

the requirements of the EU Good Manufacturing Practice guidelines. Hence installations should be validated by a pharmaceutical company or regulatory specifications regarding this should be clearly established by national or European authorities. In addition, facilities should be available for proper quality control and supervised by a qualified person [3].

Therefore, there are several activities regarding the use of medicinal gases in hospital that should be considered in order to establish detailed procedures and clear responsibilities for their management [4, 5]. These include procurement, production, storage, dispensing and distribution, manipulation, supervision and quality control, as well as evaluation and selection of the different products by the Pharmacy and Therapeutics Committee. As this is a relatively new area for hospital pharmacy,

expertise has to be developed by appropriate training.

Guest Editor

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Survey on the involvement of hospital pharmacists in medicinal gases

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The survey was initially sent to 28 countries, 14 of which answered it; a response of 50%. Belgium contributed two completed questionnaires, making 15 responses. The countries that answered were Austria, Belgium, Czech Republic, Denmark, Finland, France, Hungary, The Netherlands, Norway, Poland, Portugal, Slovenia, Spain and Turkey. We have to realise that we are surveying a developing situation. Several countries reconsidered their statements when they reviewed this report.

Procurement, distribution and quality control of medicinal gases

In Belgium (one respondent), Czech Republic, Finland, France and Turkey, the pharmacy is completely responsible for procurement of medicinal gases; seven respondents said responsibility for procurement was shared with another department, while Denmark is not responsible for procurement. Other departments involved were typically maintenance, engineering, technical, supply or procu-

rement. The Netherlands specified that the pharmacy was 100% responsibility for the quality of gases supplied, while responsibility for availability is shared with other departments.

Gases licensed as medicinal products when supplied in bulk vary widely between countries. There is no comprehensive list of licensed medicinal gases in Norway, so it is hard to find out without looking every one up. Oxygen (O₂) is the only gas supplied in bulk in all countries, but is not considered a medicinal gas in Turkey and is considered a pharmaceutical raw ingredient in The Netherlands. Nitrogen, carbon dioxide (CO₂), nitrous oxide (N₂O) and air are licensed medicinal products supplied in bulk in several countries, while the only licensed medicinal gases supplied in bulk by Turkey were inhalational anaesthetics. CO₂ is licensed as bulk gas only in Belgium.

Supplied in cylinders, medicinal gases are generally considered licensed medi-

cines. In Norway, gases labelled and marketed for medicinal use are regarded as medicinal products and must have a marketing authorisation. So some oxygen or CO₂ products may be licensed medicines, but others not. Marketing authorisation is gradually being extended to all medicinal gases in Hungary. Denmark listed O₂, N₂O and for neonates, N₂O/O₂ mixtures. However some countries listed only a very few gases. Most countries only mentioned N₂O as an inhalational anaesthetic. Presumably other inhalational anaesthetics are not regarded as gases in most countries. It should be noted that when this survey was conducted in late 2009, new medicinal gases were receiving marketing authorisation, so we provide a snapshot of a constantly changing situation.

Belgium, Denmark, Finland, Hungary, Poland, Portugal and Spain listed several gases regarded as *medical devices* in their country. Examples are CO₂, O₂, mixtures of gases and gases used for oph-

thalmology purposes. Austria and Denmark were not sure, while in the rest gases are not considered medical devices. However procurement of this category is solely the responsibility of the pharmacy in Belgium and Finland, while Portugal shares responsibility with the Supply Department.

Question 5 asked specifically about quality control of bulk gases before distribution, when they are a medicinal raw material. Austria, Hungary, Poland, Slovenia and Spain indicated that quality was the responsibility of the manufacturer. However in Hungary the pharmacy checks the quality control (QC) documentation provided. Poland complained that there is no standard QC for bulk gases. In Belgium, Czech Republic, Finland, France, The Netherlands and Portugal, the pharmacy takes responsibility, while this is shared with the Technical Department in Turkey, and the Technical Department is responsible in Denmark (the Technical Department performs the checks, but the Pharmacy Department bears the responsibility for monitoring).

Regarding the quality control of bulk gases when they are administered, the pattern was similar with the Engineering Department responsible in Austria, Denmark, Norway, Slovenia and Spain; the pharmacy was responsible in the other countries except Poland.

Regarding the aspect of the distribution and tubing, the Technical or Engineering Department was responsible in Austria, Czech Republic, Denmark, Hungary, Poland, Slovenia and Spain. The pharmacy was responsible in Belgium, Finland, France, The Netherlands, and Portugal but usually delegating the work to the Engineering or Technical Department and reserving a monitoring role for itself. Practices vary between hospitals in Turkey.

Different connectors for different gases is a legal and/or professional requirement in all countries except Poland. The Poland correspondent stated that "Connectors for connection to respirators do not differ among different gases. But anaesthetic devices have connectors

which differ among different gases and are colour coded: CO₂ is colourless and medicinal oxygen, N₂O and air are marked in different colours". Hospital pharmacists in Poland are not responsible for devices such as respirators and anaesthetic devices.

Austria, Flanders (Belgium), Czech Republic, France, The Netherlands, Poland, Slovenia, Spain and Turkey all followed an ISO standard as formal audit after installation or any change to the gas transport system. In Wallonia (Belgium), Denmark and Finland, each hospital uses its own internal procedures. Portugal uses the Portuguese regulatory agency's standard. In Hungary the installation, reconstruction or any change to a gas transport system is inspected by the appropriate authorities.

Medicinal gases produced on site

In many hospitals medicinal gases are produced either by compression or by mixing oxygen, and nitrogen on site. Quality control and release has to be performed according to the specifications and methods of the European Pharmacopoeia. This survey asked, "Who is in charge of this?"

Denmark, France, Hungary, Norway, Poland and Portugal answered that either no gases, or only medicinal air, which is not considered a medicinal gas, are produced on site. They commented that many gases can be bought ready mixed. Polish hospitals do not produce any gases on site. The Norwegian correspondent remarked, "It is prohibited to produce medicinal gases on site in my hospital and I believe in all Norwegian hospitals." Likewise in Austria, Slovenia and Spain the pharmacy is not in charge of quality control of any gases produced. This left a minority of countries in which the Pharmacy Department, perhaps working with technicians from another department, is responsible for the quality of gases produced on site. Of these countries, Belgium, Czech Republic, Finland, The Netherlands and Turkey were also responsible for the equipment used for the production of medicinal gases produced on site. Other hospitals

said that another department (such as engineering) is responsible.

Clinical issues of medicinal gases

Question 12 asked whether medicinal gases formed part of hospital formularies and if so, are they assessed and selected by the Pharmacy and Therapeutics Committee? France said, "No. It is obvious we need O₂; NO₂, NO, N₂O/O₂; Air." Neither do Czech Republic, Denmark, Finland, Hungary (most hospitals) or the The Netherlands, control medicinal gases through this committee. However Poland reported that checking documentation, norms and requirements for medicinal gases are under the supervision of pharmacy. In Slovenia pharmacists are members of the committee that sets the criteria for purchasing gases that are licensed as a medicine (oxygen, nitrous oxide). In Austria and Portugal only new medicinal gases would be referred to the Pharmacy and Therapeutics committee. In Belgium, Spain and Turkey all medicinal gases are part of the hospital formulary.

Conclusion

In most European countries hospital pharmacists play an important role in the use of medicinal gases in hospitals, although activities and responsibilities differ between countries and even in the same country. As harmonised European legislation is already in place, uniform professional standards need to be promoted that clearly establish responsibilities and procedures. Moreover, as it is quite a new field, perhaps our scientific associations should be making hospital pharmacists and pharmacists in general more aware that a thorough knowledge of medicinal gases is required. We hope that this survey may shed light on the first steps on this path.

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