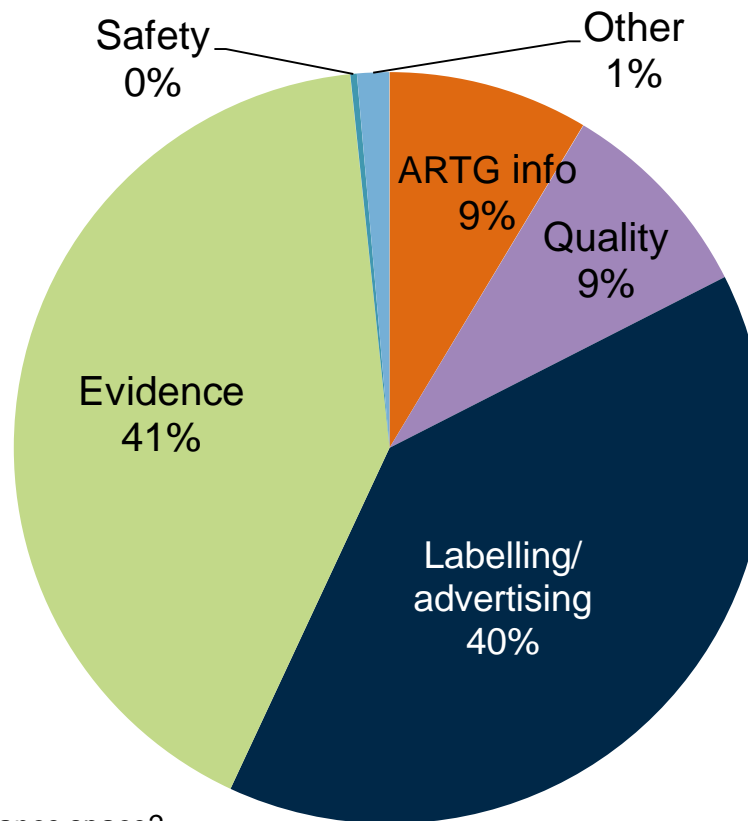
Breaking down the data

Types of non-compliance identified

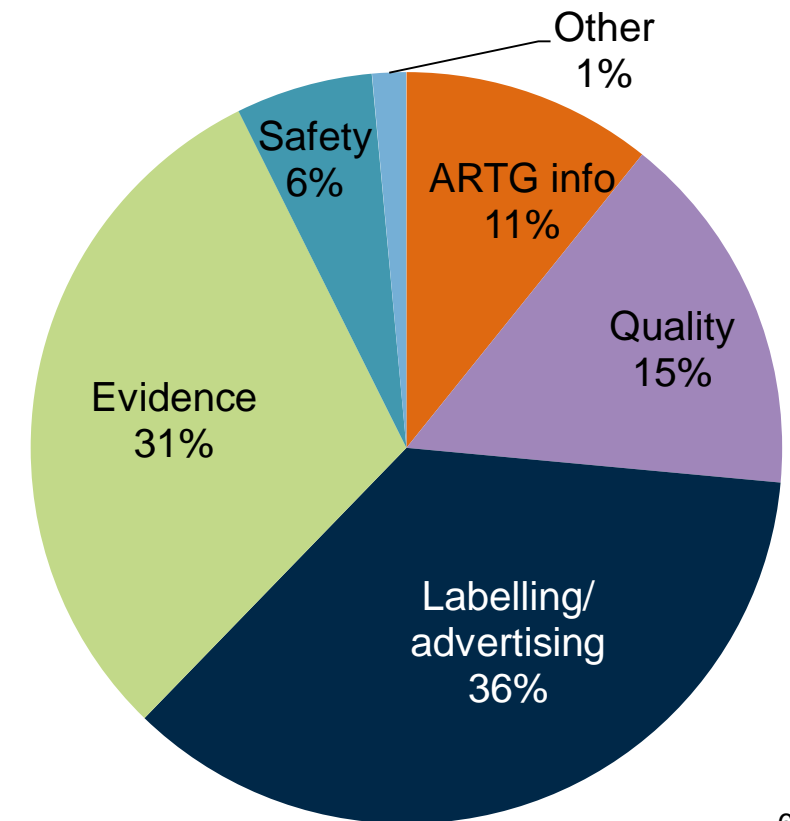
Biggest issues account for ~80% of non-compliance

- Labelling
- Advertising
- Evidence

Random Reviews



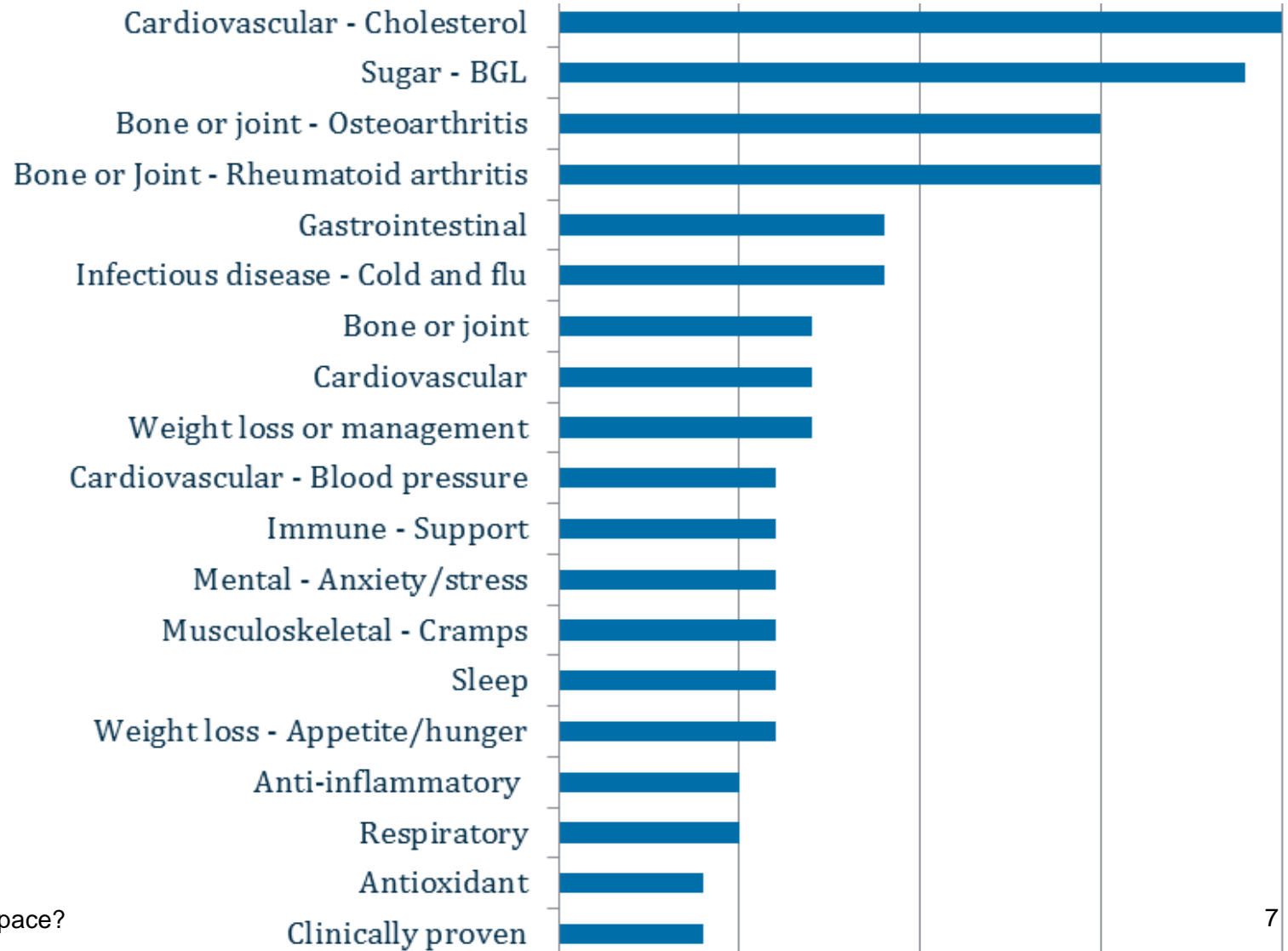
Targeted Reviews



Breaking down the data

Evidence issues in more detail (based on last half of 2015)

- Highlights
 - Biomarkers
 - Blood glucose
 - Cholesterol
 - Arthritis



Compliance projects arising from our data analysis

Blood glucose and cholesterol biomarkers project

- Indications related to the:
 - management;
 - control;
 - maintenance; and/or
 - balance
- of normal, healthy or improved blood glucose or cholesterol:
 - levels;
 - ratios; and/or
 - ranges.

'may help maintain normal blood glucose levels within the normal range in healthy individuals'

Compliance projects arising from our data analysis

Blood glucose and cholesterol biomarkers project

- Evidence requirements
 - High quality
 - Quantifiable data
 - Show how levels are maintained / prevented from falling outside the healthy range
 - Example: blood glucose
 - Reference ranges for normal glucose levels in healthy adults.

Other

glucose

fasting: 3-5.4 mmol/L

random: 3-7.7 mmol/L

According to the Australian Medicines Handbook and Royal Australian College of Pathologists

Our goals

Our annual goals

respond to more than two hundred technical enquiries

500
compliance
reviews



200

random reviews



300

target reviews



**one
hundred**
investigations

investigations result from internal and external sources and may result in a targeted review being initiated




time to
complete
a review....


140


working days

What's in store for the future

Current priorities


 **Evidence:**
Blood glucose
and cholesterol

 **Quality:**
Aristolochic
acids


 **Evidence:**
Vaginal
probiotics

 Improving
education

Upcoming priorities

 **Evidence:**
Macular
degeneration

 **Regulatory reform:**
Medicines & Medical
Devices Review

 **Quality:**
Sunscreens





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