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Reprint

European Compliance Not Only Possible, But Leading Edge

By **Jack Barrette**

As US pharmaceutical companies search for best practices to battle patient drop-off, their European counterparts have overcome Byzantine regulations and reduced margins to implement strikingly effective compliance programs.

At the CBI Patient Compliance and Persistence conference in Philadelphia, PA in April, 2004, Len Starnes, Head of European eBusiness for Schering AG, demonstrated the challenges—and successes—of conducting Direct-To-Patient (DTP) support programs in the European Union (EU).

Starnes is charged by Schering with spreading awareness about compliance programs throughout the company, especially the use of the internet and mobile channels to support pan-European efforts in all 25 EU member states.

EU Member	Yes	Vague	No	No Policy
Austria	X			
Finland			X	
France			X	
Germany		X		
Greece				X
Ireland	XX			
Italy		X		
Netherlands	XXX			
Spain		X		
Sweden			X	
UK		X		

Do Member State Regulations Differentiate Advertising vs. Info? (EFPIA 2004 Survey)

Which Regulations Apply?

In the EU all pharma compliance efforts must take into account often disparate regulations and codes of practice from the EU, member states and the European Federation of Pharmaceutical Industries & Associations (EFPIA), which represents the research-based pharmaceutical industry operating in Europe.

"The core of the problem in the EU," Starnes asserts, "is that there is no explicit differentiation between Direct-To-Consumer (DTC) and Direct-To-Patient (DTP)." DTC is specifically prohibited as it is "an offense to issue an advertisement likely to lead to NRx," but the primary EU regulation affecting Prescription-Only-Medications "only refers to advertising," says Starnes, "with no reference to the provision of information, support services, or compliance programs to patients on drugs."

To a great extent, says Starnes, "EU pharma programs must make their own interpretation of hopelessly disunited regulations. The big countries, like Italy, Germany, and Spain, for example, have published lengthy regulations governing the difference between advertising and information but these are both vague and contradictory. Only the Netherlands," claims Starnes, "is explicit and unambiguous in defining patient information. Consequently, you can drive compliance there without any significant problem." (See Chart below)

EU Member Positions on e-Channel DTP

Starnes feels that EU Member State positions on e-channel DTP programs are so different that he has devised a matrix to illustrate varying degrees of regulatory enlightenment. By evaluating national regulations and actual online compliance activity, Starnes has assigned each country a status (see Table on Pg 4).

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The EFPIA is striving to support appropriate patient programs. For example, EFPIA's "Informed Patient" initiative has established a task force to assist the European Commission in formulating a new strategy on patient information. The EFPIA is also preparing a report on current EU practices regarding information provision to consumers and patients, with a particular focus on the Internet.

Existing EFPIA Guidelines for Pharmaceutical Industry Websites do differentiate between consumer and patient information, with support for content on drug indications, interactions, clinical research, and proper use. "These industry guidelines are extremely useful with internal regulatory teams, who tend to be overly conservative," says Starnes. "They have also proven of benefit to external regulators who are seeking clarity in this new area."

Channels and Compliance Reality

The key to executing effective compliance in the EU is to recognize that the regulatory environment matches the complexity of multi-channel program implementation stride-for-stride. Marketers must embrace this complexity from program inception to match their compliance efforts to the most compatible channels–then meet the regulatory demands of each channel individually.

Nurse Support Programs

Starnes spoke from Schering AG's own experience, focusing on its Multiple Sclerosis (MS) nurse support program, which, according to Starnes, "transcends compliance and is really a 10-year effort in disease management." The nurse professionals work either for 3rd parties (i.e., private foundations or CROs), MS centers, or in some cases, directly for Schering. Schering provides funding, and Starnes notes that "the most critical factor we found was that the nurses in the program must focus exclusively on Schering patients; when they handled other types of cases as well, the result was not nearly as positive."

Legal considerations for Nurse Support programs include:

- Not explicitly referred to by European Directives or national regulations
- Patients opt-in, always in close consultation with prescribing physician
- Only qualified registered nurses used
- In most countries nurses must operate through 3rd-party organizations
- Nurses operate in compliance with their own professional codes of practice

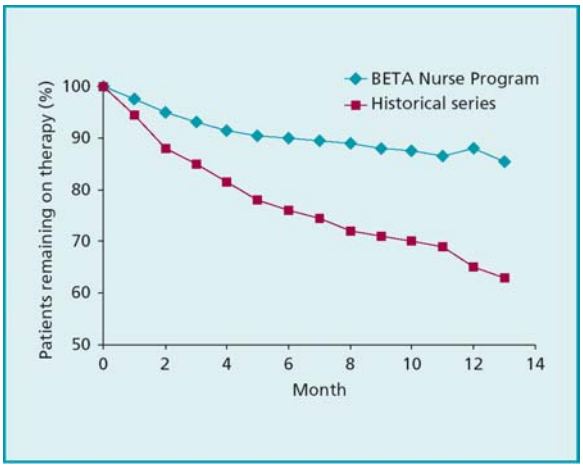
	Channels					
Compliance Message	**Internet & e-mail**	**Mobile Messaging**	**Direct Mail**	**Call Center**	**Nurse Support**	**Patient Devices**
Medication Reminders	2	4	1	3	3	5
Patient Information	4	1	4	4	4	1
Disease Management	3	2	1	5	5	1
Appointment Reminders	3	3	1	4	4	1
Refill Reminders	4	4	3	4	4	2
Tracking Health Indicators	4	3	1	4	4	1

Channel Compatibility. Which channels are better suited to specific compliance messages: 1=Low, 5=High. Adapted from: "Improving Patient Compliance," Datamonitor July, 2003.

As compliance programs develop, the utility of certain channels may not be strong enough to outweigh regulatory concerns. On the other hand, Starnes says, "nurse support programs and call centers are relatively easy to roll out and are highly effective."

The impact of the MS nurse program on adherence has been striking. Published studies have shown that after 13 months, 20% more program participants remained on Schering AG's Betaseron therapy (when compared with historical data on non-participants; see Chart on next page). "It's

very successful," says Starnes, "and it drives all of our disease management programs in MS."



Strong results from nurse support in the EU has lead to its adoption in the US as well, including the unprecedented step of opening free-standing MS centers, called B.E.T.A. Centers. Berlex, Schering AG's US organization, states in a press release that "the B.E.T.A. nurses network, which includes more than 50 MS nurse specialists, helps people on Betaseron manage their disease and offers ongoing support to patients, families and friends. B.E.T.A. Centers are an integral part of the B.E.T.A. nurse program, and are the first and only privately sponsored centers in the United States just for people with MS. Currently there are nine B.E.T.A. Centers across the country."

Most recently, an online component has been added to the B.E.T.A. Nurses (US) program: Betanurses.com builds on the success of the B.E.T.A. nurse program through a host of additional web-based re-sources and support services. "We think it will enhance the overall experience for thousands of people with MS who take Betaseron," says Ralph Makar, Vice President & General Manager, Therapeutics, Berlex.

Mobile Messaging

Mobile messaging, far more prevalent in the EU than in the US at this time, is gaining a foothold in compliance efforts. Janssen-Cilag's Evra contraceptive patch offers SMS reminders to women in Austria, the Czech Republic, Germany, The Netherlands, and the UK. Sanofi-Synthelabo France presents an online sign-up for "Observtel, telephone help to follow your treatment. Never forget to take your medication!" And AstraZeneca's German asthma site, "Leichter Atmen 24," promotes its SMS (Short Message Service) program as a primary patient support service.

Call Centers

Results from the Roche Xenical program in the UK and Ireland, presented in London this past February, show the effectiveness of call center intervention. Seven months into a 12-month study, approximately 45% of Xenical Call Center participants remained on drug as compared to 15% of non-participants.

Legal considerations for Call Centers include:

- Not explicitly referred to by EU Directives or national regulations
- Mostly addressed by local industry codes of practice
- Operations outsourced to 3rd-parties - *No direct contact pharmaco & patient*
- Patients enrol via physician, pharmacist, or directly (phone, fax, email, website)
- Calls provided by medically qualified staff - *Doctors, nurses, dieticians, etc*
- No cold calls - *All pre-agreed with patient*
- Sponsoring pharma company has access only to anonymized data

To assuage legal concerns, each of these programs carefully restricts its SMS service to current patients by requiring the EU license number from the product pack. "This number is common across the EU," notes Starnes, "and can help to simplify your multiple country regulatory issues."

US pharmas, still slow to adopt SMS, should watch accelerating US adoption as they plan their multi-channel strategies. According to mobile technology provider Upoc's annual independent tracking study, "2003 SMS penetration is up 50% from last year. Twenty-seven million U.S. mobile phone owners (twelve years and older) already use text messaging (up from 18 million last year). A surprising number of those both send and receive SMS messages (72% of all respondents who use text messaging; 85% of 12-34 year olds who use text messaging), while 21% only receive (37% of 35-54 year olds). SMS usage is clearly a part of consumers' personal lives, with 73% sending messages to friends, 70% to family members, and only 26% to business contacts. This bodes well for marketers as they search for additional ways to reach an ever-fragmenting audience."

For a cautionary view on the use of SMS technology for patient adherence, see "To Build

Patient Adherence, Pfizer Puts Technology Behind The Curtain" (PMN Reprint 33-04).

Legal considerations for Mobile Messaging include:

- Not explicitly referred to by EU Directives, national regulations or industry codes of practice
- Some countries stipulate use of 3rd party operators - *France, Italy*
- Current use primarily medication and refill reminders - *no product specific messages, hence less problematic*

Internet and E-mail programs

Smoking cessation programs are often leaders in the compliance arena, and the EU online program executed for Zyban by GSK is no exception. Conceived and tested in the UK and the US, the "Right Time" program has also been rolled out to the Netherlands.

Legal considerations for Internet and E-mail include:

- Not explicitly referred to by EU Directives or national regulations - *exception France*
- Not explicitly referred to by industry codes of practice -*exception UK*
- Profound differences in regulatory freedom at national level – *France most restrictive, Netherlands most open*

Strategies and Tactics

For pharma companies working toward compliance programs, Starnes advises teams to "talk to regulators about intended initiatives; they are more open than you think." He suggests specifically that marketers "explain the need for better compliance in win-win terms for all stakeholders, focus on the cost of non-compliance, stress DTP not DTC, and show the EU is not united on DTP." Tools are available to support the case for pharma programs, including studies to illustrate physician support for pharma-sponsored e-Disease Management (e-DM). For example, 94% of physicians in France and 87% in Germany support pharma industry e-DM programs according to a Reuters 2003 Business Insight Study, "Consumer Targeted Internet Investment." This study also found that 80% of US physicians supported such programs.

Just as important as regulators, notes Starnes, are your own internal legal teams. "Question and carefully evaluate recommendations from your own legal department," he advises, "we need to weigh risk versus opportunity, and lawyers will usually advise against 'grey area' initiatives like compliance."

"You can run compliance programs successfully in Europe. And in the near future, you will be able to run more programs, in more countries, through different channels."

The future will also see the emergence of more channel integration to fully maximize the value of compliance and disease management programs. As this trend develops the challenges facing the industry will become more complex as legal, regulatory, privacy, confidentiality and technological issues become intertwined. But just as CRM has the potential of transforming the way the industry does business, so too will the impact of patient relationship management.

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Status	Position on DTP	EU Member States
Enlightened	**DTP Explicitly or implicitly recognized**	**Belgium, Czech Republic, Denmark, Finland, Ireland, Netherlands, Norway, Switzerland, UK**
Paradoxical	**DTP Not recognized but activity nonetheless**	**Austria, Germany, Sweden**
Intransigent	**DTP not recognized at all, but no test cases so far**	**France, Italy, Spain**
New Members	**Unknown**	**Baltic States, Hungary, Poland, Slovakia, Slovenia**

Web sites related to the compliance programs cited in this article:

- Schering AG's Beta Nurse program: www.betanurses.com (US site)
- Janssen-Cilag's Evra contraceptive support site: www.evra.co.uk (requires registration)
- AstraZeneca's Asthma Mobile Messaging program: www.leichteratmen24.de (German site)
- GlaxoSmithKline's Zyban online program: www.right-time.co.uk (UK site)

Contributing Author

We thank the following writers for contributing articles for this issue.

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Resource List

The following resources were consulted in the preparation of this issue or cited within this issue.

- EU Directive 2001/83/EC. See http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2001/nov/Codifications/HumanCode2001-83/2001-83EN.pdf
- EFPIA Internet Guidelines. See www.efpia.org/6_publ/Internetguidelines.pdf
- EFPIA Informed Patient Position Paper. See www.efpia.org/4_pos/pharmareview/InfoPatientPolicyPaper.pdf
- EFPIA (The European Federation of Pharmaceutical Industries and Associations) represents the research-based pharmaceutical industry operating in Europe. Founded in 1978, its members comprise 18 national pharmaceutical industry associations (plus 6 associations with liaison status) and 43 leading pharmaceutical companies involved in the research, development and manufacturing of medicinal products in Europe for human use. See www.efpia.org
- Nursing Practice in Multiple Sclerosis: A Core Curriculum, Edited by: Kathleen Costello, RN, MS, CRNP, MSCN, June Halper, MSCN, ANP, FAAN, Colleen Harris, RN, MN, MSCN (Demos Medical Publishing, 2003)

Experts Consulted and/or Cited In Articles

The following experts were mentioned or consulted in the preparation of articles for this issue.

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