Good Distribution Practice Guidelines

Luca Giudice, Francesca Wirth, Anthony Serracino Inglott, Lilian M. Azzopardi
Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta
email: luca.giudice.11@um.edu.mt

Department of Pharmacy

University of Malta

INTRODUCTION

An update of the European Union (EU) Guidelines on 'Good Distribution Practice (GDP) of medicinal products for human use' (2013/C 343/01) was published by the European Commission on November 5, 2013. [1]

Drug regulation serves to promote and secure public health and well being. Non-adherence to GDP guidelines may lead to an increase in unwanted adverse effects caused by medicines being of poor quality. [2]

AIMS

To examine GDP guidelines and investigate the effect of the recent revisions to the guidelines on the pharmaceutical scenario in Malta.

METHOD

The study was divided into 3 phases:

1) Extensive literature review covering the regulation of distribution of medicinal products in Europe, the United States, Australia and Japan was undertaken.
2) Review of the GDP guidelines, including a comparison between the previous[3] and revised[1] version of the guidelines were undertaken. Challenges faced during the implementation of these guidelines were identified.
3) Assessment of the effect of the revised guidelines on stakeholders in the regulatory sector. Semi-structured interviews with the Director Inspectorate and Enforcement Unit and with four inspectors at the Malta Medicines Authority, the regulatory body for medicinal products and pharmaceutical activities in Malta, were undertaken. A progressive focusing technique was used in to highlight points of interest.

RESULTS

The current GDP guidelines cover all areas of the pharmaceutical supply chain whereas the previous guidelines concentrated only on 'Personnel', 'Documentation', 'Premises and Equipment', 'Deliveries' and 'Returns'. Other differences between the previous and the revised guidelines are shown in Table 1.

Older version of GDP guidelines (94/C 63/03)	Revised version of GDP guidelines (2013/C 343/01)
No chapters	Divided into 11 chapters
Brief	Very detailed
No reference to Responsible Persons	Reference to Responsible Persons
Applicable to only part of the supply chain: Wholesale warehouses and finished product reaching the customer	Applicable to all parts of the supply chain: Raw materials, active pharmaceutial ingredients, intermediaries and finished product reaching the customer
No additional chapters	Additional chapters: Quality management, Operations, Outsourced activities, Transportation and Specific provisions for brokers
No risk assessment approach	Inclusion of risk assessment approach

Table 1: Comparing GDP guidelines 94/C 63/03 and 2013/C 343/01 [1] [3]

Challenges faced by stakeholders during the transition and implementation period of the revised guidelines include:

- Greater workload on Responsible Persons (RPs).
- Financial difficulties for small wholesalers to upgrade their IT systems to meet new demands.
- Areas of uncertainty such as measures to be taken to ensure appropriate diligence, no clear details on the acceptable duration for returning goods, as well as unclear requirements regarding transportation.

The main findings from the interviews were:

- All interviewees agreed that an update in the guidelines was necessary since the 1994 guidelines are not comprehensive for the level of complexity found in today's pharmaceutical scenario.
- 3 out of 5 persons interviewed agreed that more extensive training should be made available to RPs.
- 2 of the interviewees revealed that there are still some wholesalers encountering problems as regards supplier verification when the supply chain is complex.

CONCLUSION

The pharmaceutical industry has become progressively more complex over the past two decades due to increasing competition, resulting in a higher risk of falsified medicines entering the legal supply chain. These evolvements have led to a greater requirement for controls in the pharmaceutical industry and consequently revision of the GDP guidelines.

References

1) European Commission. Guidelines of 5th November 2013 on Good Distribution Practice of medicinal products for human use. (2013/C 343/01) [Online]. Official Journal of the European Union 2013 [cited 2016 Feb 15]. Available from:URL: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF
2) Rägo L, Santoso B. Chapter 6 - Drug regulation: History, present and future [Online]. In: van Boxtel CJ, Santoso B, Edwards IR, editors. Drugs benefits and risks: International textbook of clinical pharmacology. 2nd ed. The Netherlands: IOS Press and Uppsala Monitoring Centre; 2008: p. 65-76 [cited 2016 Feb 15]. Available from: URL: www.who.int/medicines/technical_briefing/tbs/Drug_Regulation_History_Present_Future.pdf
3) European Commission. Guidelines on Good Distribution Practice on Medicinal Products for Human Use. (94/C 63/03) [Online]. [cited 2016 Feb 15.] Available from:URL: http://ec.europa.eu/health/files/eudralex/vol-4/gdpguidelines1.pdf