Risk assessment forms for pharmacy preparation

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Objectives

To develop a risk management tool that enables the pharmacist to list and balance the benefits and risks of the clinical and pharmaceutical qualities of pharmacy preparations, such as referred to by the Ph Eur in their monograph Pharmaceutical Preparations [1].

Methods

- Process analysis of the handling of the requests for preparation, defining decisive steps, levels of evidence, individuals concerned and responsibilities.
- Definition of benefits, risks and levels of evidence.
- Incorporation of these items into a practicable form that shows the balancing of benefits and risks and the decisions.
- Discussions with pharmacists and inspectorate.

Results

Possible benefits

- Unique therapeutic value if there is no comparable authorised medicine available
- Improved patient-friendliness and therefore a better compliance to therapy
- Improved safety of health care processes (RTA, RTU)
- Improved health and safety of health care personnel
- Lower costs?

Possible risks

- Uncertainty about therapeutic safety and efficacy
- Design failure causing quality defects, like poor bioavailability or poor content uniformity
- Preparation risk: if the actual pharmaceutical quality system cannot guarantee that the preparation will fully meet specifications.
- Discouraging the authorisation of medicines?

Extemporaneous vs stock

The forms for extemporaneous and stock preparation use the same benefits and risks. With extemporaneous preparations the balance refers to an assignable patient. With stock preparations the balance results in the definition of the group of (anonymous) patients for whom, or care situation in which the benefits will outweigh the risks

Actions of attending pharmacist (form front) and preparing pharmacist (form back)

Clinical benefits and risks are assessed on the front of the form by the attending pharmacist, who decides if the request adds enough value to be considered further. On the back the preparatory pharmacist assesses the risks of design and preparation. He also checks the feasibility: if necessary conditions are met like availability of starting materials or sufficient control of the health and safety risk of the pharmacy personnel. Over-all the preparatory pharmacist decides:
In case of an extemporaneous preparation he accepts the request(or not).
In case of a stock preparation he decides on the conditions on which he will make this preparation available.

Discussion

Balancing benefits and risks (Figure 1) is not a matter of mathematics but of professionalism, responsibility and transparency. The forms therefore are transparent about the decisions and show who made them.
Future practical experience will be necessary to see if the forms indeed help

- pharmacists to be aware of and record their professional decisions
- patients and inspectorate to judge that process.

Stock preparation with its numerous items per batch and orientation to anonymous patients demands a more elaborate product information on clinical and pharmaceutical qualities, a higher level of evidence and a safer quality of design. The quantification of this 'more', higher' and 'safer' remains to be discussed between professionals, patients and Inspectorate.

Conclusions

The forms for extemporaneous and for a stock preparation support a transparent review of benefits and risks. They show decisions and responsibilities and make risk management testable.

References

1. Pharmaceutical preparations (2619), section Ethical considerations and guidance in the preparation of unlicensed pharmaceutical preparations. European Pharmacopoeia., 7th edition, supplement 7.7. Strasbourg: Council of Europe; 2012.

Extemporaneous (front)

Request for extemporaneous preparation

	Final formulation or action
☐ Availability as authorised medicine checked	
Patient (name, details):	
Name physician or GP, specialism, date, discussion:	
Indication:	
Standard therapy:	
Reason of request	
☐ Non-availability authorised medicine ☐ Unique therapeutic value ☐ Improvement patient-friendliness ☐ Improved health and safety health care personnel ☐ Different: ……	Comments / references / literature / attachments:
Level of consensus about evidence	
☐ National (authorisation, guidelines, consensus), that is: …….. ☐ Regional: …… ☐ Local: …….. ☐ Individual physician, GP, pharmacist: …… Experience with this therapy: ……	
Conclusion Request will (not)* be considered subsequently.	Assessed by attending pharmacist: …… (name, initials)

* delete where not applicable

Stock (back)

Design	
Design of formulation and of preparation process	☐ Analogous to …… ☐ From literature: …… ☐ Own design, based on: …… Attachment(s): ……
Is the design well-considered enough if balanced with the added value for the patient?	Yes / No* Comments:

Feasibility		
Starting materials available?	yes/no*	Comments:
Sufficiently stable for clinical use?	yes/no*	
Is the health and safety risk of the pharmacy personnel controllable?	yes/no*	
Other preconditions	yes/no*	
Another aspect: ……		
Conclusion: preparation is (not) feasible		

Decision about suitability for stock preparation	
☐ To prepare only for patients from the own pharmacy ☐ To prepare for patients nationwide ☐ No preparation: no well-considered design available ☐ No preparation: the preparation is valuable and the design is well-considered but the preparation is not feasible ☐ Other , ……	
Result discussed with:	…….. ……
Signature: Preparatory pharmacist (name, date, signature): ……	

* delete where not applicable

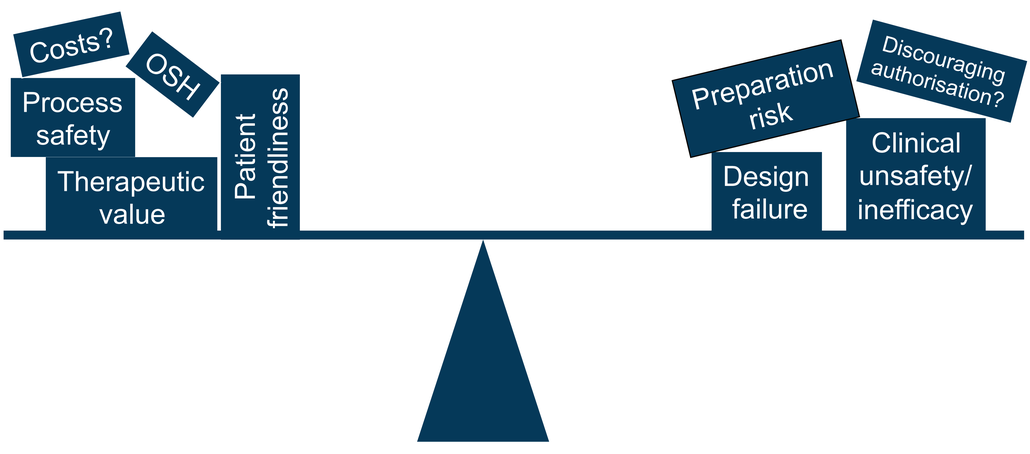

Figure 1 Balancing benefits and risks