

Dr John Skerritt
National Manager
Therapeutic Goods Administration
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15 July 2013

Dear Dr Skerritt

Thank you for the opportunity to comment on the TGA Key Performance Indicators proposal paper.

AusBiotech is a well-connected network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), food technology and agricultural, environmental and industrial biotechnology sectors; working on behalf of members for more than 25 years to provide representation to promote the global growth of Australian biotechnology.

AusBiotech would like to make the following comments:

- Column one is labelled as Key Performance Indicators (KPIs) however the listed items appear to be objectives rather than KPIs.
- Column two is labelled as proposed specific measures and reports against the KPIs. It would appear that this column would be appropriately labelled KPIs.
- In column two, the majority of what is currently labelled as specific measures are lag indicators. It would be useful to have some lead indicators, for example, for KPI 2, regarding business operations, the measure states that business operations are consistent and meet agreed service/timeliness standards, and trending is mentioned against published targets or legislated timeframes. However, it may be beneficial to have more detail regarding alarm levels that would trigger action prior to timeframes being exceeded for too long, and also to identify what those actions may be. This is already currently being reported so this detail may possibly be included in other internal TGA documents.
- Generally KPIs are stated but proposed targets are not given. The assumption is that these are being developed, as dates are given for development. It would be good to get some assurance that in the development of KPIs, alert and action targets are set. The aim is, after all, for KPIs to drive action.

In relation to specific KPIs, AusBiotech would like to make the following comments:

- **KPI 1. High stakeholder satisfaction and participation with out consultative processes**
 - The '*Surveys of stakeholders satisfaction with our consultative processes*' has a target timeframe for development of the survey of 30 June 2014. This appears to be an unnecessarily long time until the survey will go out to stakeholders.

- **KPI 2: Business operations are consistent and meet agreed service/timeliness standards**
 - In terms of volume and time taken to process complaints to resolution, it would be useful to have targets or even a statement that a baseline measure will be collected for six months and then targets set to improve on the baseline by 5% annually (as an example).
 - It would be good to have a measure of the TGA's resources (both quantity & quality) as the human resources will impact the ability of the TGA to meet this objective regarding meeting agreed service/timeliness standards. Some examples could include a target staff turnover rate (or collect a baseline measure and then aim to improve by 'x%') and/or a target pool of casual professionals that can be called on to assist in times of increased workload.
- **KPI 3: Non- compliance and safety issues identified by TGA at an early stage and appropriate, effective responses implemented**
 - Once again targets should be stated, especially for time taken from initial report to the TGA, to communicate or otherwise act upon issues. This reporting currently already happens so baseline measures should be available.
 - 30 June 2014 seems too long a time for development of narrative reporting.
- **KPI 4 Improved community and industry understanding of TGA's regulatory role**
 - AusBiotech is concerned that the benefits/outcomes from undertaking market research on the level of understanding of the TGA's regulatory role would not outweigh costs involved and would like further information on what the expected outcomes/actions are from the market research and if there will be a list of recommendations developed from this.

Yours sincerely



Glenn Cross
Acting Chief Executive Officer
AusBiotech Ltd