L-Università ta' Malta
Faculty of Medicine & Surgery
Department of Pharmacy

Crisis Preparedness and Management in Pharmaceutical Scenarios

Mireille Debono[1, 2], Maresca Attard Pizzuto[1], Anthony Serracino Inglott[1, 2]

[1]Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

[2]Malta Medicines Authority, San Ġwann, Malta

email: mireille.debono.15@um.edu.mt

INTRODUCTION

In the present context of increasingly complex and unpredictable pharmaceutical scenarios, the importance of implementing crisis preparedness and management strategies throughout the stages of the pharmaceutical supply chain (PSC) cannot be overstated.

AIMS

To investigate crisis scenarios in pharmaceutical distribution (PD) and community pharmacy (CP). Study objectives are i) crisis scenarios and crisis measure identification, ii) National Competent Authority (NCA) role evaluation and iii) development of crisis management strategies.

METHOD

Phase I: Focus Groups

- **2 Focus Groups (FGs)**

i. FGPD: Convened with 4 participants. Crisis preparedness and management in pharmaceutical distribution was discussed in FG I.

ii. FGPD: Convened with 6 participants. Crisis preparedness and management in community pharmacy practice was discussed in FG II.

Phase II: Questionnaires + Case Studies

- **2 Questionnaires (QPD and QCP)**

i. QPD: Pharmaceutical importation/ distribution setting.

ii. QCP: Community pharmacy setting.

iii. 1–5 scale used to rate probability and severity of crisis scenarios. Risk Priority Numbers (RPNs) were calculated by multiplying the average probability and severity ratings. Effectiveness and feasibility of crisis measures were rated on a 1–5 scale, and Mean Ratings (MRs) were determined.

- **6 Case Studies**

Phase III: Development and Validation of Crisis Strategies

- **2 Crisis Management Strategies**

i. Results obtained from the focus groups, questionnaires, and case studies were used to develop crisis management strategies for the pharmaceutical distribution and community pharmacy settings.

ii. Crisis scenario risk reassessment was carried out by an expert panel taking into consideration the application of the crisis management strategies.

RESULTS

Phase I: Focus group discussions (FGPD: N=4; FGCP: N=6) identified three main themes: (i) lessons from past crises, (ii) potential future crises and the effectiveness/feasibility of related measures, and (iii) the NCA's role in preparedness and management. Participants cited cost, operational constraints, and crisis unpredictability as barriers to effective implementation of crisis strategies.

Phase II: QPD participants (N=22) identified trade restrictions (RPN=13.53) and sudden regulatory changes (RPN=12.54) as the highest-risk scenarios. The most effective measures included procurement of therapeutic alternatives and communication with external entities (MR=4.2). Communication with external entities was rated as the most feasible crisis measure (MR=3.9). For sudden regulatory changes, collaboration with regulatory authorities was rated both effective (MR=4.3) and feasible (MR=4.2). QCP participants (N=47) rated critical medicine shortages (Mean RPN=14.43) and medication errors (RPN=12.30) as the highest risk crisis scenarios. Recommending alternative therapies was considered effective (MR=3.9) and feasible (MR=3.4) for shortages. For medication errors, retaining patient contact details was rated most effective (MR=4.1), while SOP development for dispensing was seen as most feasible (MR=3.7). (Figure 1).

Phase III: Crisis measures with MR≥3.0 were incorporated into the final strategies. Risk reassessment showed reduced RPNs for trade restrictions (7.68), sudden regulatory changes (3.60), critical medicine shortages (6.72), and medication errors (5.28).

Crisis Scenario	Crisis Mitigation Measures	Mean Effectiveness Rating	Mean Feasibility Rating
Supply chain disruption due to trade restrictions (Pharmaceutical Importation/ Distribution)	Maintenance of contingency stocks of critical medicines	4.0	3.3
	Supplier and manufacturing site diversification	4.1	3.3
	Early reporting of potential/actual medicine shortages to regulatory authorities	4.1	3.5
	Rationing of stock of scarce medicinal products amongst pharmacies	3.4	2.9
	Procurement of a therapeutic alternative product	4.2	3.5
	Implementation of export bans	3.5	2.9
	Domestic manufacturing of medicinal products	3.8	2.4
	Clear communication channels with regulatory/industry partners	4.2	3.9

Crisis Scenario	Crisis Mitigation Measures	Mean Effectiveness Rating	Mean Feasibility Rating
Critical medicine shortage (Community Pharmacy)	Rationing policy for distribution of scarce medicinal to patients	3.8	3.2
	Stockpiling of critical medicines	3.4	2.4
	Guidelines for collaboration with other Healthcare Professionals and recommendation of alternative therapies or medications	3.9	3.4

Figure 1: Crisis Measure Mean Effectiveness/Feasibility Ratings

CONCLUSION

This study provides a practical framework for crisis preparedness and management in pharmaceutical scenarios, offering effective and feasible crisis mitigation measures. The study demonstrated that implementing specific crisis preparedness and management strategies can potentially reduce risk in community pharmacy and pharmaceutical importation/distribution settings. High-risk areas, such as trade restrictions, remain, requiring ongoing attention.