

Europe scrutinises imported API quality

Better compliance with good manufacturing practice (GMP) has resulted from the efforts by the European Fine Chemicals Group (EFCG), according to Hovione's chief executive officer Guy Villax. But the group is still worried about the quality of active pharmaceutical ingredients (APIs) made outside Europe for European consumption, he says, and a greater deterrent effect is still needed to maintain progress.

Speaking to *Generics bulletin*, Villax says he is convinced that APIs used in European Union (EU) medicines exhibit greater GMP compliance today than they did a year ago. He has two reasons for believing this. The first is the increasing number and frequency of audits that API plants outside of Europe get from EU customers; while the second is the growing spread of articles on the subject in Chinese and Indian publications. "These articles are an indicator of the heightened deterrent effect that the EU law is having," he says.

Villax has no quarrel with the new European audit and inspection rules introduced as part of Europe's revised pharmaceuticals legislation, which should have come fully into force in October 2005 in every member state. He also says GMP regulation Q7A of the International Conference on Harmonisation (ICH) sets the right standard.

The problem, he believes, is one of enforcing the rules. "Our most pressing priorities in the EFCG are enforcement, enforcement, enforcement," he says. "We are glad to hear that the Spanish medicines agency is doubling the number of its inspectors. And to learn that several French finished-dose manufacturers using the same APIs have shared their audit costs."

"But our members are frustrated to see their products in Europe having to compete with APIs that cost less because production of these APIs is not compliant with GMP or with regulatory filings. When you have excessive price competition without proper enforcement of the regulations, the winner is likely to be the least scrupulous operator."

He also highlights the recent Written Declaration on non-European APIs, signed by the majority of members of the European Parliament (*Generics bulletin*, 12 January 2007, page 12), which "demonstrates alignment between the EFCG's message since 2004 and the elected voice of Europe". How the declaration will be followed up is still under discussion, he adds.

Villax notes that prime movers such as Emer Cooke, head of inspections at the European Medicines Agency (EMA), believe that the new rules should be given time to bite, but he bristles at the slow progress. Referring to the EFCG's forthcoming May annual meeting in Germany, he comments: "We look forward in Berlin to hearing from the head of the EMA's inspections sector about the actions taken by inspectors from the 27 EU medicines agencies, and the extent to which they are assessing that the APIs in medicines on the EU market meet GMP requirements."

Villax also queries the status of the 'Qualified Person' at the finished-dose manufacturer – the 'manufacturing authorisation holder' – who has to take responsibility for API quality in the finished medicine. "The standing and power of the qualified person varies greatly across Europe's different cultures," he observes. "In addition, the legal liability placed on the qualified person is much less onerous than that for other professionals."

Guy Villax will be presenting at the EFCG's second annual pharma business conference in Berlin on 24-25 May, together with EMA's Emer Cooke, the European Commission's Sabine Atzor and France's Jean Marimbert, representing the EU Heads of Agencies. **G**

■ More details from info@efcg.conference.org.

Pharmacy chains are on the rise in Europe

Just 13.5% of pharmacies in Europe are part of a chain of two or more outlets, according to a new study, but this is likely to change rapidly over the next few years as national pharmacy ownership rules are challenged by the European Commission among others.

The ownership controls imposed by Austria, France, Italy and Spain – which broadly state that each pharmacy must have its own pharmacist owner – are under threat from the Commission on competition grounds, the study notes, while the state monopoly of pharmacy ownership in Sweden could be about to change.

Meanwhile, the number and membership of 'virtual' chains – independent pharmacies affiliated into buying groups, often under the

Country	Pharmacy chain (%)	Virtual chain (%)
Austria	1.6	2.1
Belgium	22.0	3.8
Czech Republic	9.9	0.0
Denmark	18.4	0.0
Finland	19.4	0.0
France	0.0	60.0
Germany	5.7	62.4
Hungary	0.0	0.0
Italy	8.8	0.0
Netherlands	19.2	11.2
Norway	98.1	0.0
Poland	10.0	0.0
Slovakia	5.6	0.0
Slovenia	0.0	0.0
Spain	0.0	1.0
Sweden	100.0	0.0
Switzerland	18.0	44.0
UK	73.0	49.0
Total	13.5	27.3

Figure 1: Proportions of pharmacy numbers to be found in a chain of two or more outlets, or in a 'virtual' chain in Europe (Source – James Dudley Management)

influence of a major wholesaler – is on the increase, says the study from James Dudley Management. Both trends will have major implications for how the pharmaceutical industry accesses the retail element of the supply chain, the study maintains.

The study – which focuses on the OTC sector in particular – notes the recent efforts of the Dutch internet pharmacy DocMorris to create a branded pharmacy franchise in Germany. "The retail pharmacy concepts of DocMorris in Germany have the potential to revolutionise chain development across Europe," states the study.

Excluding Sweden, Norway has the highest density of branch pharmacies with over 98%, followed by the UK (see Figure 1). Virtual chains are the most popular in France – where multiple ownership is forbidden – and in Germany, which relaxed its laws only recently to allow pharmacists to own up to four pharmacies.

More than half of the 16,974 pharmacies belonging to a chain of two or members in the 126,152 pharmacies of 18 major European countries are to be found in the UK, the study points out. **G**

■ OTC Distribution in Europe 2007 is available from James Dudley Management (Tel: +44 (0)1562 747705; Fax: +44 (0) 1562 750275; Email: information@James-Dudley.co.uk; Website: www.james-dudley.co.uk)