Compliance Basics 1 - Elements of an Effective Compliance Programme

Introduction

When I first moved into a regional compliance officer role many years ago, I was very fortunate to find myself working alongside two very experienced compliance officers with strong US experience. At that time, GlaxoSmithKline (GSK) was pulling together its global compliance function into a cohesive team that would look across all divisions of the company, including corporate functions, to give assurance that compliance was being taken seriously at all levels. We were a new team, consisting of people with varied experience and I definitely appreciated receiving the wisdom of my more experienced colleagues to help me understand where to look. During the intervening years, I have applied what they taught me, and also learned new ways of working as the internal and external landscapes have become even more restrictive. Several years later I moved to AstraZeneca (AZ) to lead commercial compliance for their international division, where I further refined my experience and understanding. I set up a consultancy in January 2010 to enable me to use my experience to assist a wider range of organisations. What follows is my personal view of how to build an effective compliance programme based on personal experience of doing the job, and of advising those doing the job, of compliance officer at all levels.

The most useful resource that I discovered during my early days as a regional compliance officer was the guidance issued by the Office of Inspector General (OIG)[1], entitled "OIG Compliance Program Guidance for Pharmaceutical Manufacturers"[2]. This paper sets out the widely recognised seven elements of an effective compliance programme.

Seven Elements

It is important for life science (pharmaceutical, biotechnology and medical devices) companies and their staff to understand the key risks facing those companies, and to develop appropriate compliance programmes to enable them to mitigate those risks as far as is possible.

Sales and marketing activities, involving scientific communication and interactions with healthcare professionals (HCPs), within the life science industry are regulated by international, regional and local laws, regulations and industry body codes of practice that are continually evolving. Compliance programmes must, therefore, continually evolve to keep pace with societal expectations as expressed via those laws, regulations and codes.

In Europe and the UK, much guidance has been written by the various authorities to enable pharmaceutical companies to comply with specific elements of the various laws and regulations, e.g. GxP[3]. However, there is no general guidance available to companies in Europe on how to structure and manage their overall compliance programmes. There are two major exceptions to this statement. The first is Italy, which has since 2001 had its law 231/2001 that includes the minimum definition of what a compliance programme should contain. The second is Germany, which

[1] The Office of Inspector General is part of the US Department of Health and Human Services

[2] Federal Register Vol.68, No. 86, 5th May 2003, is available to download under "05-05-2003" at http://www.oig.hhs.gov/compliance/compliance-guidance/index.asp

[3] GxP is used as a generic term to include regulations relating to Good Clinical Practices (GCP), Good Distribution Practices (GDP), Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP). In the US regime, GDP is normally included within GMP, but distribution is separated out in the European regulations.

following a decision of its Federal Supreme Court in 2009, has defined the role of the compliance officer, including its hierarchical position with the company. However, in both Italy and Germany, the focus is on financial compliance (especially prevention of bribery and corruption) within all companies, not just pharmaceutical companies.

Most companies within the life science industry, therefore, turn to the OIG's "Compliance Program Guidance for Pharmaceutical Manufacturers" to gain comprehensive and sound advice on how to structure their compliance programmes, regardless of where they are based geographically. The OIG's paper sets out the widely recognised seven elements of an effective compliance programme:

1. "Implementing written policies and procedures;
2. Designating a compliance officer and compliance committee;
3. Conducting effective training and education;
4. Developing effective lines of communication;
5. Conducting internal monitoring and auditing;
6. Enforcing standards through well-publicised disciplinary guidelines; and
7. Responding promptly to detected problems and undertaking corrective action"

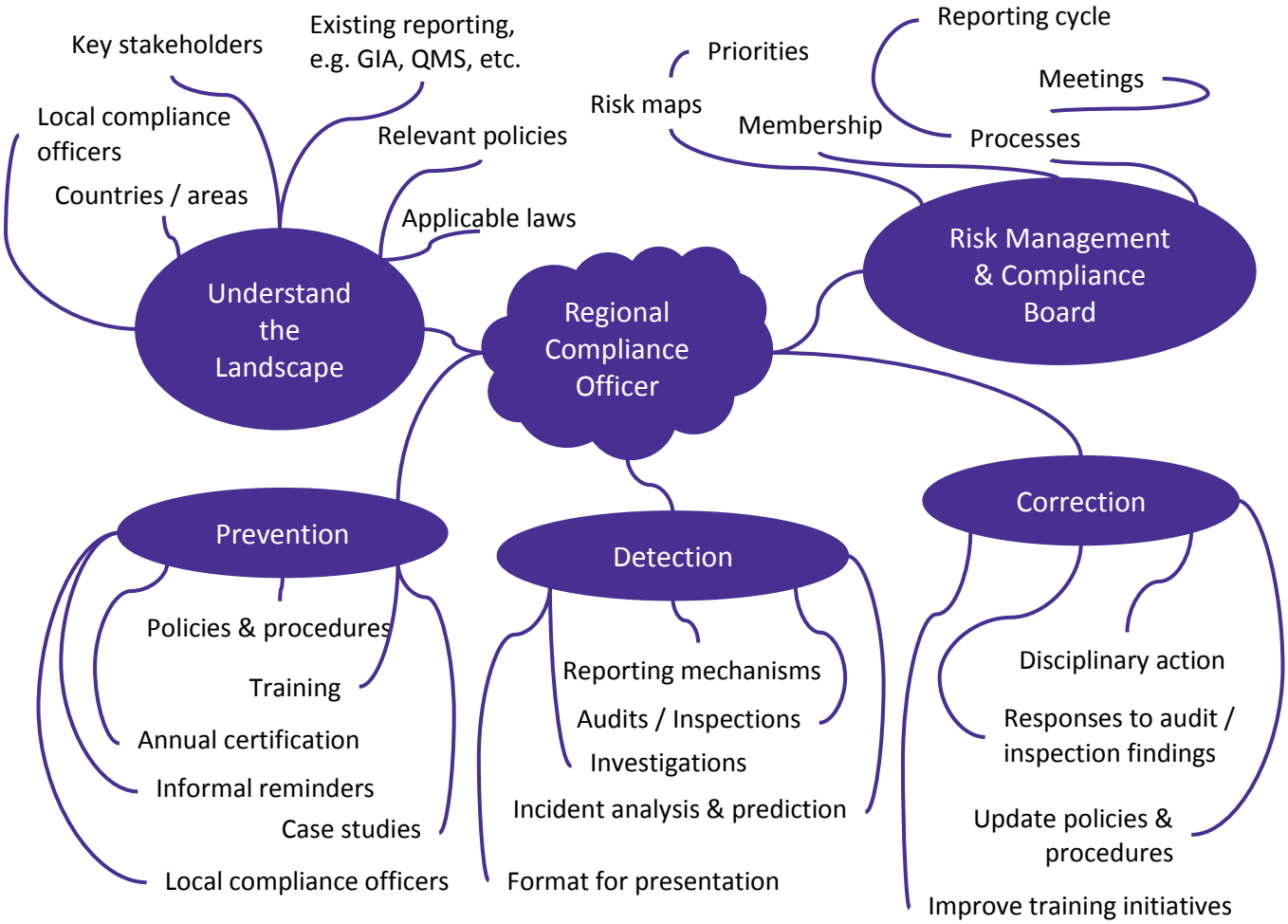
This guidance is important for several reasons. It is aimed specifically at pharmaceutical manufacturers, and so is tailor-made for the industry, especially concerning US-specific issues, such as "integrity of data used to establish or determine government reimbursement" and "relationship with physicians and other persons and entities in a position to make or influence referrals". However, much of this guidance can be applied to any industry in any country by substituting the relevant influencers, and it also contains generic guidance that applies equally to any industry in any country.

My colleagues at GSK suggested an eighth element; "avoiding bad actors", by which they meant not employing people who have a propensity to do the wrong thing, or at least put such people into roles where they have the ability to do the least harm. During my time at GSK, we had many debates regarding how to detect people who may do the wrong thing before they do it, but we never came to a satisfactory conclusion. I know of no company that has achieved this yet.

Local Interpretations

Whilst I found the OIG guidance very useful, I also needed to interpret it into something that I could make sense of and use in a European context. During my first few days and weeks in the role, I spent some time talking to various stakeholders, such as the head of the region, the global compliance officer, and the heads of legal, finance, medical, HR and marketing for the region, plus some country managers, to understand what they needed from me in my new role. Without these discussions, I would have been applying centralised guidance with no context, which would have been disastrous for my career and possibly the company. What emerged from these discussions was a clearer understanding for me and those I spoke to about what the regional compliance officer needed to achieve, and where the priorities lay. It also gave me the right foundation on which to build future relationships. As a result of these discussions, I drew a mind map that helped me to visualise what I needed to achieve in the various areas, which I have reproduced in figure 1 below. Note that I had intended that the bubble titled "understand the landscape" would be an initial introduction to the role, but I found that it was both necessary and beneficial for me to spend time keeping up to date as the internal and external landscapes changed.

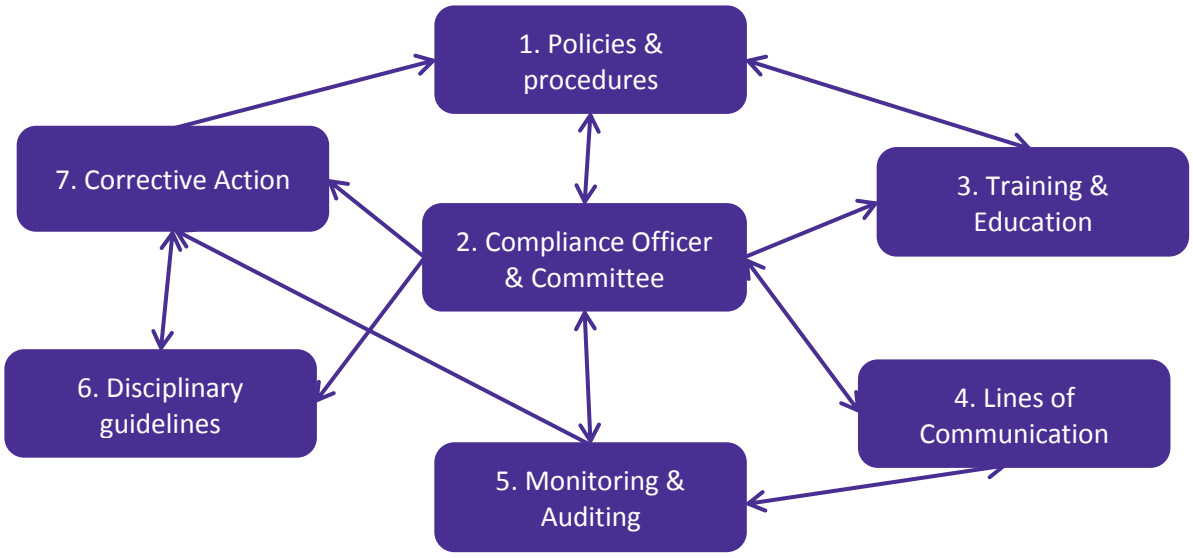
Figure 1 – Regional Compliance Officer Role



You will see from figure 1 that I labelled three of the activity bubbles as "prevention", "detection" and "correction". This enabled me to think about the amount of my time that I would ideally spend working on each part of the role. I wanted to spend around 75% of my time on prevention activities, around 20% on detection activities, and the final 5% on correction activities. As many readers will appreciate, this did not quite work out and I probably spent around 25% of my time on correction activities, which significantly reduced the time available for prevention activities. However, I was still able to spend more of my effort on prevention activities than correction activities, which I felt was important.

When I put together my mind map from figure 1 with the OIG guidance, it became obvious that OIG elements 1, 2 and 3 form part of the "prevention" activities, OIG elements 4 and 5 form part of the "detection" activities, and elements 6 and 7 form part of the "correction" activities. The Risk Management and Compliance Board also formed part of element 2. The additional element of "avoiding bad actors" would naturally fit into "prevention" activities. However, the relationships are not linear in that the elements all connect with each other in a cycle, as can be seen in figure 2 below.

Figure 2 – Showing the connected nature of the seven elements of compliance



Practical Implementation Considerations

When implementing an effective compliance programme, it is important to follow up any corrective actions by ensuring that prevention activities are aligned with what has been learned from each case, and that detection mechanisms are updated to enable similar instances of non-compliance to be detected. For example, a case may reveal that a specific policy was unclear, so needs to be clarified and the changes communicated, or the disciplinary guidelines may need to be updated to add something that was previously missing.

As a compliance officer, you will need to prioritise the elements of your compliance programme to which you will give most of your valuable time in an ideal world. I understand that "life happens", especially in compliance roles where a new case can arise at any time and take large chunks of resources to resolve. However, this is not an excuse for not planning; it just means that your plans will not always work out quite as you expected.

One of my favourite quotes comes from the 19th Century philosopher Williams James (1842-1910), who said:

"The art of being wise is the art of knowing what to overlook."

This quote recognises that unless you have a limitless budget, you will never be able to cover the whole organisation fully, so you need to determine where it is most likely that problems will develop and cause major issues for your company. The elements of compliance that you are able to temporarily overlook in order to give others a higher priority will depend on how well each of the elements has already been implemented in your company, external factors, and your organisation's risk appetite. To understand these factors, you will need to consider several key questions, including:

- Does your company already have the basics in place, including a Code of Conduct, basic training on acceptable behaviour, and what should be reported, to whom and how, etc.?
- Is your organisation currently negotiating with regulators and / or government officials in a single large market, or many smaller markets, over sanctions following a previous compliance failure?

- Are you already working to a Corporate Integrity Agreement with the US government, or equivalent elsewhere in the world? If so, could your company's activities in other countries have an adverse impact on this agreement?
- Where in your organisation are problems most likely to occur, e.g. with thousands of reps holding face to face meetings with Healthcare Professionals daily?
- Which issues represent the biggest risk to your organisation, either in terms of financial sanctions, reputational damage, or both, e.g. the serious injury or death of a patient due to a contaminated product would result in serious reputational and financial harm, a breach of the UK anti-bribery law carries unlimited financial penalties, a breach of the European anti-competition laws carries a maximum penalty of 10% of global turnover, etc.

I would also recommend that you spend sufficient resources working on the prevention activities to enable you to spend less time fire-fighting as problems arise. How much resource this will take depends very much on where your company is on its journey towards developing and implementing an effective compliance programme.

Conclusion

Implementing an effective compliance programme is not easy. It takes time, resources and knowledge, both in terms of the structure of the industry in which you operate, and the opportunities and temptations offered to people to do the wrong thing. With practice and organisational maturity, you should be able to use the guidance in this article to build an effective compliance programme that will keep your organisation safe from reputational and financial damage, and keep key personnel out of prison, including compliance officers.

The next few articles in the "Compliance Basics" series will look at some of the practical aspects of implementing each of the seven elements, including implementing global reporting lines, and also effective risk management.

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In January 2010, Sue established the management consultancy, Sue Egan Associates Limited, specialising in Corporate Governance, Compliance, Risk Management and Change Management. Sue works with clients in various sectors (life sciences companies, charities, a government agency, and other industries) to help them find innovative ways to conduct business ethically and sustainably.