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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ARCS Scientific Congress

10-11 August 2016
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

How do Listed Medicines shape up in the post-market compliance space?
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

<table>
<thead>
<tr>
<th></th>
<th>2014-15</th>
<th>2015-16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiated investigations</td>
<td>86</td>
<td>114</td>
</tr>
<tr>
<td>Completed investigations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicines prioritised for targeted review</td>
<td>24&lt;sup&gt;a&lt;/sup&gt;</td>
<td>69</td>
</tr>
<tr>
<td>Referred to another TGA area or government organisation</td>
<td>5&lt;sup&gt;a&lt;/sup&gt;</td>
<td>14</td>
</tr>
<tr>
<td>No further action taken</td>
<td>24&lt;sup&gt;a&lt;/sup&gt;</td>
<td>32</td>
</tr>
<tr>
<td>Total completed investigations</td>
<td>99</td>
<td>115</td>
</tr>
</tbody>
</table>

<sup>a</sup> Data collection commenced Jan 2015.

60% of all investigations became targeted reviews

How do Listed Medicines shape up in the post-market compliance space?
# 2015-16 Compliance data

## Reviews by type

<table>
<thead>
<tr>
<th></th>
<th>2014-15</th>
<th>2015-16</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Jul-Jun</td>
<td>Jul-Jun</td>
</tr>
<tr>
<td>Initiated reviews</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Targeted reviews</td>
<td>41</td>
<td>173</td>
</tr>
<tr>
<td>Random reviews</td>
<td>89</td>
<td>340</td>
</tr>
<tr>
<td>Total</td>
<td>130</td>
<td>513</td>
</tr>
<tr>
<td>Reviews on hand</td>
<td>188</td>
<td>151</td>
</tr>
</tbody>
</table>

## Completed reviews

<table>
<thead>
<tr>
<th></th>
<th>2014-15</th>
<th>2015-16</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Jul-Jun</td>
<td>Jul-Jun</td>
</tr>
<tr>
<td>Targeted reviews</td>
<td>156</td>
<td>158</td>
</tr>
<tr>
<td>Random reviews</td>
<td>56</td>
<td>315</td>
</tr>
<tr>
<td>Total</td>
<td>212</td>
<td>473</td>
</tr>
</tbody>
</table>

- **80% of all reviews had verified compliance breaches**
- **Random up by 560%**
- **Total up by 220%**

How do Listed Medicines shape up in the post-market compliance space?
Outcomes of completed reviews

**Random**
- Compliant, 74, 28%
- Cancelled by TGA after P2C, 15, 5%
- Cancelled by sponsor request after P2C, 29, 11%
- Compliant after P2C, 148, 56%

**Targeted**
- Compliant, 7, 5%
- Cancelled by TGA after P2C, 29, 20%
- Cancelled by sponsor request after P2C, 59, 42%
- Compliant after P2C, 47, 33%

How do Listed Medicines shape up in the post-market compliance space?
Breaking down the data

Types of non-compliance identified

Biggest issues account for ~80% of non-compliance
- Labelling
- Advertising
- Evidence

How do Listed Medicines shape up in the post-market compliance space?
Breaking down the data

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

- Highlights
  - Biomarkers
    - Blood glucose
    - Cholesterol
  - Arthritis

Cardiovascular - Cholesterol
Sugar - BGL
Bone or joint - Osteoarthritis
Bone or Joint - Rheumatoid arthritis
Gastrointestinal
Infectious disease - Cold and flu
Bone or joint
Cardiovascular
Weight loss or management
Cardiovascular - Blood pressure
Immune - Support
Mental - Anxiety/stress
Musculoskeletal - Cramps
Sleep
Weight loss - Appetite/hunger
Anti-inflammatory
Respiratory
Antioxidant
Clinically proven
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.

<table>
<thead>
<tr>
<th>Other</th>
<th>fasting: 3-5.4 mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>glucose</td>
<td>random: 3-7.7 mmol/L</td>
</tr>
</tbody>
</table>

According to the Australian Medicines Handbook and Royal Australian College of Pathologists
Our annual goals

- respond to more than two hundred technical enquiries
- 500 compliance reviews
- 200 random reviews
- 300 target reviews
- one hundred investigations
- time to complete a review: 140 working days

How do Listed Medicines shape up in the post-market compliance space?
What’s in store for the future

<table>
<thead>
<tr>
<th>Current priorities</th>
<th>Upcoming priorities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence:</td>
<td>Evidence:</td>
</tr>
<tr>
<td>Blood glucose</td>
<td>Macular degeneration</td>
</tr>
<tr>
<td>and cholesterol</td>
<td></td>
</tr>
<tr>
<td>Quality:</td>
<td>Regulatory reform:</td>
</tr>
<tr>
<td>Aristolochic</td>
<td>Medicines &amp; Medical</td>
</tr>
<tr>
<td>acids</td>
<td>Devices Review</td>
</tr>
<tr>
<td>Evidence:</td>
<td>Quality:</td>
</tr>
<tr>
<td>Vaginal probiotics</td>
<td>Sunscreens</td>
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<tr>
<td>Improving</td>
<td></td>
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<tr>
<td>education</td>
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