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in-depth report from an eyeforpharma conference

held in Amsterdam, 1–2 June 2006

by John Hosken

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Patient Compliance Europe:

in-depth report from an eyeforpharma conference

by John Hosken

Executive summary

Patient non-compliance is an expensive and widespread problem for the pharmaceutical industry. With rates of non-compliance sometimes as high as 70%, drug companies are losing around €25 billion each year simply through patients not taking their medicine. The impact on clinical outcomes, public health and healthcare costs is severe.

The Patient Compliance Europe Conference, organised by eyeforpharma and held in Amsterdam on 1–2 June 2006, explored the major issues surrounding patient compliance, showcasing research and case studies from major European pharmaceutical companies and how they are addressing the problem.

This *Conference Insights* review outlines the most pertinent issues from selected presentations at the event. It examines the most common reasons for patient non-compliance and looks at methods to combat them. It offers advice and guidance on how to implement a successful compliance programme, based on real market experiences.

The issue of who has 'ownership' of compliance is discussed: is it the responsibility of the brand manager, medical affairs or senior management? And who should play the role of educator: the doctor, the pharmacist, the nurse or the drug company?

The report finds that the overall responsibility lies with the pharmaceutical industry, which – public health aside – also stands to benefit most from an increase in compliance. Yet, despite a growing armoury of tools with which to educate patients on the value of medicine, a general apathy to tackle the issue head-on pervades the pharmaceutical industry. Despite conference rhetoric to the contrary, the industry doesn't regard compliance as a major issue. And the smart brand manager who introduces a compliance programme will be elsewhere in the industry by the time its long-term impacts are realised.

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About eyeforpharma

eyeforpharma is a strategic information provider with an unrivalled reputation and global presence in the pharmaceutical industry.

Our conferences and events are well known worldwide for attracting the highest level of speakers and attendees, in order to determine solutions to the most pressing pharmaceutical business issues today. eyeforpharma is always able to offer more real-time case studies, a stronger focus on the pertinent issues impacting your bottom line in today's evolving pharma landscape and more interaction with industry peers.

We also produce the eyeforpharma briefing, which comes out twice a month, containing original stories about projects within the industry. To obtain this free of charge, visit www.eyeforpharma.com

If you have any questions or wish to find out more about opportunities to work with eyeforpharma, please do not hesitate: contact Paul Simms on +44 (0) 207 375 7194 or psimms@eyeforpharma.com

Introduction

Doctors have probably been telling people to 'keep taking the tablets' since the earliest shamans and folk healers were first frustrated by the non-compliance of their prehistoric patients.

Today, the pharmaceutical industry is leaving an estimated US$25 billion on the shelf every year through lack of patient compliance. Events like eyeforpharma's conference, Patient Compliance Europe, now in its third year, reflect a growing recognition of the importance of patient compliance and its impact on revenues.

Current estimates put non-compliance possibly as high as 50–70%. This is despite the well-known fact that poor compliance is associated with a lower quality of life, poor clinical outcomes, increased hospitalisations and higher overall healthcare costs. Clearly, compliance is actually synonymous with patient well-being.

So, why do people stop taking the pills? The conference drew a key distinction between types of non-compliance. There is intentional non-compliance, where patients choose not to comply with a medical regimen, reflected in unfilled prescriptions or filled prescriptions not taken, or where patients refuse treatment. And then there is unintentional compliance, where patients don't understand the appropriate use of medicines, take them at the wrong time or the wrong dose, don't understand the instructions or simply forget.

There are a whole range of influencing factors at work behind non-compliance. One set of factors is the patient's general health beliefs (e.g. 'medication is dangerous', 'I will get better on my own', 'invasive or aggressive therapy is not worth it' and 'new medicines are better than old ones'). These are underpinned by the patient's general social and economic characteristics, such as age, educational level, self-rated health ('I feel OK so I stopped taking the tablets'), cultural and religious beliefs and, importantly, what friends and partners think about the medicines.

Addressing compliance issues means understanding consumer behaviour. How does the consumer perceive his/her problem? How bothered are they by it? What is motivating the non-compliant behaviour? What are the barriers to compliance? And what is the patient–physician dynamic?

John Hosken
August 2006

About the author

John Hosken has been closely involved in writing about, planning and implementing technology for the pharmaceutical industry for the past decade. After a career in financial and consultancy marketing, he joined Merck in 1997 as one of the pharmaceutical industry's first internet strategy managers. He helped the company to get involved in using the web to market to doctors in a wide range of countries, moving to Acurian to develop its franchise in the clinical trials online recruitment market, and then held a range of pharmaceutical marketing posts in agencies. He has been writing on pharmaceutical marketing and technology topics for *Pharmafocus* since 2002, and recently contributed another in-depth report from an eyeforpharma conference (held in Barcelona, 14–15 March 2006) to the *Conference Insights* series, entitled Mobile and Wireless Sales Force Strategies (kwp007).

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Patient Compliance Europe:

in-depth report from an eyeforpharma conference

Reasons for non-compliance

The proceedings began with an overview of the impact of non-compliance on healthcare revenues and health outcomes, provided by the Chairman, Mike Rea (IdeaPharma). Rea noted the growing significance of compliance, setting the stage for a variety of presentations that would look at how the industry should address the issue.

To illustrate the problem, in her keynote speech, Patricia Stenger (Bayer Healthcare) presented evidence from Bayer's MALES study into erectile dysfunction. The study, which was reported in the *Journal of Sexual Medicine*,[1] canvassed some 27,838 men in eight countries, and focused on compliance issues. Participants were asked to describe:

- the prevalence of diseases of men
- the attitudes of men towards aspects of their health and sexuality
- factors and/or attitudes that might predict barriers to seeking help among men with erectile dysfunction
- the experience of patients with current phosphodiesterase type 5 (PDE5) treatment.

Bayer found that 24% of the sample had received a PDE5 prescription, 21% had filled it and only 14% were still using it. So, less than one in four patients were compliant; in fact, non-compliance increases over time so that four in five patients do not remain on therapy.

Among men who didn't fill their prescriptions, 42% were worried that the drug was dangerous, 31% thought it was too expensive, 29% thought the problem wasn't important enough and 20% cited embarrassment. Among those who stopped using it, 34% said their erections weren't hard enough, another 34% said it didn't work at all, 29% said it was too expensive, 22% said it only worked occasionally and 9% cited side effects.

So, faced with an array of explanations for non-compliance, the question remains: what is the solution? The first step, said Stenger, is to learn more about the patient decision pathways and identify which attitudes are the most effective ones to alter. Then you can quantify which attitudinal levers are the best to invest in and develop strategies and tactics with which to achieve the greatest impact.

One model for this is the IMB approach (Fig. 1), which focuses on information, motivation and behaviour to identify motives and contrary factors: what makes someone do something and what stops them from doing it? The impact this process can have was illustrated by the effect of changing a single attitude.

Many patients take the view that using medication to treat erectile dysfunction is dangerous. Bayer established that for every unit shift in attitude along a five-point scale

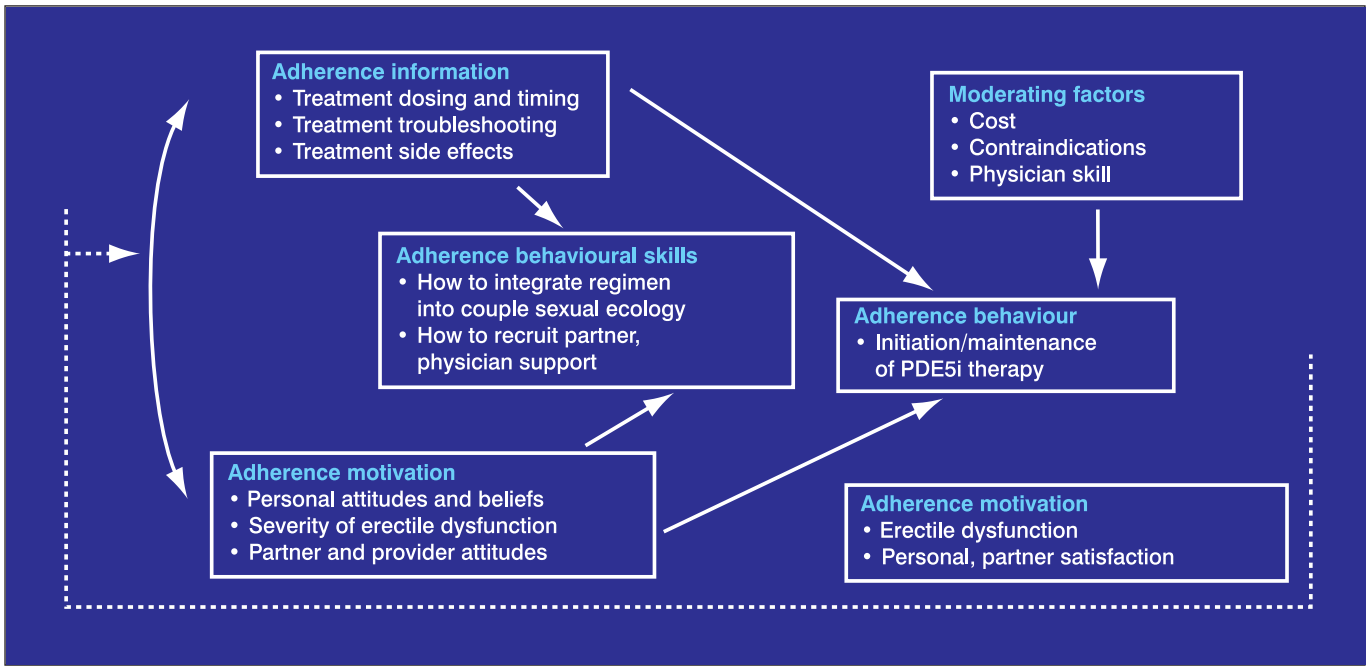

Fig. 1. The information–motivation–behavioural model of adherence in erectile dysfunction. Reproduced with permission from Stenger (Bayer Healthcare).

away from ‘strongly agree’ through neutral to ‘strongly disagree’, the patient becomes twice as likely to be using a PDE5 if he moves to ‘somewhat agree’, four times as likely if he moves to a neutral stance and eight times as likely if he moves to ‘somewhat disagree’. In other words, moving the patient from strongly agreeing that erectile dysfunction medication is dangerous to mild disagreement makes him eight times more likely to use the medication.

Stenger advised that the foundations of a successful compliance programme are simplicity, clarity and empowerment. The key mantra should be to keep it simple and make it easy. The patient information and the package insert should provide less information not more. What’s more, the information should be concise and clearly stated so that the patient is not confused by conflicting messages. It should speak to consumers in their language at a patient-friendly reading level. This enables the pharmaceutical company to empower the patient. It also allows the healthcare provider to clarify the value of the medicine. Everyone in the process needs communication and listening skills so that feedback can be properly managed and acted on. The underlying message, therefore, is “follow up, follow up and follow up.”

The foundations of a successful compliance programme are simplicity, clarity and empowerment

Implementing a compliance programme

Making breakthroughs like these requires a structured process. Dr Brigitte Schau (Boehringer Ingelheim) took the conference ‘from the development to the implementation of an effective compliance programme’ and shared some of the lessons learned.

To begin with, she outlined two key facts that underpinned the whole conference:

- Up to two-thirds of patients are not fully compliant with prescribed medical therapies, costing the pharmaceutical industry up to US$30 billion a year in lost revenues.[2]
- Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments.[3]

Companies must, said Schau, develop programmes and tools to improve the support of patients for the duration of treatment. However, there are increasing legal and regulatory restrictions in the global healthcare environment. In Europe, for example, a pharmaceutical company can’t approach patients directly and ask them why they stopped a treatment, any more than they can find out exactly which doctor is prescribing which drugs to which patient.

Up to two-thirds of patients are not fully compliant with prescribed medical therapies

Ideally a successful compliance programme will create a win–win situation for all stakeholders – patients, physicians and payers – by improving outcomes at lower cost. In designing a successful programme, potential support programme elements can offer a whole range of entry points, including, crucially, the doctor–patient relationship, since any programme bypassing the doctor is automatically doomed to failure.

The example Schau used was hypertension, which neatly covered all the bases by addressing the unmet needs of doctors on the use of home blood pressure monitoring. The main problems here are insufficient and/or illegible self-reporting of measured values, together with under- or over-reporting of home-measured blood pressure values.

Because the data are so patchy, little or no data analysis and organised reporting is done. The optimal solution would be to automate the tedious business of collection and analysis, using a validated, memory-equipped device with telemedicine transmission capabilities, including data analysis, and reporting to doctor and patient. The value propositions for doctors are obvious, but there are also significant benefits for payers. By increasing patient compliance and self-management skills, and empowering patients to reduce additional risk factors, home blood pressure monitoring can help influence patients’ overall health and well-being, improve health outcomes and, most significantly, decrease overall healthcare costs.

For the pharmaceutical industry, the compliance programme has a range of benefits from relationship building to brand building. It can support doctors by improving patient management and education. It can support patients in the better management of their disease and related issues, thus increasing patient compliance, and it can create brand loyalty through added value for participants.

The compliance programme has a range of benefits from relationship building to brand building

So, where do you start? The first steps are crucial: you need to get buy-in from senior management, and you need to select a dedicated project manager and a cross-

functional team. Both of these send the message that you are serious about compliance and you don't expect someone to do it in their spare time without resources.

Key stakeholders will need to be motivated to participate in the programme. This puts communication at the centre of the project to ensure that the objectives of external stakeholders are aligned, particularly those of the regulators. The next stage is a pilot. This may involve country-specific adaptations of the basic programme, and it will certainly involve detailed information and training that will vary from stakeholder to stakeholder. Learning points need to be fed back all the time. During the programme itself, key learning points will be developed during analysis of differences between countries. Project managers will feed insights back and foster cross-country fertilisation in a continuous improvement process.

The main key learning point from the home blood pressure monitoring programme was that needs-based research (i.e. what do you need?) is more effective than goal research (what do you want to happen?) because it can offer solutions for customers' unmet needs and, one suspects, because it is simply more manageable and realistic. The second learning point is to be clear about what your stakeholders want, and whether the programme is delivering it. This requires the evaluation of stakeholders' perceptions of added value using market research and feedback from pilots both during and after the programme. To achieve this, solutions will need to be customised as much as possible to the stakeholders' needs, in terms of local/regional/country specifics, cultural adaptations and technical aspects.

Overall, the key learning point of any compliance project is to ensure there is high acceptance of the concept internally as well as externally. There must be a strong fit to overall and brand strategy, and impact on image.

The key learning point of a compliance project is to ensure there is high acceptance of the concept internally as well as externally

Keeping internal stakeholders committed to the project is vital. There must be no nasty financial surprises during the project, which needs to show a positive mid-term return on investment (ROI). This requires a staggered approach, which can use results from pilots to show wins during the project. Finally, to spread learning points efficiently and quickly throughout the wide range of stakeholders, companies need to develop and apply a standardised process to improve the workflow and ensure continuous refinements of the programme.

Terminology and techniques for improving compliance

Bernard Vrijens (Pharmionic Systems Ltd) presented some real-life examples of compliance improvement among 15,000 patients on Pharmionic's database. Vrijens began by remarking that 'reading about compliance can be dangerous for your intellectual health'. This is because of the prevalence in compliance studies of inappropriate measurements, a lack of clear definitions and undefined concepts. After looking at confusion in the literature between the various terms used, he proposed a taxonomy of terms (Fig. 2).

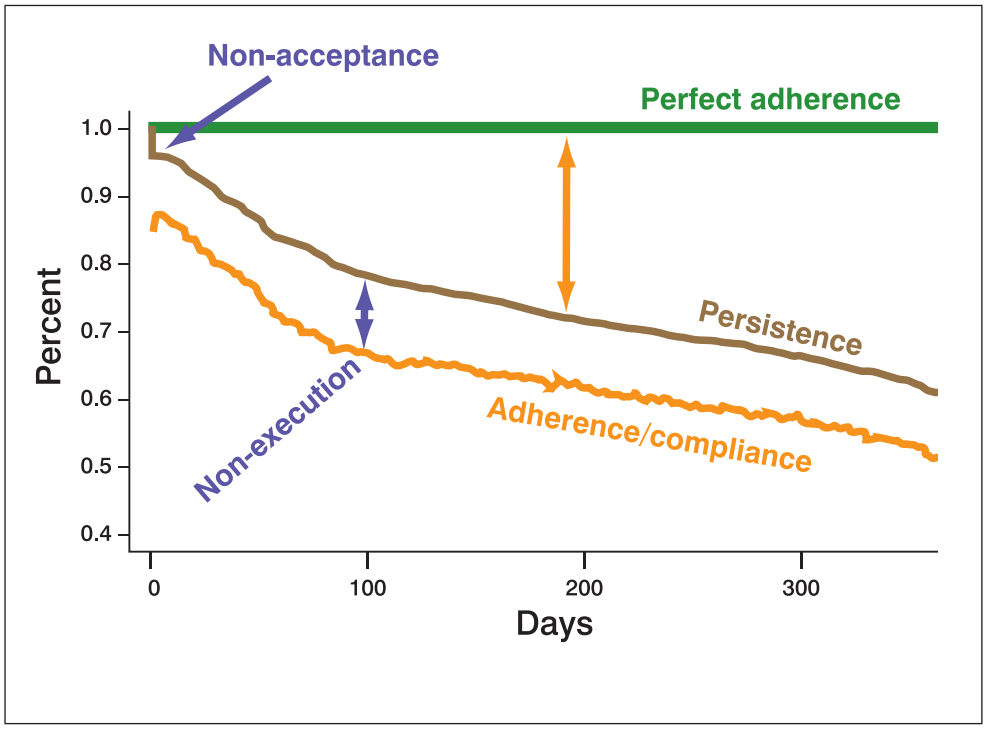

Fig. 2. A taxonomy of terms in non-compliance. Persistence is defined, for each individual, as the time between the first-taken and last-taken doses. It is graphically summarised in the cohort being studied (n=15214) as the fraction of patients who are engaged with the dosing regimen (brown line). Note the immediate drop in the fraction of patients who are engaged with the dosing regimen at the start of therapy: these are the non-acceptors (~4% of the cohort). Thereafter, the brown line gradually declines, indicating a decline in the patients still engaged with the dosing regimen. The irregular orange line plots the fraction of patients who have dosed correctly on each consecutive day. Reproduced with permission from Bernard Vrijens (Pharmionic Systems Ltd).

According to Vrijens, successful techniques for improving compliance require two main elements:

- Realistic measurement, or the objective, continuous, electronic recording of day-by-day dosing times, which can be easily interpreted by most patients.
- Scheduled appointments with feedback. Continual periodic review of the patient, by the prescribing physician, pharmacist or nurse of the patient's ongoing dosing history.

In a case study, a supportive intervention programme based on these principles resulted in a significant increase in global adherence over 300 days, in which intervention resulted in a 5% increase in acceptance, a 10% increase in persistence at 1 year and a 3% increase in execution.

Who is responsible for compliance, and who pays?

A panel debate pointed to the various approaches to compliance which often stem from individual countries' healthcare systems.

From the point of view of the patient and patient groups, Alex Wyke (PatientView) reported a good deal of resistance by patients to pressure to comply. Patients, she said, see doctors as acting on behalf of payers, whether it is a sick fund, a US Health Maintenance Organisation (HMO) or the UK National Health Service (NHS). This breeds an atmosphere of distrust. The problem is augmented by the doctors, said Vrijens, who don't feel responsible for ensuring compliance. As a result, the lack of trust extends to pharmacists, meaning that pharmaceutical companies can't go to them to help improve compliance. Vrijens' main suggestion was that pharmaceutical companies need to interact more with patients and find out what they need. The current restrictions on the pharmaceutical industry interacting directly with patients dictate that the only way to do this would be with patient groups, despite the divergence of interests that both parties have.

Pharmaceutical companies need to interact more with patients and find out what they need

Helmut Hildenbrandt (Hildebrandt GesundheitsConsult GmbH) operates mainly in the German market, where disease management has a high priority and more money is made available for better management of diseases through a risk adjustment scheme for sick funds. As a consequence, a long-term approach is effective.

Integrated care, which might be described as joined-up patient management, allows sick funds to keep 1% of the funds flowing through them if they have developed integrated care programmes. These long-term (9-year contracts are typical) arrangements have plenty of time to allow compliance programmes to show results. They also have a built-in incentive to show that the medicines approach works, since the fund is trying to avoid the patient accessing more expensive in-care services when they forget or refuse to take their medication.

The panel concurred that compliance is a huge public health problem that is of global concern. However, blaming the patient, said Stenger, is the wrong approach. The issue of addressing non-compliance must be shared. Rea pointed out that one of the roots of the problem is that the pharmaceutical industry doesn't develop solutions, it develops pills. As such, there is little impetus to develop compliance programmes. Some pharmaceutical managers shy away from compliance on the Machiavellian grounds that it might improve compliance for their competitors as well, and Rea suggested, perhaps tongue in cheek, that there might be a role for branded compliance to counter this.

Compliance is a huge public health problem that is of global concern

Wyke thought that compliance might be higher if individualised care was available. At the moment, treatments are based on a fictional 'average' patient, and more bespoke care and selection of medication offered a way forward. She also pointed to the many symptomless diseases in which a feeling that not much is wrong with you can be overshadowed by a sense of dependency on a pill.

Another area of concern, which is very different from compliance, is the fact that many patients simply never come forward because they don't want to pester doctors, or don't have health insurance. In such cases, their condition often isn't apparent until they are admitted to an Accident & Emergency Department. Stenger also pointed to another hidden area, where unintentional non-compliance takes place. People using asthma inhalers often haven't been shown how to use them properly or use them incorrectly, and so don't get any benefit and stop using them. Problems like these have simplistic solutions. Another area in which long-term compliance could be improved is the treatment of HIV, but governments aren't willing to help improve compliance because they don't see any value in it, and pharmaceutical companies aren't interested either.

Routes for providing valuable information

Dr Roman Rittweger (Advisors in Healthcare) focused on the concept of value-added services (Table 1). He defined them as "Any service in addition to classic

Top 5 value-added services	Top 5 goals
1. Medication brochure	1. Increasing compliance
2. Patient/physician education	2. Differentiating from competitors
3. Cooperation with payers/physicians/pharmacies	3. Increase in sales
4. Webpage	4. Product differentiation
5. Newsletter/email	5. Strengthening brand equity

Table 1. The top five value-added services and their goals for the pharmaceutical industry. Reproduced with permission from Rittweger (Advisors in Healthcare).

marketing that supports the brand in increasing sales and differentiating the product, addressing all stakeholders." The drivers behind the growing adoption of this concept are threefold:

- a need for better customer relationship management (CRM), because getting new prescriptions through the sales force is too costly
- the growing importance of CRM in pre-marketing
- the need to build business-to-business marketing to payers, providers and institutions.

The bundling of the buyer market by health insurers, hospitals and intermediaries also intensifies price pressure, but experience in many markets shows that price is gaining too central a position in negotiations, to the detriment of quality or service levels. By implementing value-added services, pharmaceutical managers hope to increase compliance, to differentiate the brand from competitor brands and to increase sales. The top five goals of value-added services for the pharmaceutical industry (Table 1) are to:

- increase compliance
- differentiate from competitors
- increase sales
- differentiate product
- strengthen brand equity.

For instance, Aventis' Allegra offers value-added services for asthma sufferers through its website. The objective is to acquire new customers through offering an allergy management tool providing information, such as pollen and weather forecasts and personal reminders.

Links with payers to drive down health costs are also appearing, initially in Germany and the USA, but now gradually spreading to other countries. Payer AOK and generics firm Ratiopharm set up the INVADE project to decrease the number of patients who suffer a stroke or dementia, by emphasising the control of risk factors to improve disease outcome. AOK received indirect rebates on specified medication, whereas the benefit for Ratiopharm has been higher sales. In the UK, Pfizer and Haringey Teaching Primary Care Trust have an initiative in heart diseases and diabetes to empower 600 long-term patients in Haringey to better understand and manage their health. Patients enrolled in the scheme benefit from individual attention from four dedicated, trained care managers. Care managers educate patients about disease, and actively guide and support them towards the most appropriate NHS service. The project has access to care management technology tools developed by Pfizer Health Solutions.

The obstacle of regulation

Regulations are a clear limiting factor on what the pharmaceutical industry can do to encourage compliance, but is this likely to change any time soon? Wyke looked at the regulations surrounding compliance. Routes to patients are limited by law or code of conduct, but since these limits vary considerably from country to country, a 'one size fits all' approach is impossible.

Regulations are a clear limiting factor on what the pharmaceutical industry can do to encourage compliance

Another issue is the quality and type of information that drug companies are allowed to provide. Patients may not be receptive, may not have their needs fulfilled or may not understand what they are being told. Patient information leaflets are a case in point. Only about 6% of patients read patient information leaflets every time, and another 31% only read information leaflets about new medicines. Clearly, the majority of patients don't read them at all. Sticking to the letter of the law on the patient leaflet might backfire, because they list all side effects without quantifying them. That means that patients will only read patient information leaflets if they are new or changed.

Another sticking point is direct-to-patient advertising. A recent television advert for a vaccine in Ireland drew fire on the grounds that it was against the spirit of EU legislation. In Australia and New Zealand, the regulators are merging, but New Zealand, like the USA, allows direct-to-consumer (DTC) advertising and Australia doesn't. The new regime took the 'temperature' of doctors in a research poll, and found that 43% of New Zealand doctors approved of the ban on DTC advertising, although they supported giving as much information as possible after the drug has been prescribed.

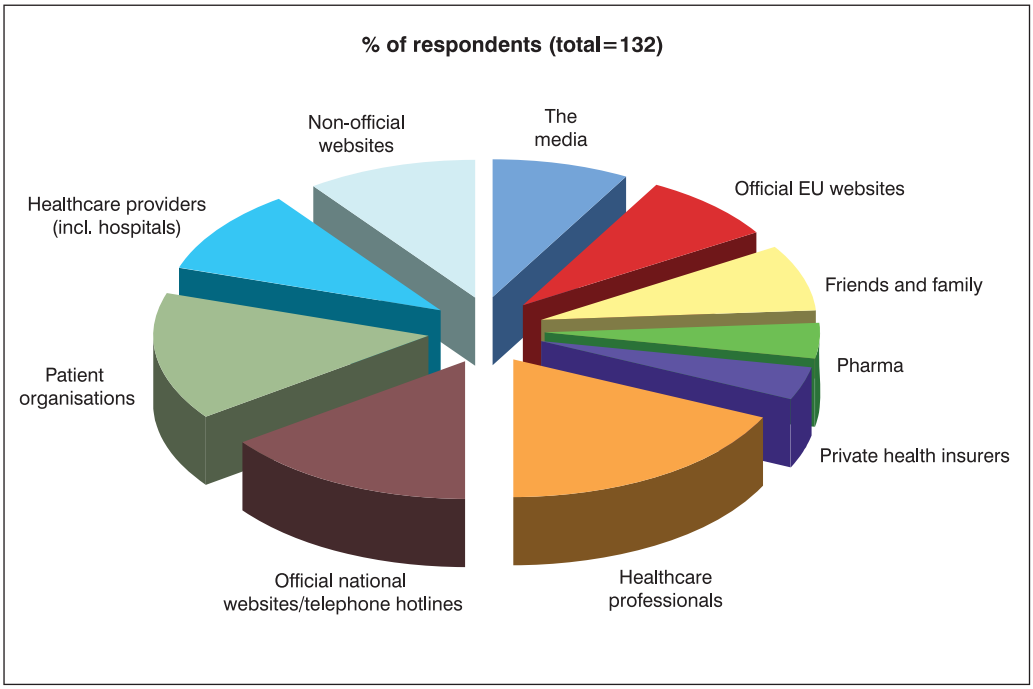

Fig. 3. How will people get information about treatment options in the future? Reproduced with permission from Wyke (PatientView).[4]

How will people get information about treatment options in the future? Overall, the answer was 'from everywhere, in almost equal proportions' (Fig. 3), although doctors and patient groups form the largest slices of the cake by a small margin.

Slowly and cautiously, new mechanisms for patient information are emerging. For example, Cancer BACUP in the UK now carries information on branded medicines on its website. Wyke concluded with the thought that if doctors have no problem with patients accessing information about branded drugs after they have been prescribed them, patient information should be written more clearly and in patient-friendly language.

Patient information should be written more clearly and in patient-friendly language

Tools and technologies

The conference moved on to look at tools that companies can use to improve adherence. Stephan Kerkojus (Stallergenes) and Tanja Antwerpes (Antwerpes & Partner) presented a mobile and web solution. Compliance, they said, is about obedience, and mobiles are to do with social life. So, sending updates via SMS means tapping into a different set of associations in the patient's mind. SMS is secure, so it is appropriate for patient communications. On the other hand, doctors use the web for research not for communication. Whereas 20% of patients speak to doctors via email, only 6% of doctors use email to talk to their patients.

Stallergenes manufactures hay fever products, which have traditionally experienced poor compliance, with 37% of patients dropping out in the first 6 months. Despite the product needing 3–5 years of compliance, the trend seems to be that once the pollen stops, the patient stops. To combat this, Stallergenes developed web-based compliance tools, offering 24/7 online follow-up, reminders and feedback tools. The process is simple. Users register their name, doctor's details and allergies on an intranet, and can complete a patient diary, or connect to their doctor's mobile for remote data input. The data are available to the doctor or the practice nurse for online monitoring, and the doctor is paid €25–75 per patient.

Another tool is interactive voice recognition (IVR). Bill Byrom (ClinPhone) looked at how interactive technologies can be used in intervention programmes to improve compliance and persistence. In the MERET (Memory Enhanced Retrospective Evaluation of Treatment) study, at baseline, patients record data on salient dimensions of their disorder symptoms (e.g. pain, emotions) and effect on functioning, which are captured in their voice, vernacular and affect. At endpoint after 4 weeks of treatment, the baseline recording is played back, which aids recall of baseline status, and the patient is asked how they felt then. Baseline recordings provide effective pretreatment memory anchors, with direct access to thought processes and personal experiences at baseline, whereas intonation, emotion, hesitation and word selection aid patient recollection of baseline condition.

Another study looked at home monitoring of hypertension. Its conclusions were that home monitoring improved patients' awareness of their condition, their awareness of the effects of drug treatment, and their motivation to maintain therapy and adhere to regimen. It seems that patients improved clinically because they

could discuss the results of the monitoring with their doctors.

Fig. 4 outlines a typical pattern of reasons for non-compliance and suitable interventions by which to maintain adherence in patients prescribed an antidepressant. The programme starts with pre-emptive information about what to expect, such as side effects, and then switches to benefits of starting use, reinforced by the patient feeling the benefits of continued use and feeling better. In a typical programme where compliance plays a part in wider IVR services for the patient, the main outbound message options are:

- pre-emptive addressing of common issues
- coaching
- reminders
- medication compliance
- repeat prescription
- collection and tracking of patient-reported outcomes
- personal progress tracking and feedback
- motivation for those on long-term preventative medication.

For instance, in a treatment for tuberculosis in South Africa where 80% of patients have mobiles, the process was lightened up by adding fun elements like tips, jokes or pearls of wisdom, and for these and other reasons, only 5 of over 300 treatments failed. One of the refinements of the process is to build in branched logic so that, depending on the answers the patient gives, the system can decide what to talk about next time, and a sophisticated, almost-human 'conversation' can take place with the patient.

Which channel, what time?

With plenty of potential channels to the patient – including print, mobile, IVR and web – what is the right channel for your patients? Moreover, how do you decide, and how do you motivate treatment-resistant patients?

A panel debate looked at these key questions. Len Starnes (Schering AG) defined the right channel as the most appropriate channel for the most appropriate interventions, taking cost issues into account. Michel Dubery (Rapp Collins Consumer Health) added demographic and timing considerations: a 25-year-old female will need different messages from an 85-year-old man with the same condition. What's more, you need to communicate at a time when the patient is most likely to stop compliance, usually in the first few months. Di Stafford (The Patient Practice) refined the idea still further, noting that you need to communicate at a time that suits the patient, and not necessarily at a time that suits marketing schedules.

You need to communicate at a time that suits the patient, and not necessarily at a time that suits marketing schedules

Moderator Jay Bolling (Roska Direct) focused on the first channel, the most obvious but often one that receives little attention: the physician's office. A specialist is more likely to develop a relationship with a patient than a GP, but even then the specialist has only 6 minutes in the USA and slightly longer elsewhere. There is a need to conserve time. In oncology cases, the doctor also wants someone else to carry the patient's emotional burden, so

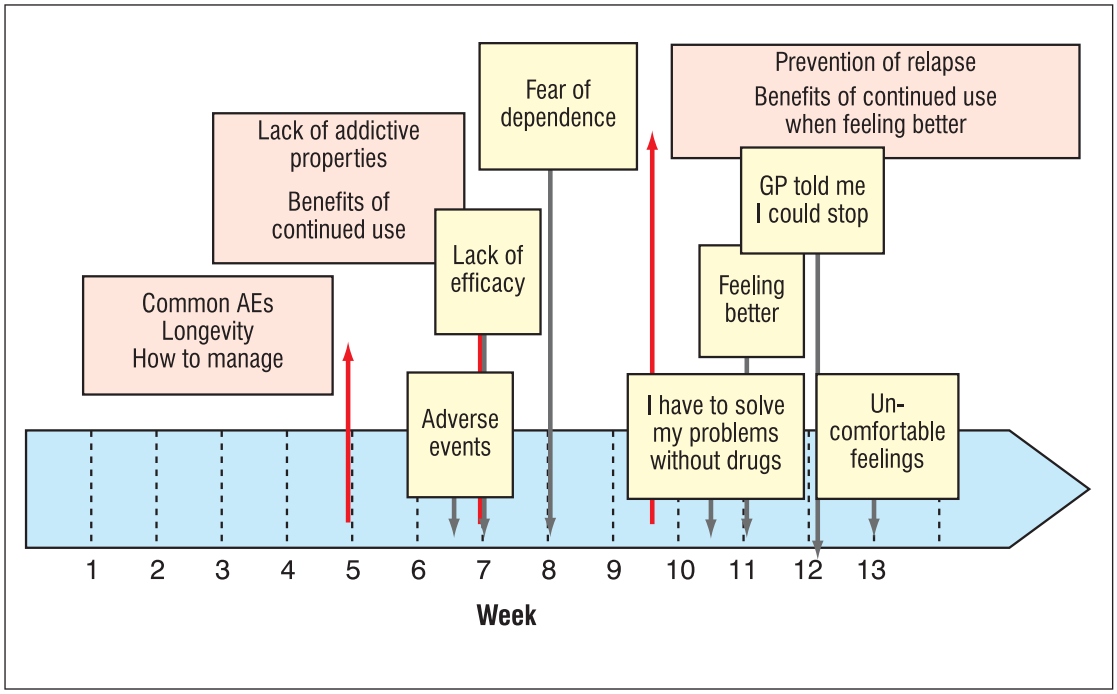

Fig. 4. A typical pattern of reasons for non-compliance and suitable interventions by which to maintain adherence in patients prescribed an antidepressant. Reproduced with permission from Bill Byrom (ClinPhone).

one line of attack is to provide a programme that takes on that burden.

The next channel is the pharmacy. Bolling thought that pharmacists were wide open. The value exchange from the pharmacist's point of view is clear: 'If you want me to do this, give me some money'.

The group commented on a list of other important channels that can be used to encourage compliance. Despite the lure of online, direct mail still has a role. Patients can take mailers to their doctors and discuss them. In fact, people like using both media, underlining the fact that companies should use all available channels. Better still, they should develop as many synergies as possible between the different channels.

Companies should use all available channels. Better still, they should develop as many synergies as possible between the different channels

Call centres are another route. Clearly, these need to use healthcare professionals, but, with adequate back-up, frontline students can be used to take information, register and transfer calls appropriately after screening. The quality of systems is crucial, and they need to be able to deal with factors such as reports of side effects. New developments such as voice-activated IVR can automate the process to an extent, but for chronic conditions in particular, the patient wants to build up a relationship with a person, so a case manager approach is more effective.

Patient organisations are another vital channel because they talk to government and payers. These tend to appear high on search lists and have credibility with new patients and carers, so the pharmaceutical industry needs sometimes to go through them. However, relationships between the two parties are delicate and sometimes fraught. Contracts are needed to be absolutely clear what is expected from both sides.

The patient and adherence programmes

The point of view of patients with multiple sclerosis, a chronic and incurable condition, was put eloquently by Nick Hicks (European MS Platform, External Consultant) in his paper 'If only medicines could talk'. Hicks used the term 'adherence' rather than compliance. This is technically a more accurate term, and has less of an overtone of compulsion than 'compliance'.

Half of all patients with multiple sclerosis don't take their therapy despite robust evidence that early treatment can prevent the devastating long-term consequences of this condition (non-adherence to medication is common in many chronic diseases). Drop-offs occur among about a quarter of patients in the first 3 months due to unmanaged side effects; after 6 months drop-off stabilises, although patients may have concerns about efficacy.

Non-adherence to medication is common in many chronic diseases

Adherence programmes are typically nurse-driven, although patients with multiple sclerosis meet healthcare providers at a range of touch points – consultant neurologists, physiotherapists, GPs, neuropsychologists – all of whom can have an influence on adherence.

One aspect of multiple sclerosis, like many other chronic conditions, is that patients become expert in their condition. They are seeking better information about the disease and its treatments, better communication from healthcare providers and generally want to take a more active role in coping with their illness. Patients are at the centre of multiple sclerosis treatment, expecting information, asking questions and demanding answers. Practical support and the ability to improve quality of life are usually the patient's main concerns. This is what makes the nurse so crucial to adherence. Trust is the key in this partnership, and barriers to trust, where the doctor effectively 'loses' the patient, can come from incomprehensible language used by the doctor, lack of time, or possibly the doctor's fear of litigation inhibiting him/her from using plain language.

Managing the patient's expectations is a key aspect of adherence. Patients may not grasp, for example, that data from a clinical trial don't predict the likely outcome for an individual patient, so the nurse's job is partly educational. Adherence rates improve with education, as shown in Austria where this has been an important focus.

Adherence rates improve with patient education

The Global Adherence Programme[5] being run by Biogen Idec will evaluate the adherence to approved disease-modifying therapies for relapsing multiple sclerosis. Its secondary objectives are to explore factors that influence adherence: social and economic factors; health system/healthcare team factors; therapy-related factors; condition-related factors; and patient-related factors. Data from more than 2600 patients will be available later this year.

For the study, doctors were trained in communication (something that doesn't happen at medical school) and in coaching techniques. Preliminary results show that 87% of patients in the programme have never forgotten

to take medication and 83% didn't want to stop after 1 year.

Hicks' final advice was to find out what is enabling or inhibiting compliance in your programmes and, if necessary, change it. The critical success factors are improving health literacy, because an informed patient is more likely to comply, and to put the patient at the centre of the process.

Who 'owns' the compliance programme?

In a panel session on which disciplines are needed to deliver compliance programmes effectively, it was felt that a wide range of departments in the conventional organisational chart need to be brought together. These include legal, regulatory, medical, marketing and sales. Stafford remarked that one kick-off meeting contained no less than 26 people.

The second key feature is the need to focus on outcomes, and to be ready for the long haul, in a programme that will last from 2 to 5 years. The compliance programme needs to be anchored in the company vision, preaching the mantra that pharmaceutical companies are not here to sell products, but to focus on outcomes. Being able to deliver real-life viability becomes an increasingly competitive factor. Increased consumer power means that the pharmaceutical industry has to go beyond short-term product sales. This all means that top management has to be persuaded to buy into something that won't pay out for 5 years. At the same time, product teams have to deliver sustainability to produce real evidence, which doesn't sit too well with the usual 2–3 year stint that each brand manager serves. An ambitious brand manager is not going to wait around 5 years for the completion of a compliance programme that may or may not prove successful.

So, if the brand manager isn't the natural owner of compliance, perhaps it should be the medical affairs team? They will have to evaluate the programmes and may help with some of the funding, so would it make sense for them to take charge. The problem is that funding is open-ended. If nurse time with the patient isn't going to be reimbursed, someone has to pay for it.

Is there any precedent or business case for beefing up compliance and making it a higher priority? Mark Nuijten (Erasmus University) provided a hypothetical business case and showed how the process might work. This case has to be seen against a background of cost containment, which traditionally on the supply side set price limits, and on the demand side set fixed reimbursement payments, so that patients switched to cheaper competitors. The traditional process didn't take the benefit of the drug into account. Today, there are five hurdles: the traditional three of safety, efficacy and quality have been joined by clinical and cost-effectiveness, and affordability and impact on services.

Real-life data are more important than registration data, mainly because clinical trials involve forced compliance. The business arguments stem from the costs of non-compliance: the cost of other drugs, the cost of hospital admissions or other more costly care which the payer has to meet. Data requirements vary from audience to audience. Patients are interested in effectiveness and quality of life. If the drug delivers these, and drug costs go up, total cost of care will go down. The calculation, therefore, will involve the five hurdles mentioned above, the impact on the drug budget and on the total health budget, and the overall cost-effectiveness. This is shown by comparing registration and real-life data for a hypothetical product 'Z' with those for a selective serotonin reuptake inhibitor. Product Z has a higher impact on the drug budget but produces a major reduction in the overall health costs (Table 2). The reason for the gap between registration data and real-life data is non-compliance (Table 3). Reducing non-compliance increases the drug costs but reduces the total health

	Registration data		Real-life data	
	Product Z	**SSRI**	**Product Z**	**SSRI**
Efficacy	Similar		Similar	
Safety	Side effects		No side effects	
Ease of use	Similar		Similar	
Effectiveness	67.0%	63.0%	57.5%	53.3%
Quality of life	0.81	0.75	0.77	0.72
Drug budgetary impact (million)	€32.1	€27.3	€25.0	€20.6
Health budgetary impact (million)	€318.6	€354.1	€544.1	€648.5
Cost-effectiveness	Dominant		Dominant	

Table 2. A comparison of registration and real-life data for a hypothetical product 'Z' with those for a selective serotonin reuptake inhibitor (SSRI). Product Z has a higher impact on the drug budget but produces a major reduction in the overall health costs. Reproduced with permission from Mark Nuijten (Erasmus University).

	Non-compliance		Difference	
	30%	15%		
Effectiveness	58%	65%	7.5%	13.0%
Quality of life	0.77	0.82	0.04	5.2%
Drug budgetary impact (million)	€25.0	€26.4	€1.5	5.9%
Health budgetary impact (million)	€544.1	€318.6	-€225.4	-41.4%
Cost-effectiveness	**Cost-effective**	**More cost-effective**		
Sales of Z (million)	€19.0	€27.6	€8.6	45.4%
Compliance programme cost	€0.0	€5.0	€5.0	–
Profit	–	–	€3.6	–

Table 3. The reason for the gap between registration data and real-life data is non-compliance. Reducing non-compliance increases the drug costs but reduces the total health costs, and effectively pays for itself through increased sales. Reproduced with permission from Mark Nuijten (Erasmus University).

costs, and effectively pays for itself through increased sales.

Patients are interested in effectiveness and quality of life. If the drug delivers these, and drug costs go up, total cost of care will go down

Are pharmacists the answer?

In a final panel debate, the group looked at how collaboration with key stakeholders can open up new opportunities. Adrienne van Strien (GSK, Netherlands) chose pharmacists. Pharmacists have traditionally partnered GPs in the Netherlands, and their role is to give good advice to patients. Hence, their relationship with patients is already established. They are more easily accessible than doctors, said van Strien, and since you don't need an appointment, they enjoy lots of patient contact. They also have huge databases on medication and a high level of skill, so in theory they are in a position to enhance the compliance process. Besides pharmacists the wholesaler can be a stakeholder with collaboration possibilities. In the Netherlands, wholesalers are buying up pharmacists: 40% of Dutch pharmacies are now owned by wholesalers.

Workshops

There were also several workshops during the conference. These covered benchmarking, ROI, patient education and the future. In the ROI session, delegates thought that compliance was held back by the need to substitute something else in the marketing mix for a compliance programme. Some thought that the industry could use soft measures of ROI such as patient satisfaction, although it was argued that that merely delays the inevitable and ROI will always have to measure prescriptions. In consequence, all activities aimed at increasing sales have to be directed towards the prescriber.

In the 'future' workshop, two key underlying questions were posed: why isn't compliance a senior management concern?, and why aren't there such people as compliance managers? Part of the answer is that brand managers should have ownership of compliance, but there is very little research to convince them or enable them to sell the idea upwards. It was noted that brand managers should sell down as well as up, since the sales force may not be aware that they can benefit from improved compliance, so the use of programmes for sales people is seen as a likely future initiative.

Conclusions

While all this was going on in the conference rooms, a slightly more jaundiced view of the compliance issue was emerging in the corridors and over lunch and drinks. The pharmaceutical industry doesn't regard compliance as a major issue for a range of reasons. The first is that the lifetime of a compliance project is typically 5 years, whereas a brand manager is usually only in post for about 2 years. This means that not only will the brand manager who launches a compliance programme not earn brownie points for a successful compliance programme, neither will their successor. In fact, the kudos will fall to someone who probably didn't even work for the company when the programme was launched.

This timing issue for individual brand managers also impacts on whether the programme will run at all. Is there any point in diverting precious resources from more immediate marketing concerns, such as a direct mail campaign to GPs, which is likely to produce a measurable ROI, even if it is relatively slow? There are

no magic bullet solutions to the compliance problem, so getting buy-in and funding is a slow process.

The pressures on the pharmaceutical industry from outside also contribute to the problem. For new drugs, concerns about safety may inhibit companies from encouraging wavering patients to keep taking the medication, in case there really is a problem. For older drugs, the process of life-cycle management may mask non-compliance, since sales are likely to decline anyway.

Then there is stock market pressure. Investors and analysts want to see rising earnings per share and focus on the pipeline of new drugs to the exclusion of any factors inhibiting the sales of drugs already on the market. If a smart analyst published a paper of drugs with compliance problems, you can be pretty sure that the problem would be addressed and probably dealt with almost overnight.

Another, perhaps better-founded, problem with compliance is that although it may be possible to convert a proportion of unintentional non-compliers by reminding them, intentional non-compliers are a much harder sell. Maybe the solution, as one delegate suggested during a coffee break, will be nano-based time release pills in a subcutaneous implant. The answer may simply be to take the unpredictable human element out of the equation altogether. There will be a host of other issues to consider if and when that happens, but that would be the subject for another conference.

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Drug Safety for Marketed Drugs

A KeywordPharma **Conference** **Insight** edited by **Martin Fagan** Published April 2006

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In-depth report from the eyeforpharma conference, Amsterdam, 22–23 November 2005.

Executive summary

Safety surveillance has much to offer as a powerful knowledge-based tool capable of defending company products in the marketplace while conducting its primary function of safeguarding public health. However, this asset is not translating much beyond the cloistered walls of its practitioners in industry and health authorities.

Clearly, a formidable arsenal has been developed over time: a scientific conceptual base, legislation, data systems, sophisticated technological support – hard- and software – monitoring and analytical systems, quality controls with audit and inspection, and communication tools. The eyeforpharma conference on Drug Safety for Marketed Drugs, held in Amsterdam on 22–23 November 2005, demonstrated that, as a whole, this arsenal works. And yet there is a lack of awareness of its impact where it matters – the end user (the medical practitioner and patient).

This *Conference Insights* review comprises the highlights of a selection of presentations from the eyeforpharma conference, providing a platform for how and where the industry can improve drug safety. Crucially, it also outlines how companies can communicate the true and undoubted value of safety surveillance.

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About the editor

Martin Fagan is a Senior Executive Director with over 25 years experience in the healthcare, pharmaceutical, NHS (public sector) and data/IT/CRM industries, both in the UK and internationally. He has experience in start-up, rescue, organisational restructure, spin out and sales/marketing/business development in the pharmaceutical, B2B and IT industries, as well as in NHS supply. He also has extensive experience of commercial databases and patient data in clinical research, and knowledge of NPfIT and current NHS changes and opportunities through his current role as Vice President Market Insight Solutions for Infonetica.

Martin qualified as a toxicologist and, after a brief spell in research, progressed through the commercial arm in the pharmaceutical and supplies industries, including 4 years in Asia responsible for trade with over 10 countries. He established his own consulting company, Infozyme Consulting International, in 2001.

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