Driving Business Compliance with IT Processes

Erik Vollebregt and *Mathias Klümper* describe a process-oriented and IT-driven business compliance approach that can help pharmaceutical companies avoid contravening fraud and abuse rules in the European Union and the US.

Business compliance is becoming an increasingly important requirement for the pharmaceutical industry. Drug companies are becoming subject to a growing number of regulations both in the European Union and US as part of efforts by governments, regulators and industry itself to prevent fraud, unfair competition, unscrupulous advertising and marketing practices and inappropriate interactions with healthcare professionals.

Drug companies are becoming subject to a growing number of regulations concerning business compliance

Many companies have adopted a business compliance programme to manage, and demonstrate that they are adhering to, the rules. Traditionally, they have used paper-based business compliance procedures that revolve around a document containing the rules by which the company considers itself bound.

However, while this method may work for smaller firms, it is ill-equipped to deal with the complex requirements of modern and larger companies.

An even bigger problem is that employees do not always use the compliance tools available to assist them in their compliance efforts, either because they are unaware that such tools exist, or they do not accept them.

A new, more process-oriented approach to business compliance is, therefore, necessary. This method, which comprises more structured and IT-driven processes, enables companies to integrate business compliance requirements more efficiently, thereby creating a more effective system that puts less of a strain on company resources. In addition, by decreasing risk of compliance exposure, it would allow firms to become more attractive to investors and buyers. This article describes in detail what such a programme should entail.

A programme comprised of IT-driven processes would enable companies to integrate business compliance requirements more efficiently

Origin and development of business compliance

Business compliance is a term that stems from the US and was originally used in the financial sector. Today, the number of EU and US statutes that require business compliance of companies outside the financial industry is growing.

More recently, attention has focused on preventing conflicts of interests among healthcare practitioners, with respect to them receiving inappropriate advantages from companies, and ensuring that firms do not contravene rules on advertising and marketing or otherwise engage in unfair competition.

In the Netherlands, for example, the government is planning to take business compliance in the pharmaceutical industry to a new level by requiring full transparency in interactions between healthcare professionals and industry, among others, with respect to the development of medicinal products[1]; this is very similar to proposed US legislation[2]. Pharmaceutical industry associations are also toughening up their code of ethics rules that companies can adopt voluntarily.

International considerations

Historically, some jurisdictions have not rigidly enforced the rules concerned with business compliance − either because competitors have not actively sought their enforcement through the courts or self-regulatory mechanisms or because the authorities have not given them priority. However, international legislation in this area has changed matters fundamentally.

The US

In particular, the US has implemented very strict business compliance rules that apply both to companies listed on a US stock exchange as well as their foreign subsidiaries, agents or distributors. As such, the rules ought to be observed by any US exchange-listed company that conducts overseas operations.

The US has implemented strict business compliance rules that apply to companies listed on a US stock exchange and their foreign subsidiaries, agents or distributors

The US Foreign Corrupt Practices Act consists of an antibribery provision, which seeks to thwart the giving of a thing of value to a foreign official for the purpose of obtaining business. It also contains a books and records provision, which requires companies to meet certain standards with respect to their record-keeping. The penalties under the FCPA are both civil (ie fines) and criminal (for example, management within reach of the US authorities can be imprisoned).

In recent years, FCPA enforcement has increased and enforcement actions are no longer focused solely on the actions of US companies but are also being sought against US companies

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FCPA lawsuits have resulted in heavy fines

for the actions of their foreign subsidiaries, agents and distributors. Also in recent years, the US Securities and Exchange Commission and the US Department of Justice have specifically targeted drug and medical device companies in FCPA enforcement actions. These lawsuits, which have resulted in multimillion-dollar fines, often stemmed from payments, gifts and entertainment provided to employees of state-owned hospitals, as these employees are treated as "foreign officials" under the FCPA. Therefore, given the FCPA's broad reach and the heavy fines that can be imposed on violators, it is critical that all business organisations with operations both in the US and the EU implement and follow a written compliance programme.

Sarbanes-Oxley

In addition to the FCPA, companies listed on US exchanges must also comply with the Sarbanes-Oxley Act of 2002, which deals with fiduciary responsibilities of the management. Sarbanes-Oxley strengthened corporate accountability and governance of public companies through rules that required companies to bolster their internal controls and to verify that their accounting and financial statements accurately reflect the current financial status of the company.

Key to the act is that it places the onus on a company's chief executive officer, chief financial officer and co-auditors to certify the accuracy of the firm's financial reports. By requiring top-level corporate management to personally sign off on the accuracy of the corporate books and records, Sarbanes-Oxley aims to make those executives more wary about ignoring or hiding questionable transactions. Prior to Sarbanes-Oxley, companies that discovered evidence of questionable transactions would typically investigate the incident and impose internal remedial measure, but would not disclose these incidents to authorities or shareholders. As a result of the personal accountability of companies' management, firms have a strong incentive to disclose both suspicious transactions as well as the steps that a company takes to address such incidents.

Firms must establish and maintain an effective business compliance programme to minimise exposure to liability under the FCPA and the Sarbanes-Oxley Act

An essential component of a company's effort to minimise its exposure to liability under the FCPA and Sarbanes-Oxley is to establish and maintain an effective business compliance programme. Both the DOJ and the SEC have noted that the existence of an effective and well-implemented corporate compliance programme is a factor that is considered in determining whether to bring charges against the company[3]. Further, the Federal Sentencing Guidelines use the existence of an effective compliance programme in deciding whether to mitigate the penalties that have been imposed on a business[4]. It should be noted that under the case of *United States v Booker*, the US Supreme Court held that the Federal Sentencing Guidelines are no longer mandatory for sentencing courts[5]. However, despite the fact that the guidelines are now technically advisory, trial courts are still required to consider them in deciding an appropriate sentence. In addition, many judges continue to use the guideline range for sentencing defendants, just as they did prior to the *Booker* decision.

Therefore, a key component of a company's strategy to minimise its liability exposure to US corporate governance legislation is to establish and maintain an effective compliance programme and (particularly with respect to the FCPA) to ensure that a similar programme is set up for any controlled foreign subsidiaries as well as foreign subsidiaries with substantial minority ownership, verifying that such a programme also comports with local laws and customs.

The EU

In the EU, examples of business compliance rules are the advertising and marketing provisions for medicinal products in Directive 2001/83/EC and the national rules implementing these provisions[6]. Furthermore, each EU member state has legislation with respect to (criminal) liability of the management for fraud committed by the company.

Industry association codes

In addition to adhering to mandatory laws, companies need to take into account self-regulatory rules. The European Federation of Pharmaceutical Industries and Associations has a code of conduct on the promotion of prescription-only medicines to, and interactions with, healthcare professionals[7]. The code, which was to be transferred into the national codes of conduct by all EFPIA member associations by July 2008, reflects the requirements of Directive 2001/83/EC. It fits into the general framework established by the directive, which recognises the role of voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies when complaints arise.

EFPIA's code of conduct is enforced at national level through EFPIA member associations

The code is enforced at national level through EFPIA member associations, which in some cases go beyond existing laws and regulations. The transformational provisions of the national member associations, for example the FSA in Germany or the Stichting CGR in the Netherlands, are binding for the member companies and infringements can be sanctioned by an arbitration body.

The International Federation of Pharmaceutical Manufacturers & Associations, which represents the research-based pharmaceutical, biotech and vaccine sectors, also has in place a code of pharmaceutical marketing practices. Key elements of the IFPMA code include more restrictive provisions on travel, gifts and scientific events, plus the establishment of a code complaint procedure and a code compliance network, bringing together code experts from all over the world.

Many IFPMA member associations, such as the Pharmaceutical Research and Manufacturers of America, have developed their own marketing codes, which apply on their own national territory. These must reflect the minimum standards of the IFPMA code, but may contain more stringent provisions.

IFPMA member associations with their own codes handle alleged breaches occurring in their own national territories. In countries where there is no national code, the IFPMA investigates complaints. If the IFPMA code is found to have been breached, the association will publish the name of the company concerned and its offence(s). Complaints can be notified to the IFPMA secretariat, which will ensure that they are dealt with by the appropriate body. However, there are no direct enforcement tools, such as the arbitration body of the member associations of EFPIA.

Underlying basic principles

Business compliance rules have been observed to focus on four basic principles: separation, transparency, documentation and equivalence. By adhering to these principles, the risk of criminal or other liability of a pharmaceutical company and its employees can be substantially reduced.

The risk of criminal or other liability of a company and its employees can be substantially reduced by adhering to four basic principles

Separation

The separation principle requires a clear separation between the sales transactions and any (further) co-operation between healthcare professionals, medical institutions and pharmaceutical companies. Thus, financial contributions to healthcare professionals, in particular physicians, must not be made contingent on sales transactions with their medical institutions. Distributions of any kind may, in particular, not be granted as a means of impermissibly influencing a procurement decision of a medical institution in favour of the company.

Transparency

The transparency principle requires the disclosure to superiors/employers of all allocations or actions by which employees of medical institutions will, or could, potentially benefit. If an employee of a medical institution is acting within the scope of his or her primary occupation and is using the premises and staff of the medical institution, a contractual relationship between the company and the medical institution should exist that delineates the parameters of what would constitute an acceptable exchange. If the employee is acting in his or her secondary occupation, any form of co-operation requires approval or at least the express acknowledgement by the superior.

By strictly adhering to the transparency and approval principle, civil service requirements will be complied with and criminal prosecution can be averted. Moreover, a preliminary factual and legal review of co-operation by the superior/employer of a clinic physician can substantially reduce the impression that an advantage has been accorded to a physician in order to get a decision in favour of the pharmaceutical company.

Criminal prosecution can be averted by strictly adhering to the transparency and approval principle

Documentation

The documentation principle requires that all services and co-operations with medical institutions and clinic physicians are detailed in a written agreement or a written form. The documents should be stored in accordance with the retention terms in the respective applicable civil and commercial law and also with the applicable criminal statutes of limitations.

Equivalence

As for the equivalence principle, the services rendered by the medical institution or physician must be adequate to merit the compensation paid by the pharmaceutical company. There are a number of criteria that can be used to determine what constitutes adequate compensation, for example, the specific qualification and expertise of the contract party, the difficulty of the services to be rendered and the value of the services rendered for the company.

Current business compliance approach and problems

Business compliance is essentially a risk management tool. The risks emanating from the relevant rules are, however, difficult to manage as a result of the following characteristics of business compliance rules:

The risks emanating from business compliance rules can be difficult to manage

- the rules are not always mandatory or their enforcement depends on actions brought by competitors;
- the rules are non-directive; they set out what a company must achieve but not how to do it. They must also be interpreted by regulatory and legal staff;
- the rules are continuously changing (and if the rules themselves do not change, the regulator's policy or issued guidance change); and
- a company's implementation of the rules is generally non-certifiable because agencies do not, or will not, normally sign off on a company's specific interpretation of the rules as laid down in its standard operating procedures.

Since business compliance is basically a risk management tool, business compliance can pragmatically be defined as the set of deliverables, processes and documentation necessary to satisfy a company's interpretation of a given regulation, standard or policy. There are many rules and, consequently, risks to manage.

Implementing a business compliance programme normally takes place in a number of phases...

Once a company has identified the need for a business compliance programme, the implementation normally takes place in a number of phases. First, a factual review is performed with the aim of obtaining a clear picture of contractual relationships, unilateral activities and other practices within the scope of the envisaged programme. This review typically consists of a factual due diligence on the company's documentation and interviews with the firm's commercial, regulatory and legal staff to form a picture of undocumented activities. Subsequently, the facts that surface out of the review are subject to legal and regulatory analysis, as well as analysis under any existing company policies. On the basis of that analysis the risks can be identified.

The next step involves setting up and implementing the programme as described in SOPs, training staff in how to use the procedures and identifying any issues or concerns with the programme.

Finally, the persons charged with remedying issues under the compliance programme address the issues identified and start dealing with any new issues that come up. In addition, the programme itself must be adapted to comply with changes in the law and relevant self-regulatory rules, as they arise.

Poor integration of compliance tools

Being compliant means that a company can substantiate that it meets both the performance and procedural requirements of its compliance programme.

Performance requirements relate to the company's ability to deliver functionality or tasks in the field concerned, and include producing a specific audit log or a financial report as mandated by a regulation. Procedural requirements relate to the company's ability to demonstrate adherence to its SOPs.

...but companies often fail to meet performance requirements and/or procedural requirements

However, because of the way in which companies traditionally implement and set up a business compliance programme, they often fail to meet either the performance requirements, the procedural requirements or both.

One problem often encountered is that business compliance as a process is not integrated in company processes, but is rather "imposed" on existing processes as an extra procedural layer. In addition, the processes for dealing with issues that arise in (draft) contracts or contacts with healthcare practitioners often create a bottleneck. Persons charged with the additional responsibility of solving such issues (for example, in-house legal counsel) are often not sufficiently freed-up to deal quickly and efficiently with the additional tasks required of them by the business compliance programme.

Finally, the template documentation that a company has available is often not flexible enough for the commercial staff to use without significant reliance on legal or regulatory staff, which in turn leads to the bottleneck problems described above. This happens, for example, when the rules concerned are not properly translated to an SOP with which the commercial staff can work.

As a consequence, companies may fail to deal with business compliance issues in a timely or even effective manner. This defeats the ultimate goal of business compliance, which is to allow companies to meet their compliance obligations, on a consistent basis, now and well into the future. In addition, commercial staff may become less inclined to raise business compliance issues because of the problems discussed above, resulting in potential exposure to the very risks that the business compliance programme seeks to mitigate. This results in compliance problems that relate both to performance − the system cannot deliver the functionalities requested (for example, because of bottlenecks) − and procedure − the system is not able to demonstrate compliance with SOPs (for example, as a result of commercial staff circumventing procedures because they do not work for them).

Elements of a compliance programme

The following section looks at the key elements that should be contained in a business compliance programme and examines how they can be implemented effectively.

Compliance code and guidelines

At the core of a business compliance programme is a code that contains the substantive rules by which the company considers itself bound

The core of any business compliance programme is a code that contains the substantive rules by which the company considers itself bound and a set of guidelines for procedures for the internal application of that code.

Contract management

To ensure that the company's commercial staff have the necessary instruments to achieve compliance, a business compliance system normally includes a set of standard documentation such as (letter) agreements and standard forms and a procedure for reviewing divergent documentation proposed by external parties.

Compliance officer

The compliance officer is charged with supervising compliance with the code and related procedures and answering queries from the organisation about compliance dilemmas. The compliance officer does not need to be based in the legal department or be a qualified lawyer if he/she has sufficient access to the legal department for reviewing legal matters. In some cases, companies even outsource the function of the business compliance officer, for example, to an external lawyer.

Follow-up of contracts

Once a business compliance programme has been implemented and agreements and/or practices are identified as being non-compliant with the rules, the company is faced with the challenge of either changing the practice or amending the agreement concerned. This is typically a challenge with respect to long-term contracts or scientific co-operation agreements.

There can be a challenge with respect to long-term contracts or scientific co-operation agreements

Compliance hotlines

Compliance hotlines are designed to provide a convenient and direct way for any company staff to bring a compliance matter to the attention of the compliance department. Although a compliance hotline has many advantages for a company, it raises many complex questions about labour law, privacy, the exchange of personal data cross-border (including to non-EU jurisdictions) and the monitoring of employees in the workspace.

In some EU member states the works council of a company needs to be involved before implementing a compliance hotline, for example, in Germany. In addition, cultural issues in the countries concerned may influence the decision on whether to implement a hotline. In particular, smaller companies tend to outsource their compliance hotline, for example, to external lawyers. This might also increase the acceptance of the hotline within the company.

Training

Training is an important part of familiarising the organisation with the compliance programme and overcoming reluctance within the organisation to employ the new procedures. Training should preferably be aimed at enabling commercial staff to use the compliance materials and to help them identify issues that require escalation to the compliance officer.

Internal and external audits

After a business compliance programme is implemented, the organisation's compliance with it must be monitored on a continuous basis. Internal and external audits serve as a way to ex-post monitor the company's compliance and to identify opportunities for improvement. Audits allow a company to verify whether the risks that the company thinks it is managing are actually managed by the instruments it has implemented for that purpose.

An organisation's compliance with its business compliance programme must be monitored on a continuous basis

An electronic approach

The key elements of a compliance management system described above can only be effective if employees use them in practice. However, it is often the case that employees do not know that such tools exist, or they do not accept them.

This is where adopting a more structured and IT-driven approach can improve matters. Such a system would close the gap between the existence of compliance tools on the one hand and the lack of compliance on the other hand. It would give a company the opportunity to progress to a new stage in the compliance maturity continuum and to start using business compliance as a competitive advantage (see Figure 1). It would allow firms to be run more effectively and to become more transparent and ultimately more competitive. A company would also become more attractive to investors and buyers because of the decreased risk of compliance exposure.

Replacing *ad hoc* or undocumented processes with sustainable, more structured and IT-implemented processes allows a company to capture the meta-data and metrics that will enable it to realistically assess current regulatory and marketing practices and consistently improve its SOPs or their execution. In addition, to demonstrate compliance, organisations must always be prepared to respond to compliance audits. Document-oriented compliance systems – rather than those that are process-oriented – are typically slower to respond to such requirements, less precise and often incomplete, which can cause authorities to believe that the lack of documentation equals a lack of compliance.

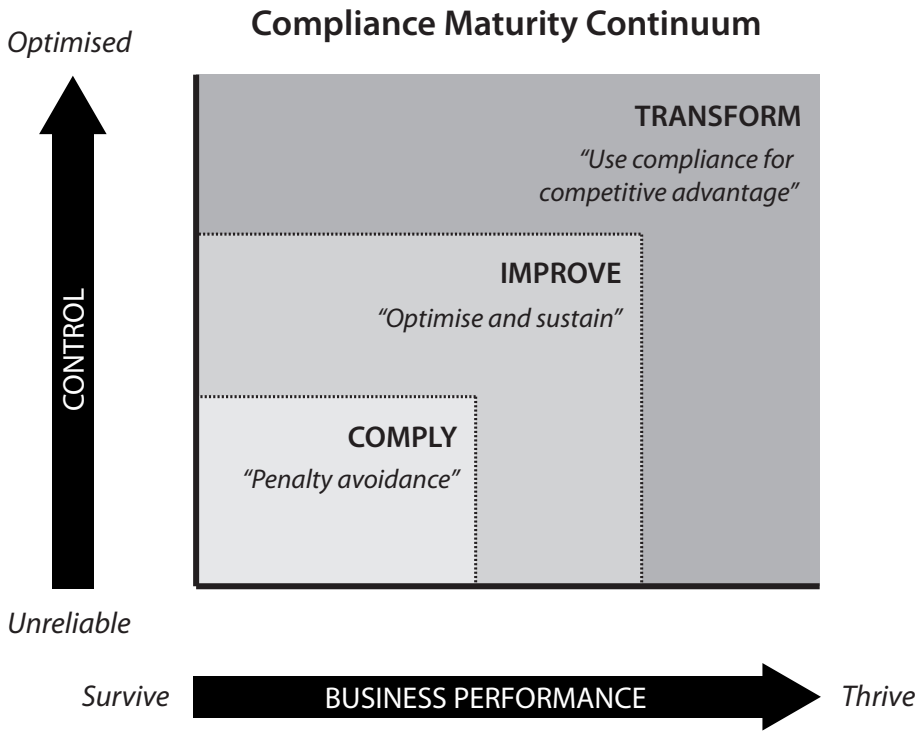
IT-implemented processes allow companies to realistically assess current regulatory and marketing practices and consistently improve their SOPs

Process-oriented approach

Despite having adopted elements of a compliance programme, pharmaceutical companies often experience problems and deficiencies with regard to the required processes. Even today, where almost all business decisions are process-driven, many firms do not use a process-oriented business compliance approach to handling co-operations with medical institutions and healthcare professionals.

Although the aforementioned elements of a compliance programme have increasingly become the market standard for handling co-operations with medical institutions and healthcare

Figure 1. How IT-based business compliance can result in a competitive edge



Companies could progress to a new stage in the compliance maturity continuum and start using business compliance as a competitive advantage

professionals, in practice this is not enough to ensure compliance by management and by the staff members involved.

The core element of a state-of-the-art compliance management system is a process-oriented business compliance approach to handle co-operations with medical institutions and healthcare professionals. This means that the management and the relevant business units define uniform processes and workflows with clear process descriptions. Furthermore, the decision-making rules must be defined such that each employee that is involved in co-operations with healthcare professionals knows all processes.

Electronic approval procedures

Many alliances with healthcare professionals and medical institutions require internal approval by the first-line sales manager or the business unit manager due to the pre-defined company processes. Certain cases also require an approval from the compliance manager and/or the legal department.

However, many alliances in the day-to-day business of a pharmaceutical company are entered into without the required internal approval because the competent person in the company was either on a business trip, on holiday or had simply forgotten to approve the agreement.

In practice, the absence of the necessary approval significantly increases a company's exposure to a compliance liability risk since the cases that have to be approved are often cases that require greater scrutiny due to, for example, compensation that is outside the normal realm of compensation or unrecommended meeting venues.

Firms that implement electronic approval processes based on their existing IT structure can minimise liability risk without requiring any further resources

Implementing electronic approval processes that are based on the existing IT structure of the company can close these potential liability gaps without requiring any further resources. For electronic approval processes, the marketing or sales employee who is directly in contact with the healthcare professional or medical institution should initiate an electronic approval. The colleague who has to give the approval is informed by email about the case that he or she has to review and approve, including automatic reminders and escalation steps.

Electronic circulation of documents

Currently, documents relating to alliances, for example, agreements and invitations, must be circulated within the company to obtain the required approval from the relevant corporate decision-makers. This is usually performed using paper-based circulation procedures. However, increases in business travel make it more difficult to secure the necessary approvals, since paper-based circulation requires the decision-makers to be physically present in the company.

Furthermore, paper-based circulation processes entail the risk of documents getting lost or delayed in someone's physical outbox.

Electronic circulation processes can help reduce the circulation and approval times and can be based on the existing company IT structure. Company decision-makers would be able to review the relevant documents and give their approval straight away from any location via email on their Blackberry or laptop.

Intranet-based training

Company employees are often not properly trained in business compliance issues when they join the company or when amendments to the compliance guidelines have been made.

Intranet-based training sessions for all employees can facilitate communication of the basic business compliance knowledge contained in the compliance guidelines and help to increase the awareness for compliant interaction with medical institutions and healthcare professionals.

Intranet-based training for all employees can help communicate basic business compliance knowledge contained in the guidelines

In practice, new employees joining the company could be invited to participate in an intranet-based interactive compliance training session, and should receive a reminder in case they fail to participate within an appropriate period of time.

Electronic support tools for contract management

Electronic support tools can help reduce errors that can occur when using a paper-based contract management system. An electronic contract management system may not only assist the employees in choosing the correct standard form agreement for the co-operation at hand, but may also enable the company to document the relevant parts of the co-operation within the meaning of the documentation principle, including the automatic archiving of all required documents under the existing retention policy of the company. Last, but not least, electronic management of documents in an IT-implemented process ensures that the last versions of document templates are made available to the persons that need them.

Summary and outlook

Given the current and expected future focus on transparency in contacts between industry and healthcare professionals and on preventing undue influence of healthcare professionals, the demand for companies to manage business compliance will increase. Non-compliance exposes firms to risks that need to be managed. The effectiveness of a company's risk management determines its exposure to risks.

Demand for companies to manage business compliance is expected to increase

There are a number of reasons why a company's risk management strategy, specifically with respect to its business compliance efforts, might not to be as effective as the company thinks it is or would like it to be. As explained in this article, many of these risks stem from the way that companies implement business compliance programmes: document-oriented rather than process-oriented.

IT-implemented business compliance procedures that are embedded in the company's procedures address this and can help companies achieve a higher degree of compliance. Staff support for business compliance increases because it enables employees to achieve their personal goals within the company. Furthermore, the degree of compliance and compliance bottlenecks and/or hot spots can be more precisely identified and addressed. This provides the company with important data for identifying risks and for improving its compliance system.

This way business compliance becomes less of a burden on the company and more "second nature". It is this "second nature" that will give the company a competitive advantage over those competitors that fail to manage their compliance risks effectively.

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