



THE RISK MANAGEMENT OF THE PHARMACY PREPARATIONS IN THE HOSPITAL PHARMACIES



Adriana Durcanska

Hospital pharmacy, Teaching Hospital, Skalica, Slovakia

PC9021

What was done?

The quantitative risk assessment of the pharmacy preparations for stock in hospital pharmacies (HPs) in accordance with Resolution EDQM CM / Res (2016) 1;

- specify the decision criteria for the risk assessment;
- the risk management of the pharmacy preparations for stock in the country;
- to design a check list of the risk assessment for extempore preparations.

Why was it done?

The quality and safety standards of pharmacy preparations are not harmonised throughout Europe. They fall under the national competencies of individual European countries. The impact of application of the Resolution EDQM CM / Res (2016) 1 in HPs vs. introduction of GMP.



How was it done?

Out of the total number of 53 hospital pharmacies contacted, 5 pharmacies sent a suitable file.

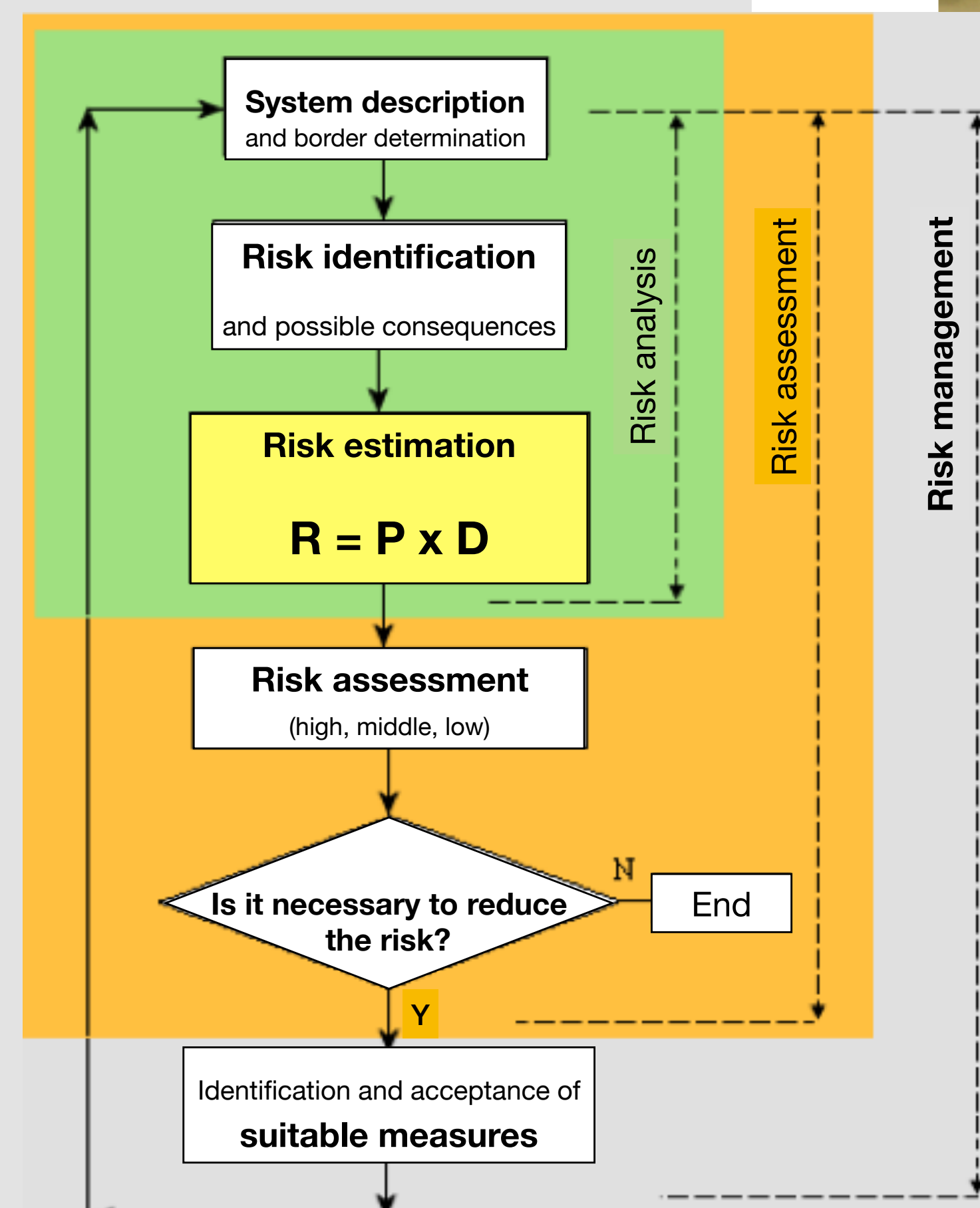
Table 1 - part List of preparations

Preparation	Package (g/pc)	Pieces (year)	Venena/ Separanda / Innoxia	Sterility	No therap. effect	Supply (Int/ Ext)	HP 1	HP 2	HP 3	HP 4	HP 5	HP 6
1 Cremor cum acido lactico	60,5	20	I			I	x					
3 Pasta cum olei icoris aselli	100	50	I			I	x					
	50	100	I							x		
	3000	15	I			I						x
8 Solutio argenti nitratis aquosa	10,1	10	S			I	x					
21 Coll. tetracaini 0.5%	10g	330	S	x		I		x				
60 Stylli phenobarbit. 0,01g	0,51	310	S			I		x				
80 Digoxini plv. 0,015mg	30	10	V			I					x	
152 Sol. formaldehydi 2%	1000	13	I		x				x			

Table 2 - part Specified decision criteria for risk analysis

Content of API	yes	no
1. Type of preparation/ dosage form		
parenteralia	5	0
inhalations, sterile dosage forms (ophthalmic preparations)	4	
enteral dosage forms	3	
topical preparations	1	
2. Volume of production per year (units)		
liquid dosage forms /kg, solid dosage forms (powders) /pcs of packages > 2000	5	
oral solid dosage forms /pcs > 120 000	5	
rectal dosage forms /pcs > 40 000	5	
topical dosage forms /g > 200 000	5	
ophthalmic dosage forms /g > 200	5	
3. Pharmacological effect of API		
venena	5	
separanda	3	
innoxia	1	
4. Process of preparation		
aseptic filling	5	
final sterilisation	4	
dissolution, mixing (not reconstitution), dilution	2	
filling (nonsterile medicines)	1	
5. Supply		
Externally	5	
I:E ≈ 1:2	4	
I:E ≈ 1:1	3	
I:E ≈ 2:1	2	
Internally	1	

Figure 1 Algorithm of risk assessment and risk management



What has been achieved?

A total of 170 types of medicines are being prepared in HPs. One HP had the result of the risk ≥ 100 when preparing ophthalmic medicines. Annex A is a check list designed to assess the risk of extempore preparations.

Table 3- part HP 2¹, HP 3², HP 6³

Preparation	API	Supply	Preparat. process	Dos. form	Pharmacolog. effect	Production volume	Result
Solutio iodi aquosa 100g ¹	1	1	2	1	3	1	6
Suppositoria metronidazoli 500,0 mg 100pcs ¹	1	1	2	3	3	1	18
Coll. tetracaini 0.05% ²	1	1	5	4	3	5	300
Supp. metronidazoli 500mg pro adultis (Massa A) ³	1	1	2	3	3	2	36

Annex A Request for individual preparation extempore

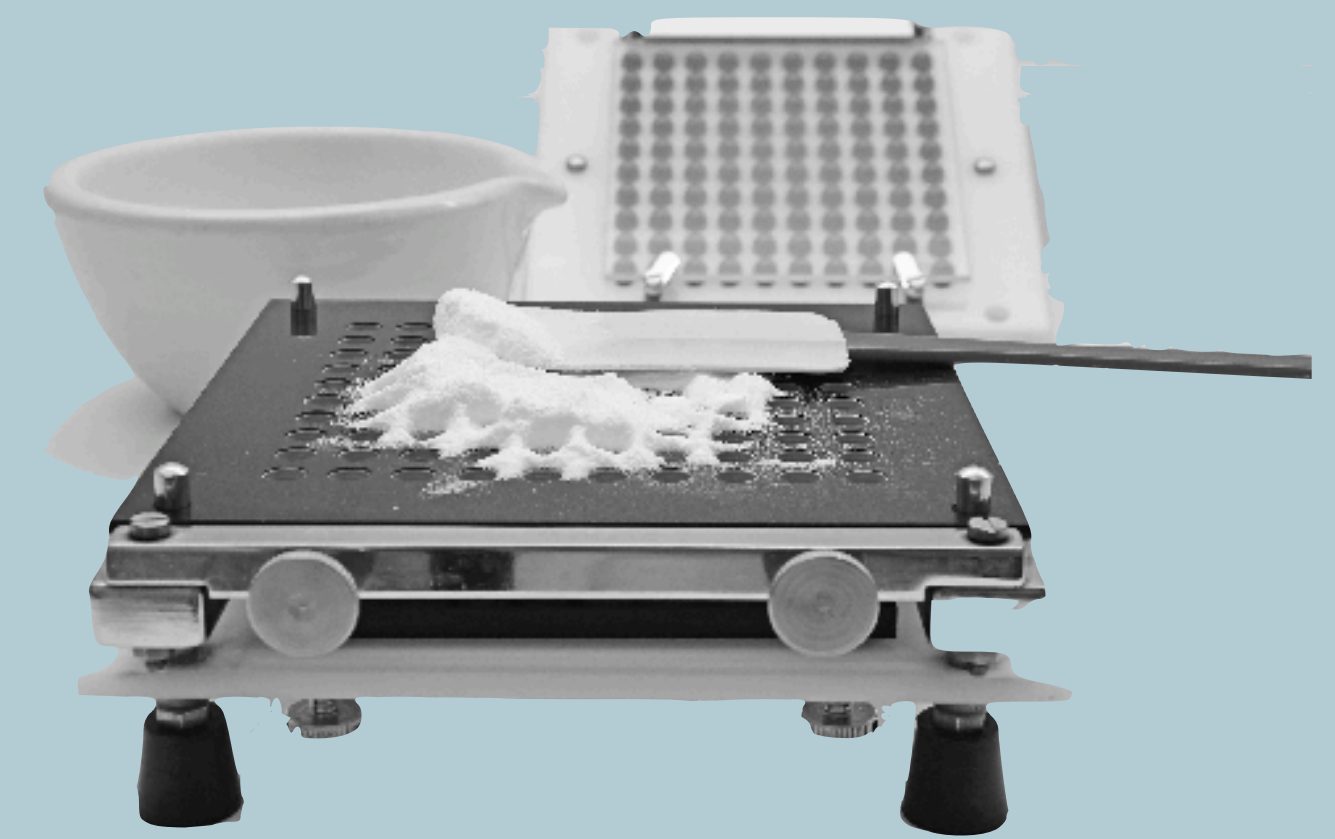


Table 2 - part Specified decision criteria for risk analysis

Figure 1 Algorithm of risk assessment and risk management



What next?

The aim of using the document is to be a guideline for hospital pharmacies of the country. The management is and will be forced to consider its introduction or to use another model: hospital - GMP / outsourcing / central pharmacy preparing and distributing.



<https://www.eahp.eu/gsis/risk-management-pharmacy-preparatio ns-hospital-pharmacies>

