AusBiotech response regarding the TGA Regulator Performance Framework

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AusBiotech is pleased to provide input into the new TGA key performance indicators (KPIs) and reporting measures based on the Australian Government's Regulatory Performance Framework.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology (devices and diagnostics), food technology, industrial and agricultural biotechnology sectors. The industry consists of an estimated 900 biotechnology companies (400 therapeutics and diagnostics and 400 – 900 medical technology companies) and employs in excess of 45,000 Australians.

AusBiotech would like to commend the work of the TGA and its efforts to work with industry to reform and improve its service. It is fundamentally a world-class organisation and is to be congratulated for its achievements in recent times, where it has been seeking and enacting continuous improvement via consultation with stakeholders.

AusBiotech welcomes the six KPIs comprising the regulatory performance framework as they relate to regulated entities.

We question the use of the word 'potential' output/evidence headings and assume this will be removed in the final document. There is also a lack of tangible benchmarks against which the TGA's performance could be compared. Ideally objective measurements against defined KPIs would provide greater clarity.

Areas that lend themselves to measurement include:

- Assessment times
    - This should include a change that defines the assessment timeframes for different application types (e.g. manufacturing changes, label changes, intended use changes, etc.);
- Consistency in questions from different assessors when reviewing equivalent/similar devices and/or areas;
- Creation of guidance documents for the areas currently without adequate guidance (e.g. changes to conformity assessments);
- Application-specific feedback on decisions. (i.e. useful information about what was lacking from an application rather than just a reiteration of the regulations.)

Perhaps there is a need for an additional document that identifies any improvements and determines specific timelines of action. For example, 2.1(b) 'Improvements made to guidance documents' is vague and may add very little or be very significant. Identifying the areas where regulated entities have requested additional guidance and detailing the priorities and timelines would be very helpful. The same treatment would make sense in 2.3 (a).

Regarding 2.3(c), we contend that articulating the underlying reason for a decision should not be confined to consumers and health professionals. Specific feedback to industry is also required and perhaps could be measured by an industry survey to estimate the level of satisfaction.

Whilst 'output' 2.3 (b) "Percentage of pre-market applications and post-market activities processed in target timeframes" is useful, it is also important to capture the time taken for applications that missed the target timeframes to understand the possible variance in application processing time (to assist industry to plan for the worst case scenario). It would be appropriate that the different application types are split out in the reporting (e.g. conformity assessment applications). It is also important to show the time an application spends with the applicant during a submission (e.g. answering questions) versus the amount of time spent with the regulator (e.g. actual review time). This latter would correlate with metrics already in use by the FDA and the PMDA.

The framework appears reasonable but the execution and the measurable endpoints used will impact the level of relevance and system improvement of the regulated entities. The general statement approach taken here is appropriate if accompanied by a work plan, which is transparent and communicated to industry outlining the actions and timeframes. Failure to complete the additional determination of tangible measures will significantly reduce the worth of the framework as presented.

AusBiotech supports the regular reporting undertaken by the TGA and the willingness of the TGA to focus on meaningful output measures.

Yours sincerely

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