

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

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In My Opinion



The Council of Europe resolution on pharmacy preparation

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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

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. Editor-in-Chief, **EJHP Practice**

Professor Arnold G Vulto

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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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marketing authorisation, long-term planning of big pharmaceutical companies, focus on blockbusters and a rather complicated and rigid system for market authorisation. Another cause may be the costs of maintaining a local representative, for instance to carry out pharmacovigilance. Such costs weigh more heavily if the country or the patient group is relatively small. All these causes could be collected under the observation that the pharmaceutical industry is a commercial operation and needs appropriate regulations. The character of preparation in hospital pharmacies is by contrast one of great flexibility in answering every day's changing demands, mainly driven by health care as a goal and safeguarded by the caregiver's professionalism. Considering this flexibility as necessary to supplement the insufficient coverage, then it should be a basic principle of any regulation.

The resolution puts restrictions on large-scale pharmacy preparation, by calling good manufacturing practice (GMP) and product files the standard. This seems to be justified and represents a move towards a more level playing field with industry. Licensing pharmacies that supply externally and the requirement to establish notification of certain preparations and national inventories can also be justified. However, by including these requirements, the resolution creates a sort of shadow system which may reduce the drive to apply for marketing authorisation. I wonder if industry will be satisfied with this answer.

Whilst regulating preparation for large-scale external supply, the resolution at the same time tries to regulate all other pharmacy preparation activities. These extend from stock preparation to extemporaneous preparation for an individual patient and manipulating dosage forms and are even related to reconstitution on the ward. It is hardly surprising that those diverse tasks, which need flexibility as said above, are less easy to regulate. I do not think the resolution accomplishes this task well. I find it difficult to make a distinction between the different types and do not find a clear indication that the activities are put in the context of care.

However, I consider the risk assessments that are mentioned to be an indication that professional decisions are acknowledged. Risk assessments can be useful instruments to support professional decisions and to render them transparent for other parties involved. A risk analysis instead of detailed regulation enables the pharmacist to include many circumstances in his decision process, thus answering the need to be flexible in everyday care.

Risk assessments should, however, be performed with care. The type of method should match the risk or the process being analysed; experts warn against losing this relationship. The resolution proposes a risk assessment method, quantifies the results and couples them to a rather far-reaching decision: whether or not GMP should be applied. So it recommends one, even quantitative, method for all types of risk assessments necessary for pharmacy preparation. This seems to me tricky and its quantification even seems an error. Listing criteria for risk assessment may be relatively harmless, though it may suggest completeness. It probably suits large-scale

production but I think the other situations in pharmacy preparation need more consideration of patient and therapeutic criteria. Quantifying and coupling the result to whether or not (industrial) GMP should be applied is not substantiated by scientific evidence or logic. This method may possibly not reflect the risk of the actual situation. So if the outcome, for instance, is that GMP has to be implemented, it is far from sure that this diminishes the risk for the patient. Professional quality assurance of the pharmacy preparation might have been simpler overall advice. Maybe this overshadowing of expertise caused the irritation felt by the professionals at the EAHP Congress.

Does all this muttering mean that we could do without any sort of guidelines and just be professionals? Of course not—guidelines could be of great help to preparing pharmacists if they concentrated on basic qualities such as flexibility and patient care and effective risk management. Anyhow, I think that first of all, any process or situation that has to be managed by guidelines should be defined.

I guess there are different cases. The first is companies that avoid marketing authorisation by misusing the freedom of professional pharmacy preparation. To me this seems to be a problem for legal authorities and inspectors. The second is the concern of the Inspectorate for the quality of pharmacy preparation. As there are hardly any facts, this perceived problem must be based on theoretical considerations. Probably the mere creation of guidelines in every European country could reduce this concern. A very real third case is the need for a more intense exchange of knowledge between European preparing pharmacists. The pharmacists who attended the meetings [2, 3] that preceded the birth of the resolution already expressed this wish. I think EAHP could play a facilitating role with a follow up to the BEAM course of 2010 [1]. EAHP may try to improve the advice given by the resolution and relate risks not only to the product and the process but also to the situation of the patient, the therapy and the healthcare setting.

More exclamation and question marks can be put in the text of the resolution. But I would like to round off with a comment that the Europe of authorities seems to be much more united than the Europe of preparing hospital pharmacists. Or in other words, EAHP probably has also to professionalise its representation in official meetings and negotiations. This also includes support with modern ICT for informing its members and for getting feedback from them, thus preventing any splashdown of resolutions like the one I have tried to read now.

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