

Intensive wholesaling: who should pay?

Accessibility of medicines and remuneration were central to the discussions at a recent meeting, reports Matthew Wright

Governments hold the key responsibility of ensuring access of medicines to patients, Liam FitzGerald, chief executive of Irish pharmaceutical wholesaler United Drug, told participants at the European Association of Pharmaceutical Full-line Wholesalers (GIRP) annual general meeting, held in Prague last week.

"Manufacturers, wholesalers and retailers all play a role in ensuring medicines are available," he said. "However it is wholesalers, critically in my view, that ensure availability when and where a patient needs their medicine. Drugs are not the same as consumer products: they save lives, and ready availability as and when patients need their therapies is providing a basic but essential element of a good public health service."

Mr FitzGerald went on: "Attempts by any stakeholder to cherry-pick product ranges or to price services without due recognition of the cross subsidisation nature of our service, or to delimit wholesaling to a pure logistics op-

eration, will ultimately do patients a disservice and will compromise the de facto public service that we provide. The issue for our industry, I think, is to make this message heard."

He added: "Certainly, we all need to seek out other services that allow us to capitalise on new outsourcing trends by the manufacturing industry and, indeed, by governments. However, in doing so, we often deny our full-line wholesaling heritage and fail to focus on communicating that service's value to all elements of the healthcare value chain."

Mr FitzGerald said that a number of governments recognise their responsibility to patients via public service legislation that sets out the role and requirements of full-line wholesalers. "Whether or not this public service is defined in a country's legislation, full-line wholesaling performs this vital public service role by default through its modus operandi, and this service has a basic cost. . . . Our service has a cost that is rooted, in a very fixed way, in the totality of what we do. In a very low

margin business characterised by low returns on invested capital, small changes in product mix, or in compensation for what we do, has a disproportionate effect on our profitability."

Mr FitzGerald believes that other players within the industry do not fully appreciate the role of full-line wholesalers in the overall provision of public healthcare. "As I often argue, everybody knows what a manufacturer does, everybody knows what a pharmacist does, but nobody seems to know or value what happens in between until it is under threat," he said.

"The most difficult element," argued Mr FitzGerald, "is demonstrating the high fixed cost associated with the intensity and public service nature of what we do. It is not possible to fully separate out one product or customer group and cost a service exclusively around them." He questioned: "Who should pay for the fact that full-line wholesalers provide such a comprehensive and intensive service?" He described this as a complex dilemma.

Access issues not distribution related

There are significant access issues for UK patients but they are not primarily distribution related. So said Richard Barker, director general of the Association of the British Pharmaceutical Industry.

With regard to patient access to new medicines, Dr Barker said: "The introduction of the National Institute for Health and Clinical Excellence, and its equivalents elsewhere in the UK, and their assessment of technology in terms of cost effectiveness have represented, [and] continue to represent, a significant barrier. We can talk for a long time about how legitimate the barrier is, but the barrier is certainly there."

He went on: "But even if NICE were to approve a medicine, the local uptake is extremely slow and extremely variable. And that represents, I think, the most important and significant barrier to access to medicines in the UK."

Mr Barker commented on the changes that have occurred around medicines distribution in the UK: "As yet no substantial impact has been made on product availability. But the issue of the integrity of the supply chain remains a significant, indeed growing, issue particularly in the area of counterfeits. We need



Richard Barker, representing the interests of UK pharmaceutical industry

to focus collectively as an industry on addressing and resolving this problem, rather than necessarily pointing at each other."

Dr Barker said: "Track and trace technology, which we are talking to all our participants in the supply chain about, offers a valuable way forward."

But he went further: "We cannot expect to stay where we are at a time of seismic shifts in health systems and in the pharmaceutical companies that supply products. I believe that direct to pharmacy and a ban on repackaging would help to secure against counterfeiting for the benefit of patients and, ultimately, the benefit of all of us who believe in a secure supply chain."

In brief

Innovation not available EU-wide

There is no value in developing innovative medicines if these cannot be of use to all patients in the EU, said Antonie Egeland, of DG SANCO's health strategy unit. Some products, particularly those with small markets, are not made available in every EU country, which "drives significant inequality in access between member states", she said. However, Ms Egeland made clear: "Member states are in charge of the organisation of their own healthcare systems and they have to take into consideration the budgets they have available."

Small-step innovation questioned

The diminishing number of valuable drugs coming out of the R&D pipeline has led to a rise of "me too products" or "small-step innovation", Gerard Van Odiijk, president and chief executive of Teva Pharmaceuticals, told participants. "Small-step innovation will have head-to-head competition with generics. And how can you justify the exclusivity period and the high price that comes with that, versus a generic competitor?" He said this leads to the question: "Is there a right of existence for this small-step innovation and, if so, what is the value in that?"

The European Association of Pharmaceutical Full-line Wholesalers (GIRP) held its 49th annual general meeting, entitled "Accessibility of medicines: remunerating performance", in Prague on 2 June. Matthew Wright attended the meeting courtesy of GIRP.

Pharmaceutical Forum discussed Single-digit growth and poor R&D pipeline behind supply changes

The third and final meeting of the Pharmaceutical Forum will take place in the autumn, Christian Siebert, former head of the unit on competitiveness in the pharmaceutical industry and biotechnology, EC Directorate-General for Enterprise and Industry, told participants.

Dr Siebert explained that the high-level Pharmaceutical Forum is a shared responsibility between the Directorate-General for Health and Consumer Protection (DG SANCO) and the industry department, involving close working with a range of stakeholders. This work is undertaken in three work streams: information to patients; pricing and reimbursement; and relative effectiveness.

He also drew attention to a recent session looking at wholesaling and distribution, within the forum's pricing and reimbursement working group. Dr Siebert told participants that GIRP had contributed constructively to this meeting, as well as the broader Pharmaceutical Forum process, with its expertise and understanding of the sector.

He said that specific features of distribution were highlighted through this work, for example, the specific role and responsibility of wholesalers that carry the full assortment of pharmaceutical products, and the issue of public service obligations for wholesalers. Dr Siebert also said there was debate around the

density of wholesalers present in certain EU areas, "together with the challenges that might come from new ways of distribution, such as mail order, internet and direct to pharmacy".

"It was underlined that this might lead to possible risks for the distribution of individual products, particularly lower price and maybe low demand segments," he said, adding that there were concerns over increases in the number of transactions that could occur if wholesalers reduce the amount of "bundling" of orders between manufacturers and pharmacies.

In a separate presentation, Bernard Amoury, vice-president, supply chain, Sanofi-Aventis, told wholesalers that manufacturers are changing their supply models "to protect ourselves, not to attack you". He said that Europe is an increasingly difficult area for the industry to do business: "Our problem is to survive."

□ **PGEU defends wholesaling** The traditional model of pharmaceutical wholesaling is extraordinarily successful, said Mika Vidgrén, president of the Pharmaceutical Group of the European Union. "Medicines are not like any other products. It is amazing that in Europe today we still have to make this point," he said. "The distribution of medicines is not simply a logistics function."

He added: "The patient should always be at the centre of our common work."

Adel Al-Saleh, of pharmaceutical market consultancy IMS, told participants about the pressures prompting pharmaceutical companies to change their models of medicines supply.

He said that growth in the pharmaceuticals sector is now in single rather than double digits (5–7 per cent growth over the next three years), with trends moving away from blockbuster drugs. Smaller players, such as biotechnology companies, are now driving growth and bringing innovation to the marketplace, Mr Al-Saleh suggested. He added that the efficiency of research and development and its contribution to the production of new products is under pressure — "that model is broken" — and that the generics industry is now dominating large therapy areas.

He told the meeting that manufacturers are moving quickly to new supply models, which would impact on how access and distribution will look in the future. "We believe that community pharmacy will continue to be at the core of dispensing," Mr Al-Saleh said, but he added that new channels would mean the pharmacist will, in some cases, be excluded and, in others, get access to drugs differently.

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