Shaping future regulatory enterprise

Five new guidance documents for clinical research were issued by CDSCO over last 1 year. These guidance documents include

- Checklist for submission of biological (vaccine) applications (December 2010).
- Constitution of 12 new NDACs (March 31, 2011).
- Reporting of SAEs occurring in clinical trials (May 31, 2011).
- Approval of clinical trials and new drugs (July 2011).
- Compensation in case of injury or death in clinical trials (Nov 18, 2011).

All these guidance documents have been developed with an intention to bring in considerable procedural clarity. Other expected benefits include transparency, faster review of applications, improving credibility through introduction of independent expert process, and enforcing a mechanism of human subject protection.

Indeed, these guidance documents have the potential to bring in the benefits described earlier. Checklists for vaccine submissions, Guidance of SAE reporting, and approval of clinical trials help clarify expectations from the regulator. Industry and other applicants can use these to ensure alignment potentially impacting review cycle times. The NDAC process is expected to borrow expertise (clinical/research) for improving credibility. Lastly, compensation guidance demands undertakings from sponsors to enforce human subject protection.

In reality, experiences of stakeholders vary and there is a considerable gap between the intent and outcomes. In fact, major metrics for applicants’ regulatory experience including cycle time of approvals, regulatory queries, and clarity on expectations have not really seen any improvement as envisaged.

How does one explain this unexpected outcome? Is this part of overall learning when a new system is being introduced? Or is there any other explanation for this discrepancy?

We believe the key issue is of the need for an overarching regulatory vision. In the absence of a clear definition of the future regulatory state with strategic priorities and a clear road map, the specific actions (such as guidance documents issued) might seem ad hoc, reactive in response to specific events, disjointed and often directive.

As India becomes an increasingly important country on global commercial and research map, the regulatory system needs to develop and articulate its conception of a future state, its fundamental foundations as well as building blocks of this future state. The vision exercise is extremely critical as we see a developing explosion of commercial and research landscape in the near future. The specific regulatory agenda including policy, people, capabilities, and processes arising out of such an overarching vision and building blocks will have a greater alignment with all stakeholders and significantly increased probability of success.

Take an example of US FDA. The US FDA developed strategic priorities for 2011–2015 in April 2011[1] and a strategic plan[2] for advancing regulatory science in August 2011. FDA articulated its vision statement as “FDA will advance regulatory science to speed innovation, improve regulatory decision making and get safe and effective products to people in need. Twenty-first century regulatory science will be a driving force as FDA works with diverse partners to protect and promote the health of our nation and the global community.” This is a clear depiction of the FDA future state with expected outcomes. FDA identified eight priority areas based on this vision and clearly defined implementation strategies for each.

Another example is EMEA. It developed road map 2015[3] with clear articulation of its vision and three strategic priorities including addressing public health needs, facilitating access to medicines and optimizing safe and rational use of medicines. Each priority is linked with specific action plans ensuring process of cross stakeholder alignment.
In India, we have had our initial beginnings. The Mashelkar committee report of 2003 was an excellent first step in this direction. It stressed on the need for creating a world class regulatory system focused on protecting public health by ensuring provision of safe, effective, and quality drugs and pharmaceuticals based on scientific excellence and best possible regulatory practices. The report outlined core values.

1. Professionalism through integrity, diligence, objectivity, excellence, commitment, and consistency;
2. Accountability through open and transparent operations;
3. Achievement through professionalism and effective, efficient and timely work practices, which are focused on outcomes;
4. Open and effective communication with all stakeholders.

The committee report recommended structural solution through creation of a Central Drug Authority to address the issue of multiple regulators for this sector. It has also suggested specific guidance to address key gaps in the current regulatory system.

It is obvious that over the last few years, Indian regulators have demonstrated a clear intent to recast the regulatory system toward a transparent, credible, accountable, and responsive regime. The foundations with clear definitions of guiding principles are in place. A description of future regulatory that balances innovation with patient safety is necessary. Developing regulatory roadmap for 2020 with stakeholder participation will ensure translation of the intent to reality. Specifics of policy, people, capabilities, and process will be milestones in future regulatory enterprise.

Chandrashekhar Potkar
Medical Director, Pfizer Ltd,
Mumbai, India

Address for correspondence:
Dr. Chandrashekhar Potkar,
Medical Director, Pfizer Ltd, Off S. V. Road,
Jogeshwari (W), Mumbai 400102
E-mail: editor@picronline.org

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