Improving Industry Reputation with a Seal of Compliance

Mathias Klümper and *Hans-Peter Walther* describe an innovative German initiative for compliance management.

While their contribution to healthcare is indisputable, pharmaceutical companies tend to be considered untrustworthy by the general public, political stakeholder groups and, increasingly, by their market partners.

Pharmaceutical companies tend to be considered untrustworthy

Reports of investigations into suspicious practices by individual firms and allegations of corruption among their employees are common. The introduction of binding codes of ethics for drug companies by self-regulation industry associations has done little to improve industry's reputation. Violations of these codes, to which most companies are committed, are also common.

In Germany, talks are under way on how pharmaceutical companies can uphold their compliant practices and communicate them effectively and credibly.

Among the methods being discussed is a "seal of compliance" initiative that we helped develop with German self-regulatory industry organisation AKG eV (*Arbeitskreis Kooperation im Gesundheitswesen eV)*, which represents small and medium-sized pharmaceutical companies and is related to Germany's pharmaceutical industry association, BPI. The AKG seal of compliance is based on a clearly "defined quality measure for compliance" and involves the audit of a company's existing compliance system by an independent party.

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AKG is the first, and, to date, only, organisation of its kind to offer its members the options of having their compliance system audited by an independent party and certification of corporate compliance management. Following a successful audit, members apply for the AKG seal of compliance.

This paper describes the AKG auditing and certification system and discusses its benefits. The system might also be of interest to other European and international self-regulatory organisations and to medical device companies.

Under pressure

Political pressure on governments and public prosecutors to stamp out corrupt practices is growing, with the compliance activities of managers and employees working for drug firms moving increasingly under the spotlight. In Germany, growing public awareness over the matter is resulting in more charges being filed with public prosecutors. In addition, some public prosecutors are intensifying their collaboration with statutory health insurance organisations.

In light of this situation, companies are asking themselves how they can ensure that they are in the best position to exercise damage containment – should the need arise – for themselves and their staff, and maintain the trust of their customers and business partners.

A first step companies must take towards ensuring the integrity of corporate behaviour is to develop and implement effective compliance management in their day-to-day business.

But implementing effective compliance management is not enough. Individual companies are finding it hard to present a convincing public image on the strength of their own healthcare compliance management efforts. Their achievements on the compliance front remain unrecognised by the public because they are overshadowed by the media reports of negative practices by other companies. Companies also fail to communicate their compliance activities adequately in most cases and, hence, do not distinguish themselves clearly and visibly enough from the "black sheep" of the industry.

Achievements on the compliance front remain unrecognised by the public

As such, they may lose out on the opportunity to not only minimise so-called "soft risks" (eg risk of gaining a poor reputation) and "hard risks" (eg risks of criminal and administrative law sanctions) through effective compliance management, but also to add to the value of their company on a sustained basis, by positioning themselves on the market as a trustworthy company committed to healthcare compliance.

Compliance management in corporate practice

Healthcare compliance is not just about providing guidance on good ethical and legal practice for individual employees who interact with healthcare professionals and medical institutions. It is also a key feature of management.

Breaches of compliance are not always intentional. In many cases, they are born of ignorance and poor compliance management. Any resistance to implementing a compliance system can be

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linked to the fact that compliance activities have an immediate impact on sales – as illustrated by the following quote from a pharmaceutical company manager[1]: "If all sales staff were to meet compliance specifications, they might see their sales collapse in the first instance."

A goal of compliance management is to minimise or eliminate the public image-harming impact of any irregularities

Healthcare compliance management in the strict sense is mainly understood by industry to concern governance of all business processes or company activities that involve collaboration with healthcare professionals and patient organisations, with the aim of ensuring that all of a company's management and staff act in accordance with codes of ethics and in compliance with the law.

The primary goal is to minimise, if not eliminate, the criminal justice risk and public image-harming impact of any irregularities.

Typical deficits in compliance management

Healthcare compliance management requires the involvement of a variety of departments in the company's value chain. If the importance of effective and efficient compliance management is underrated, industrial processes will be significantly impaired, to the point of endangering corporate goals. Common deficits of compliance systems are as follows:

- little or no active implementation of clear and understandable in-house specifications and regulations showing which business practices are illegal or contrary to industry codes of ethics;
- non-transparent or imprecise description and communication of relevant business processes and pertinent decision-making rules;
- lack of awareness of compliance requirements or failure to accept – both by employees and business partners – that the "good old ways" are not allowed;
- poor resolve on the part of top management to give up "successful" business practices and to systematically punish violations of compliance rules ("wink and nudge policy");

Poor documentation is a common deficit found in compliance systems

- poor documentation, even by companies with extensive compliance systems; and
- unavailability of IT support tools[2] that are able to ensure effective and efficient compliance.

Though pharmaceutical companies are already using individual tools and processes for enhancing compliance and they have established suitable internal policies on a piecemeal basis, there is generally an overall lack of comprehensive compliance management systems to ensure healthcare compliance within companies.

Elements of a compliance management system

Elements considered necessary for the successful control of a compliance management system are: involvement of the top management; a compliance structure; defined processes; training programmes; and electronic support tools.

Most pharmaceutical companies now recognise the necessity of code of ethics-conforming practices and healthcare compliance. In addition, many smaller companies are using tools and processes to enhance compliance.

Nevertheless, healthcare compliance management is put into practice in very different ways by industry. The gamut of compliance standards ranges from bureaucratic over-organisation and total regimentation to a total lack of rules and uncertainty amongst employees. In practice, very few compliance systems are ideal.

Companies are failing to make the most of opportunities to motivate their employees to engage consciously in compliant practice

On the whole, companies are failing to make the most of opportunities to motivate their employees to engage consciously in compliant practice through an effective and efficient compliance management system, and to proactively build trust in the company on the part of customers, patients and the general public in a way that adds value to the firm.

This reluctance is all the more surprising because most pharmaceutical managers believe that systematic observation of compliance measures on the part of all stakeholders would have a positive impact in the medium term on the pharmaceutical industry's tarnished reputation.

Company audits: rationale and procedure

Companies largely accept that there is a need for regular internal and external audits to secure and maintain effective and efficient compliance management systems. However, extensive scrutiny of health compliance management in the pharmaceutical or medical technology industry is by no means standard practice today. Specific audits in the sense of an inventory of a company's current business processes and practices take place – if at all – only before the first implementation of an extensive compliance system, or as part of internal or external financial audits performed by large auditing firms.

The AKG is currently the only voluntary self-regulation organisation to offer its member companies the option of certification of corporate compliance management.

A prerequisite for obtaining the AKG seal of compliance is to undergo a healthcare compliance audit. The audit is in reference to sanctionable regulations of the AKG code of ethics on collaboration with healthcare professionals and patient self-help organisations.

More flexible and modular auditing structure

The AKG inspection and rating system is divided into the following six modules: Module 1 (Compliance management organisation, processes and tools); Module 2 (Continuing medical education events); Module 3 (Contractual co-operation); Module 4 (Non-interventional studies (NIS)); Module 5 (Unilateral benefits); and Module 6 (Collaboration with patient organisations).

The six modules of the AKG inspection and rating system cover over 200 separate inspection criteria

The six modules cover more than 200 (separate) inspection criteria. Elements common to all the modules concern benefits/gifts of any kind, attention to the general basic principles of collaboration, ensuring compliant practice (continuing education, processes, tools) and taking into account the involvement of third parties that companies appoint to conduct services. Third parties are of particular importance because AKG member companies are liable for their behaviour.

To ensure the independence of the AKG audit, external auditors conduct inspections. The inspection criteria are defined in a specified inspection and rating system and cannot be influenced by the auditors or by the audited company.

To ensure that there can be no suspicion of favouritism for member companies, the AKG requires that auditing and consulting work be held separately for the companies concerned. Given the lack of universally applicable regulations on the matter, the AKG follows § 319 HGB (German Commercial Code) and the German Corporate Governance Code of Ethics (DCKG). The principles of separation of auditing and consulting contained in these rules can be summarised as: "No auditing by the consultant." The principles also demand disclosure of consulting relationships between auditing firm and audited member company.

In addition, inspection agreements between member companies and the auditing firm and final audit report contain – together with a statement of independence and impartiality of the auditors – a number of other regulations and binding statements specified by the AKG that aim to ensure the rectitude and independence of external audits.

The AKG audits proceed in clearly defined steps

Audits proceed in clearly defined steps. After the auditing agreement is concluded and a first briefing between the auditing firm and audited company has taken place, the auditors receive certain core documents specified on a checklist for their perusal.

Perusing the checklist – ie Part 1 of the assessment ("what it says on paper") – mainly involves checking in-house specifications against external references (AKG codes of ethics). This part of the assessment also provides a basis for drawing up an individual plan of action for a main on-site inspection of a company.

The main inspection of the company – ie Part 2 of the assessment ("what actually happens") – involves looking at the practical implementation of internal and external compliance requirements. The audits are conducted in individual and group interviews on the basis of the inspection and assessment system described above. The auditors also take a sufficiently meaningful number of samples in all inspection modules to enable more in-depth analysis either on-site or later on.

An audit report includes a summary of deviations plus corrective action

The audit ends with the compilation of an extensive audit report. The report includes a summary and overall audit rating in the form of an executive summary, a summary of deviations plus corrective action, and detailed results on the inspection modules, with the respective rating and commentary on all inspection criteria studied. It also contains a timed list of the audit procedures, an outline of the agreements reached, a list of the documents provided, points of contact and audit participants.

Tough criteria for the seal and pilot audits

The AKG seal of compliance is testimony to the observance of high healthcare compliance standards by a company. The high standards reflect the tough criteria for issuance of the seal. For instance, a minimum overall total of 75% of the test criteria relevant to the audited company must be met, with no scores below 60% for any of the modules. Another criterion is that the member company has no history of obvious breach of the AKG code of ethics. Certification is issued only if the audited company presents a plan for corrective action to remedy any deficits identified at the audit, and fully implements those measures promptly.

The seal of compliance is issued for a limited period of two years only

To uphold the high standard and associated credibility of the seal of compliance, it is issued for a limited period of two years only. In the case of repeated and/or serious breach, the certification board may vote for premature withdrawal of the seal of approval.

To date, five AKG member companies have undergone auditing. All the companies agreed that the audits not only presented their current status of healthcare compliance management and identified any deficits, they also provided practical information on compliant practice.

The pilot audits revealed that lack of co-ordination with other corporate regulatory systems was not uncommon

Overall, the audits revealed that companies still tend to underestimate the complexity and level of organisation involved in the development of effective and efficient compliance management. Particular deficits identified related to employee training, release processes and documentation management. Lack of co-ordination with other corporate regulatory systems (eg accounts, quality management systems) was not uncommon. It also transpired that established management tools (eg budget control) are inadequate as a means of ensuring that people behave in accordance with codes of ethics.

Auditing and certification opportunities

As already mentioned, pharmaceutical companies and their managers are under increasing media scrutiny. Poor conduct on the part of individual companies has tarnished the reputation of the entire industry. Regardless of good conduct records by individual companies, it is becoming increasingly difficult for firms to win back the trust of customers, patients, doctors and the general public.

The innovative approach of the AKG – ie optional auditing and certification of corporate compliance management – opens up an array of opportunities and benefits for member companies. Opportunities and benefits can be identified both for the company's internal operations and in terms of its public image. The AKG audit report and its summary of a company's status quo enables senior management to gauge the state of their compliance systems at a glance. The report identifies healthcare compliance achievements and effort expended to date. It also identifies any gaps in the compliance system. Hence, the audit report can provide a company with a basis for improving and restructuring its compliance system.

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While compliant practice improves a company's public image, its inherently motivating effect on company employees should not be underestimated. The healthcare industry is one in which many employees choose to work in the belief that it will allow them to make a positive social contribution to human health. This belief plays a major part in their professional motivation and self-image, which, in many cases, are boosted by a sound company compliance programme.

Successfully applying for a seal of compliance following successful auditing provides member companies with a tool to enhance their public image. A concern for the pharmaceutical and other industries is that positive compliance efforts of individual companies are not perceived and acknowledged as such by the general public. All too often, the only publicity on compliance activity comprises negative headlines drawing attention to suspected corruption. With the AKG seal of compliance, a specific compliance brand has been created that enables member companies to present the values it embodies to the outside world.

Outlook

The pharmaceutical industry suffers from never-ending bad press. When news comes to light of corruption allegations against a single company, the entire pharmaceutical industry falls under collective suspicion and all drug companies suffer for the wrongdoing of the few. The introduction of voluntary self-monitoring and binding codes of ethics with in-built sanctioning mechanisms have done little to improve public trust in the drug companies.

A key problem is that individual companies have been unable to present a convincing image of themselves to the public on the strength of their own healthcare compliance management efforts, beyond those of belonging to a self-regulation association.

This is where the innovative approach of external, independent auditing and certification of member companies' compliance systems comes into play.

Standardised auditing based entirely on compliance with the relevant code of ethics standards followed by certification and issuance of a seal of compliance does more than give AKG member companies a means of reducing soft risks. A much more important aspect is the hitherto virtually impossible improvement in terms of the hard risks.

The AKG seal of compliance is an outward sign of a company's credibility in terms of ethical conduct

The AKG seal of compliance is an outward sign of a company's credibility in terms of ethical conduct, which is a much more significant element of a company's value chain than any short-sighted, solely profit-based corporate act can ever be.

The coalition agreement of the current federal government in Germany explicitly mentions improvement of trust between market partners in the healthcare system as a priority goal of its healthcare policy. The agreement states: "We need a culture of trust instead of excessive bureaucratic rules." The AKG initiative should serve to boost trust on the part of market partners. The seal of compliance should give member companies more scope for action on a sustained basis, which would result in better and more ethical business outcomes.

References

1. Durch vermintes Terrain, Compliance 11/2009, p 1, www.compliance-plattform.de
2. Vollebregt E, Klümper M, Driving Business Compliance with IT, *The Regulatory Affairs Journal– Pharma,* 2009, **20**(7), 421-427

