Following our Ethical Compass: The importance of Risk Minimisation and implementation principles before commercialisation

Åsa Mattsson, Snr Director Patient Safety Risk Management (Process & Implementation)

Kristin Knalstad, Director Patient Safety Risk Management

09 Oct 2024

Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to AstraZeneca, its directors, officers, employees, volunteers, members, chapters, councils, Communities or affiliates, or any organization with which the presenter is employed or affiliated.

Agenda:
Risk Minimisation

Importance

Options and Limitations

Challenges

Before Commercialisation

We would love to hear from you!

Importance of risk minimisation

- Safety of the patient
- Public Health Impact
- Regulatory compliance
- Ethical responsibility

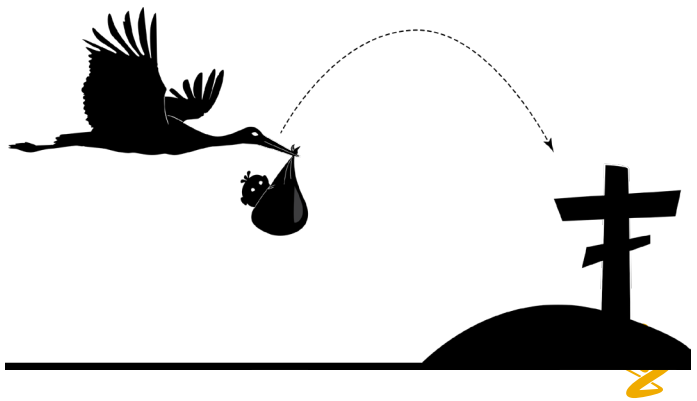
Ensuring that the benefits of a medicinal product exceed the risks by the greatest achievable margin and thus preserve access to medicines for patients.

Risk minimisation through the product lifecycle

Clinical development phase

Pre- authorisation phase

Post-authorisation/Product maintenance phase



Principles of RMM

- Raise awareness about the potential risk with relevant HCPs in order that the risk is managed appropriately.
- Enhance awareness of patients/caregivers on careful monitoring, early detection and steps to be taken.
- Must be effective
  - Should have clearly defined inteded outcomes
  - defined implementation pathway and should fit into already existing treatment framework for other medications, where relevant.
- Must NOT be burdensome to HCPs or patients:
  - … and therefore should fit into local standard practice and healthcare systems.
- Must be proportionate to the risk
- Appropriate interactions between stakeholders (HA, HCP and patient representatives)
- Non-promotional nature or elements

Reference: GVP XVI R3

Risk minimisation options and limitations

Routine	Additional	
• SmPC • Package leaflet • Labelling • Pack size • Legal status	Educational/safety advice tools • Guides • Checklists • Forms • Patient Cards • Patient diary	Risk minimisation control tools

Increasing risk/increasing intervention

Limitiations
- Reactive approach
- Reliance on HCP
- Dissemination challenges
- Local regulatory interpretation and implementation

Reference: GVP XVI R3

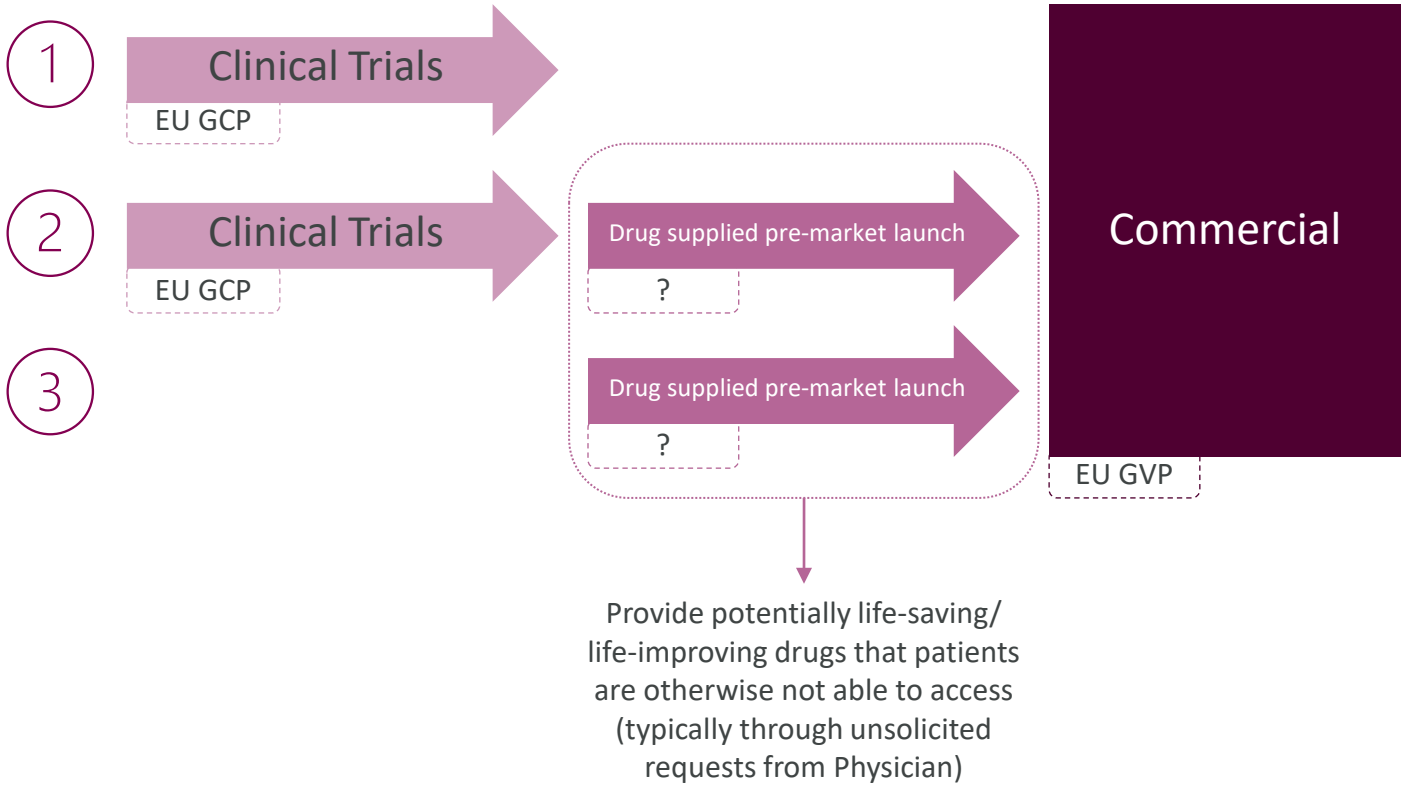
Global aRMM strategy and implementation challenges

- Engagement with Healthcare professionals and Patient representatives
- Digital tools challenges
- Maintaining consistency of central strategy whilst complying with differing country specific legislation
- Complex regulator landscape and local implementation
- Compliance and oversight

Objective: Protecting patients in an effective and appropriate way

Risk Minimisation before Commercialisation

Patient Journey prior to commercial (post-marketing) use



Gaps and Challenges

- Limited regulations and guidance, and what is available is generally not harmonised between countries
- Arguably more important to implement appropriate risk minimisation measures in the pre-commercial stage, as the prescribers may have less experience and knowledge of the product
- Nomenclature and definitions vary between countries and companies

Navigating through the jungle of nomenclatures and definitions

Risks remain the same regardless of how & when drug is supplied

Topic submitted through PV net Scientific Community and selected for discussion in the Sep 2023 meeting[1]

Confirmed inconsistencies:

- Nomenclature and definitions vary between companies (n=13)
  - *None of the programme types were used by all 13 companies*
- For drugs with aRMM in the RMP, only 3 companies responded that they provide aRMM (or equivalent safeguards) in supply prior to commercialisation
  - *The majority did not answer this specific question – indication that this need has not been considered? (n=6)*

[1]Reference: Navitas Life Sciences, PV Scientific Community, Bi-monthly Call – 19 September 2023:
Q1. What is the extent of the 'managed access' programmes you have in place? (n=13)
Q4. For medicinal product with aRMM in the RMP, do you provide aRMM to managed access programmes? (n=6)

Patient Safety Introduced a new overarching term: Managed Access

An umbrella term to encompass all mechanisms by which product is made available to patients prior to approval or commercial use

Established principles for risk minimisation in Managed Access

If aRMM is included in the **Core RMP (pre-approval)**, or the **approved RMP (pre-marketing)**, aRMM equivalent safeguards should be implemented in Managed Access mechanisms

Principles & Process for aRMM equivalent safeguards in Managed Access embedded in our procedural framework:

- Cross-functional collaboration
- Company-wide Standard
- Flow chart to determine when aRMM equivalent safeguards should be implemented
- Training, training, training !!!!

We would love to hear from you!

How are risks minimised in Managed Access mechanisms in your company?

Future harmonisation?

Questions?