PROPOSING GUIDELINES FOR RESPONSIBLE PERSON ELIGIBILITY IN MALTA

Simon Corrieri, Anthony Serracino-Inglott
Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida

Corresponding author: Simon Corrieri
Email: simon.corrieri.08@um.edu.mt

ABSTRACT

OBJECTIVES To assess the current training and further education available to prospective Responsible Persons (RPs), to gather feedback from current RPs and industry stakeholders' experiences and to recommend guidelines on what training and experience prospective RPs should undergo to become eligible for the role.

METHOD A focus group was organised with key stakeholders from the industry including representatives from the Medicines Authority, University of Malta and the Central Procurement and Supplies Unit (CPSU). Feedback on individual experiences was gathered.

KEY FINDINGS The most common recommendation from the focus group was the emphasis on the importance of having practical experience relative to the size and complexity of the operation.

CONCLUSION Guidelines to be proposed for a framework on accepting RPs should consider experience supported by knowledge on obligations and duties to be fulfilled by the RP.

KEY WORDS Good Distribution Practice, Regulatory Affairs, Responsible Person Eligibility

Introduction

Article 79(b) of EU Directive 2001/83/EC states that the holder of a wholesale dealer's license in Europe is to have "a Qualified Person designated as responsible, meeting the conditions provided for by the legislation of the Member State concerned."[1] To comply with this directive the Maltese Law specifies that the Responsible Person (RP) has to be registered with the Pharmacy Council as a pharmacist and recognised as suitable by the Malta Medicines Authority (MA).[2] The MA does not interview prospective candidates to assess their competence and knowledge prior to recognising their role as RP. It currently recognises any registered pharmacist that is listed on the wholesale dealers license application form. Principles of Good Distribution Practice (GDP) require that RPs have experience and knowledge in areas related to distribution of medicines such as risk management, change and deviation control.[3]

Method

Legislation regarding eligibility for RPs in Europe was identified. The search yielded minimal results. Guidelines and recommendations from concerned organisations were assessed and relevant findings recorded. Non-European frameworks for countries where a mutual recognition agreement exists with the EU such as Canada and third countries were explored to gain an outside perspective on the subject. A focus group was carried out with stakeholders from the pharmaceutical industry. The group consisted of 6 participants representing pharmaceutical regulatory authorities, academia and the pharmaceutical industry. The questions asked aimed to gather current perception of the different stakeholders on the role of the RP, procedure for becoming a RP and the need for a RP. Challenges that RPs face and recommended training for RPs were also discussed.

There was agreement that experience was the most important asset required by a RP... This experience had to be relevant to the complexity of the activity involved

Results

There was agreement between the focus group participants that the RP is mandated to release medicines for distribution by ensuring that they have been stored and distributed in accordance with GDP guidelines. It was agreed that this can be done through establishment of an effective quality system that is relevant to the complexity of the distribution activity. RPs must be practical, knowledgeable and able to adapt to the exigencies of the company whilst being aware of their corporate social responsibility without compromising on product quality or integrity.

In the first question, the participants were asked to state what they understood by the term 'Responsible Person'. The current RPs described their current function as: ***"Releasing medicine for use, carrying out the registration process and monitoring, taking care of legal aspects involved and documentation keeping".*** Participants with less technical backgrounds focused on quality of medicines: ***"The person who is the gateway for medicinal products to be released on the markets following purchase from a manufacturer and wholesale dealer supplier ensuring that GDP guidelines are adhered to, safeguarding the integrity of the medicines".*** The representatives from the Medicines Authority made reference to the national and EU legal framework: ***"The Responsible Person is the person mandated by law to ascertain what the activities of a wholesaler are in line with the legal requirements and EU GDP guidelines. On a practical level the RP is the person to see that the products passing from the suppliers to the clients are safe and their quality has been maintained".***

There is a general consensus that the industry understands that the function of a RP is to release medicines for distribution and safeguarding quality of medicines throughout the supply chain through compliance with GDP guidelines. The group highlighted the legal responsibility of the RP and the authority this brings about in decisions regarding acceptance or rejection of goods.

The second question of the focus group asked the participants to describe the role of the RP. The answers were similar for all participants since they were aware of the role of the RP and where jurisdiction started and ended. It was understood that the RP is the key player in the supply chain and that the role takes over from the Qualified Person in the chain of responsibility. The role of an RP is to ensure compliance with GDP guidelines through use of an effective quality system. The third question of the focus group aimed to disclose challenges faced by RPs from aspects of the industry. Different feedback was given from each stakeholder. The established RP felt that the constant struggle between the lack of appreciation of the role of the RP and financial costs involved with compliance was the biggest challenge. A participant who was a newly appointed RP felt that the major challenge faced was the lack of resources available to provide support in improving knowledge. The stakeholder from the industry stated that the biggest challenge was the struggle faced trying to obtain and deliver the medicine quickly to the patient despite delays due to regulatory procedures. Another challenge faced was the costs with respect to GDP compliance. The regulator's perspective was more balanced as both sides of the story were laid out. There were compliance and financial pressures involving the RP and license holder.

The final question aimed to identify the expectations of the industry regarding the experience and background of the RP and their opinion in reaching the desired level of knowledge and experience. There was agreement that experience was the most important asset required by a RP. This experience had to be relevant to the complexity of the activity involved. Knowledge on basic and advanced concepts was deemed important but secondary to experience.

Discussion

Maltese Legislation dictates that the RP must be a pharmacist and must be deemed suitable by the Medicines Authority.[2] The RP who is nominated by the License Holder, must ensure that wholesale dealing activities are carried out in line with EU Guidelines of GDP. A company may have more than one RP who is nominated for the same license, in such cases all RPs would be equally responsible for the activities carried out by the company. The rationale behind the law choosing pharmacists as the sole eligible candidates for the role of RPs was that the pharmacy course adequately prepared pharmacists for the role. As regulations increased in complexity, there is a need for course updating. To tackle this problem, new credits and modules may be considered within the course and as refresher courses. Moreover from this study it transpired that the focus needs to be on experience.

Conclusion

Although having improperly trained or inexperienced RPs is a local problem, the consequences of an error committed by these individuals may have ramifications all over the European Community. The European Union relies heavily on its member states' controls to ensure that a single European market can be maintained in a safe and absolute manner. As the saying goes, "Experience is the best teacher" (Anon) and having experienced RPs is one way of mitigating the problems stated above. RPs are part of a team of individuals and are responsible for compliance. They have obligations to their employers and patients. This study has highlighted the importance of including experience within guidelines for criteria necessary to become an RP. More awareness is needed about the importance of the RP's role as prospective RPs need to be fully aware of the responsibility they are taking on, as well as the consequences of their actions. The industry needs to appreciate and support the RP in their work as without support the RP cannot function.

References

1. European Commission. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [Online]. Official Journal of the European Union 2001; L311/67 [cited 2016 Feb 02] Available from: URL: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf
2. Subsidiary legislation 458.37 Wholesale distribution and brokering of medicinal products and active substances regulations [Online]; 2012 [cited 2016 Feb 02]. Available from: URL: www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11275&l=1
3. European Commission. Information From European Union Institutions, Bodies, Offices And Agencies, European Commission Guidelines Of 5 November 2013 On Good Distribution Practice Of Medicinal Products For Human Use [Online]. Official Journal of the European Union 2013;C343/1 [cited 2016 Feb 02] Available from: URL: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF