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No stakeholders, no solution

Sometimes I like the comparison of drugs with other hi-tech commodities such as computers or chips. Have you noticed that in the computer market we are still getting more and better quality for less money? I fail to understand why the drugs market is different, new drugs are always more expensive. And yes, there are times that certain chips are much in demand, so relative shortages may occur, and prices can go up temporarily. But with drugs? New drugs seemingly have a right to exclusive marketing at any price, and oops, become unavailable all of a sudden. Or if a patent runs out, and the profit incentive is no longer there, the drug may also be taken from the market, irrespective of patient needs. The profit principle in the drug market has gone so far that, as a result of unattainable demands of production and stock efficiency, drugs increasingly become unavailable. JIT ('just in time') increasingly means available too late or not at all …

Is this new? We examined the drug shortage problem repeatedly between 2004–2007 [1, 2]. Dr Walter Deutschmann from Bremen, Germany, wrote an exemplary analysis [3-5]. Every hospital pharmacy in Europe, and we have thousands of them, is spending significant time every day to make sure patients do not suffer from drug companies failing to fulfil their duties to deliver drugs that have been granted a marketing licence. Because of these efforts, many shortages go unnoticed by physicians and patients. It looks as if due to lack of public concern the industry sees no problem in turning the efficiency screw to the next level … But now unique drugs are becoming unavailable, it is spreading like the plague. Who complains? Who has the power to take counter action?

It is a global problem. In 2002, our US counterpart the American Society of Health-System Pharmacists published an extensive report [6] based on a stakeholders meeting/Drug Shortages Summit, and this was repeated a year ago (5 November 2010, visit www.ASHP.org/drugshortages), together with the American Society of Clinical Oncology, the American Society of Anesthesiologists, FDA and the Institute for Safe Medication Practices. A repeat was needed as things had gone from bad to worse, and for some drugs a crisis situation had been reached. Main conclusion: not much they can do, the pharmaceutical industry has organised its rights in such a way that they can decide what to do or have found ways to blame others. In the October 2011 issue of *American Journal of Health-System Pharmacy* the results of a US-wide survey were published, indicating that the labour costs in US hospital pharmacies of dealing with shortages were well over US$200 million (Euros 145 million) annually [7].

We all know it is the same in Europe. We have developed an 'ethical pharmaceutical industry' that has become, some say, the most tightly regulated industry. Maybe true for market entrance, but we left the back door open! Valuable drugs become unavailable for some time or forever at the whim of the same companies. What can we do to stop what looks like a whole industry misbehaving?

I have learned in European politics that for the European Commission to take action it is important for stakeholders to complain that something serious is going wrong. We should not mutter, we should shout aloud that this shameful situation has existed for many years and is only getting worse. Nothing happens because the regulators I talk to all say they are powerless. But article 81 of Directive 2011/83/EC of the European Parliament states that it is illegal for holders of a marketing authorisation not to supply licensed products and that they have a responsibility to cover the needs of patients.

In The Netherlands we have a simple saying 'Things will change if you hit them in the purse'. So I have the following suggestions:

- If a company is authorised to exploit the highly protected drug market, and they do not deliver, they should be fined up to 100% of last year's turnover of the product that has not been supplied.
- Other companies should be given the right to introduce a generic version of the product, and be allowed to refer to the registration file of the non-compliant company.
- If a drug is not available in one country, but easily available in an approved form in another EU country (which means quality guaranteed), the licence should be suspended in the country that does not deliver and free importation of the drug be allowed from the country that can supply.
- If you have a choice of drug provider, avoid those manufacturers that do not supply drugs that are apparently not sufficiently profitable and explain why you do this: this is called feedback on delivery performance.
- Make it publicly known in your hospital which companies perform badly with drug shortages and tell physicians to avoid drugs from that company, because their favourite drug may be the next in short supply.

Yes, these suggestions may have all kinds of serious disturbing effects on the EU drugs market. It is like Newton said, 'action causes reaction'. Let it happen, let us shake up the current drug market. Too long, companies have believed they can permit themselves such bad behaviour, but now enough is enough. I find it a shame that every second week I get on my desk a drug shortages update, continually listing some 40 products with delivery problems. We are too nice, we should become militant, complain about this appalling customer service that you would not even accept from your bicycle repair shop.

As hospital pharmacists we are in principle in a position to use our production skills to solve some of the problems. But if you read the compelling *In My Opinion* in this issue from Ms Yvonne Bouwman-Boer from the Dutch Scientific Institute of Pharmacists, you find that in the future we will be confronted with serious limitations to our ability to cope with unforeseen drug shortages and even to provide personalised medicines. She explains clearly how drug regulators—who are well organised—are setting up legislation for hospital pharmacy preparation which is going to cost a fortune

to society, which may impose impossible restrictions on many of us, and which will not solve any problems, since there are not any. She explains that well-organised regulators are using their power to introduce strict quality regulations intended for large-scale production in industry, but which were never meant for small-scale production in hospital pharmacies. It looks like a remedy that is far worse than the disease. Again, as individuals we are powerless, but as a group of more than 21,000 well-trained professionals we have a voice!

As the EAHP, together with patient and physician associations, we should complain to the European Commission about the disgraceful behaviour of pharmaceutical companies, abusing their profitable rights to exploit the highly-protected EU drug market. We have seen already to what harmful side effects such protection might lead. I feel we are letting a terrible wrong occur. EAHP is now representing more than 21,000 EU hospital pharmacists, who suffer every day from this profit-driven nuisance. Let us unite as EAHP, it is time to take action, we are, together with our patients, the stakeholders; we should take the initiative to mobilise the European Commission to stop the 'no shows' of the most profitable market sector they have created by their protective legislation, and to retain small-scale production of drugs in hospital pharmacies without unnecessarily costly and complicated regulations. With a failing industry, this is a necessity to guarantee the availability of much needed medicines for our patients. That is also part of the original treaty of Rome! Patients, physicians and pharmacists are stakeholders, and they should force the European Commission to sensible solutions. Because what counts in the end and it should be the real concern of the politicians in Brussels, Belgium, is the safe and continuous provision of medicines by well-qualified hospital pharmacists in the interest of patients. Let them create solutions, not more problems.

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References can be found on page 18.

Professor Arnold G Vulto
Editor-in-Chief, EJHP Practice

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In My Opinion

The Council of Europe resolution on pharmacy preparation

Yvonne Bouwman-Boer, PharmD

A resolution on 'quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients' [1] appeared out of the blue during the 2011 EAHP Congress. Mention of this Council of Europe resolution rather surprised and even irritated those attending the two seminars on 'Hospital-based versus industry production'. They feared more irrelevant European interference in the everyday battle against drug shortages, quality problems with drugs and management of safe reconstitution on the wards. They expected it to be detrimental for their patients.

Is this resolution, which styles itself a 'major breakthrough in patient safety', as bad as they expected? Being involved in guidelines and procedures on pharmacy preparation, I am happy to have been invited to give my opinion.

Let us start with one message to which no pharmacist will object: 'the European Ministers formally confirm with this resolution that pharmacy preparation is an important—even indispensable—element of pharmaceutical care.' They acknowledge that the pharmaceutical industry cannot always cover the needs of patients. The European Directorate for the Quality of Medicines and HealthCare (EDQM) notes, however, a lack of European harmonisation on pharmacy preparation, and has now with this resolution set a standard for national requirements for quality and safety assurance. A standard to facilitate European harmonisation and 'a major breakthrough to protect patient safety' may sound noble, but most pharmacists would not put it that way as pharmacy preparations normally do not cross national borders and the resolution is not referring to actual quality problems.

Further reading probably reveals a more obvious reason for the origins of this resolution: 'quality and safety gaps between medicinal products prepared in pharmacies and those prepared on an industrial scale have to be avoided.' Assuming that 'on an industrial scale' is to be read as 'by industry', then this resolution may provide authorities with a response to industry's reproach that pharmacies are allowed to produce medicines under much easier conditions than industry itself. This seems most relevant if we focus on large-scale preparation and external supply, which is some companies' business.

By merely stating that the pharmaceutical industry cannot always cover the needs of patients, EDQM avoids questioning the cause and the character of this insufficient coverage. Some causes I know of are the large investment in research and facilities needed to obtain

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