Falsified Medicines Directive: Challenges Faced by Small Member States

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INTRODUCTION

Falsified medicines can be considered substandard in quality, formulation, labelling and/or without appropriate registration with the competent authority.[1]

The Falsified Medicines Directive (FMD) or Directive 2011/62/EU, which amended Directive 2001/83/EC, was implemented in February 2019 to decrease the use of falsified medicines.[2]

AIMS

The aim of the study is to gather perspectives of Maltese community pharmacists, Maltese wholesalers, National Medicines Verification Organizations (NMVO) and National Competent Authorities (NCA) related to the implementation of the Falsified Medicines Directive

METHOD

Three questionnaires were developed and validated: questionnaire 1 was intended for Maltese pharmacists working in community, questionnaire 2 was intended for medicinal product wholesalers of Malta, and questionnaire 3 was intended for National Medicines Verification Organization (NMVO) and National Competent Authority (NCA) of European Union member states, European Economic Area (EEA) and European Free Trade Association (EFTA).

RESULTS

Questionnaire 1: Forty-six out of 129 Maltese community pharmacists answered the questionnaire. The pharmacists (Figure 1) agreed that they are aware of falsified medicines on the market (n=44), the FMD, terms (n=35) and its components (n=40), and pharmacy staff are compliant with scanning and decommissioning procedures related to detection of falsified medicines (n=36).

Questionnaire 2: Sixteen out of 44 Maltese medicinal product wholesalers answered the questionnaire. The wholesalers (Figure 2) agree that they are aware of falsified medicines (n=13), the FMD, terms (n=14) and its components (n=16), aware of the importance of FMD and scanning (n=14), and are up-to-date with FMD updates (n=15).

Questionnaire 3: Nine NMVOs (Austria, Croatia, Finland, Poland, Iceland, Norway, Sweden, Luxembourg and Belgium) and 7 NCAs (Poland, Slovenia, Iceland, Latvia, Croatia, Malta and Estonia) from 29 countries within the European Union answered the questionnaire. Difficulties met during the FMD implementation process are summarized in Figure 3.

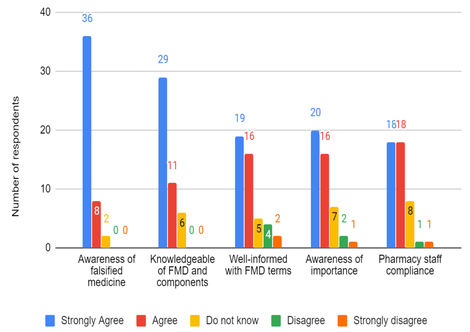

Figure 1. Pharmacist knowledge and preparedness of the FMD implementation (N=46)

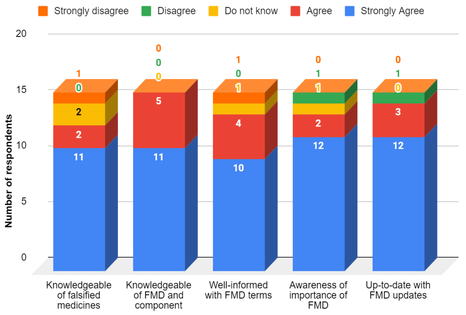

Figure 2. Knowledge and awareness of wholesalers with FMD (N=16)

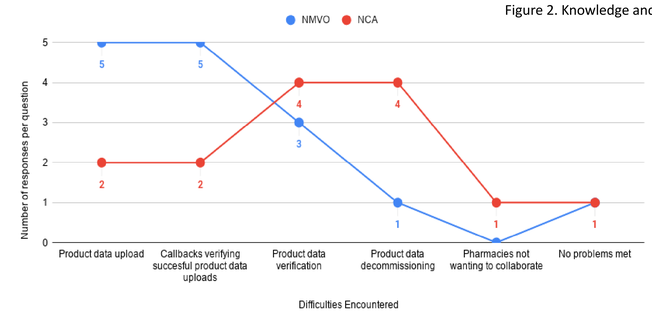

Figure 3. Summary of difficulties encountered by NMVOs and NCAs in using the repository system (N=16)

CONCLUSION

Community pharmacists and wholesalers in Malta are in line with the implementation process as required by the delegated regulation. The NMVOs and NCAs are in good communication with each other in terms of minimizing the risk of entry of falsified medicines in the market. The results gathered would be of use in improving the implementation standards of the country, contributing in understanding the daily processes of the FMD implementation, and enhancing patient healthcare outcomes.

REFERENCES

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