Can companies ever achieve 100% compliance?

Maria João Martins
19 April, 2017
Agenda

1. Introduction
   - 1.1. Pharmaceutical Business
   - 1.2. Factors influencing the new ethical basis for business conduct
   - 1.3. Industry Regulators
   - 1.4. Code Principles & Ethical Interactions

2. Addressing the question
   - 2.1. Definition of Compliance
   - 2.2. Achieving 100% compliance depends on 5 factors
   - 2.3. What are the benefits of a strong culture of Ethics & Compliance?

3. Summary

4. Conclusion
1.1. The Pharmaceutical Business

- The pharmaceutical industry is complex, innovative, and highly globalised, with many companies operating in multi countries.

- The industry is characterised by:
  - Risk averse consumer population.
  - Lengthy and costly R&D process.
  - Severe competition for intellectual property.
  - Strong purchase pressures.
  - Restrictive governmental laws and regulations.

- Changing industry dynamics, new models of business, shifting regulation and legislation, and changing community expectations are all driving significant evolution in the self-regulation model of compliance and ethics of the pharmaceutical industry.
1.2. Factors influencing the new ethical basis for business conduct

- Globalisation.
- Greater community awareness of the impacts of business on social and environmental issues.
- The development of international agreements and organisational guidelines on ethics and rights.
- Economic crises.
- The growth of transparency generally with developments in technologies such as the internet and social media.
- As the world is coming together, businesses are under more scrutiny now than ever.
1.3. **Industry Regulators**

- The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)’s Code of Practice has served as a basis for the creation of national codes of conduct for pharmaceutical industries all over the world.
- The IFPMA Code of Practice, together with national industry association codes (i.e. ABPI and IPHA) complements other regulations laws (e.g. MHRA) and guidelines (e.g. EFPIA codes) that together regulate the ethical compliance of the pharmaceutical industry.
- The IFPMA’s Code of Practice is a model of self-regulation for pharmaceutical industry’s activities in medicines promotion, communication and interaction with key stakeholders such as healthcare professionals, medical institutions and patient organizations.
- All pharmaceutical companies operating in UK and Ireland all follow the Code of Practice from the ABPIA and IPHA, respectively.
1.4. Code Principles & Ethical Interaction

1. Pharmaceutical companies will conform to high standards of quality, safety, and efficacy as determined by regulatory authorities.

2. The health-care and well-being of patients are the first priority for pharmaceutical companies.

3. Pharmaceutical companies’ interactions with stakeholders must at all times be ethical, appropriate, and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.

4. Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products.

5. Promotion must be ethical, accurate, balanced, and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.

6. Pharmaceutical companies will respect the privacy and personal information of patients.

7. All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry-sponsored clinical trials in patients.

8. Pharmaceutical companies should adhere to applicable industry codes in both the spirit and the letter. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.
2.1. Definition of Compliance

- Compliance is defined as conforming or adapting to a policy, procedure and control ("a Rule"). From this definition, compliance is assumed to be 100% of an effort.
  - Total compliance is defined as 100% of an activity; in other words when compliance is 100%, each individual identified in a target audience complies with an activity.
  - Compliance can also be loosely defined as achieving a "comfort level," or a stable process, within a predefined margin of error.

**Which means:**

Achieving 100% compliance means there is **NO VARIATION** in business processes or published policies and procedures.
2.2. **Achieving 100% compliance depends on the following 5 factors:**

- **Nature the Organisation’s Business.**
  - If lives are at stake, achieving the highest possible compliance is always the goal.

- **Organisation’s Vision and Mission.**
  - Depends on the organisation’s strategic goals and management.

- **Content of Policies and Procedures.**
  - Depending on the subject matter of a policy or/and procedure, achieving a compliance level of 100% may not be possible.
  - It depends on users behaviour and effort, and requires communication and training when the target audiences cannot see a direct benefits.

- **Organisation’s Receptivity to Change.**
  - To reduce the organisation's "resistance to change" mentality then put into place business processes and procedures to help the organisation evolve from a "reactive" into a "forward-thinking" or "proactive" organisation.
… And the following questions are:

- How would a global company ensure that all its employees in its operating companies worldwide follow each and every law and regulation?

- How can Executive Management of that company be assured that their people are acting according to the even higher standard of behaviour demanded by its stakeholder community?

  They can’t.

- Even if this company were 99.9 % successful in its compliance efforts, that’s still 100 % instances of non-compliance every day BECAUSE rules, laws and regulations cannot cover all areas of conduct.
  
  - Misconduct seems hard to manage – after all, it’s hard to control the actions of every employee, especially at large, global organisations.
  
  - Experience teaches that codes and legislation cannot stop all forms of bad behaviour.
2.3. What are the benefits of a strong culture of Ethics & Compliance?

1. Quality improvements.
   - A good compliance program should help prevent errors or failures before they occur or detected at an early stage, which reduces the need to repeat or re-do tasks.

2. Greater Efficiency / Operational efficiency.
   - The more compliance is embedded in an organisation DNA the more efficient and effective tasks become.

3. Trust and Brand Loyalty.
   - Having in place a clear, effective and broadly communicated compliance programme helps an organisation to signal to key stakeholders that compliance is a top priority for your company.

4. Risk Management.
   - All companies face significant strategic, operational, financial and other risks and those risks are multiplied in highly regulated industries such as healthcare.
   - The most effective and efficient compliance programmes are those that are fully integrated into a broader risk management program.

5. Competitive Differentiation.
   - Ethical and compliant behaviour is a differentiator that helps to drive better outcomes more efficiently while reducing Ethical & Compliance risks.
3. Summary

No compliance programme can avert all the misconduct by individuals; an organisation can get closer to achieving a greater and sustainable level of compliance and make significant improvements along the way by:

<table>
<thead>
<tr>
<th>Continuous Improvement Approach</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>List and prioritise risk areas</td>
<td>List and prioritise risk areas and the relevant law and regulations, which should be taken into account to continuously improve Code of Conduct and polices.</td>
</tr>
<tr>
<td>Write policies and SOPs</td>
<td>Agreeing strategy and Policies and Procedures at Senior level.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Training</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor and create Compliance Metrics</td>
<td>Develop compliance metrics for country based assessments.</td>
</tr>
<tr>
<td>Audit</td>
<td>Develop audit plans and centralise audit reports.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Responses to problems and corrective actions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Investigate breaches, misconduct-root cause analyses and agree with Senior Management CAPAs and/or enforcement actions.</td>
</tr>
</tbody>
</table>
4. Conclusion

- I conclude that achieving 100% compliance of policies and procedures is an ambitious goal!
- The increasing emphasis on the culture within the organisation and providing guidance on ethical business practices and principles is a trend expected to accelerate in an organisation dedicated to high compliance standards.
- Organisations with strong cultures within which people understand the organisation’s ethical stance and principles will be better prepared to deal with unforeseen compliance risks.
- **The significant message is that Trust and Ethics are key to the pharmaceutical industry and the broader healthcare sector.**
- Competitive advantage in the future will come by distinguishing a company through its **Integrity and its people.**