SIG

Measuring impact of pharmacovigilance activities

Mandate

Develop methods for modeling health outcomes of pharmacovigilance activities, based on epidemiological parameters and identification of relevant data sources

- This includes recommendations on methods and the identification of areas for further development

- Modeling in this context includes measuring and evaluating the outcome of pharmacovigilance activities to predict the harm that can be avoided.

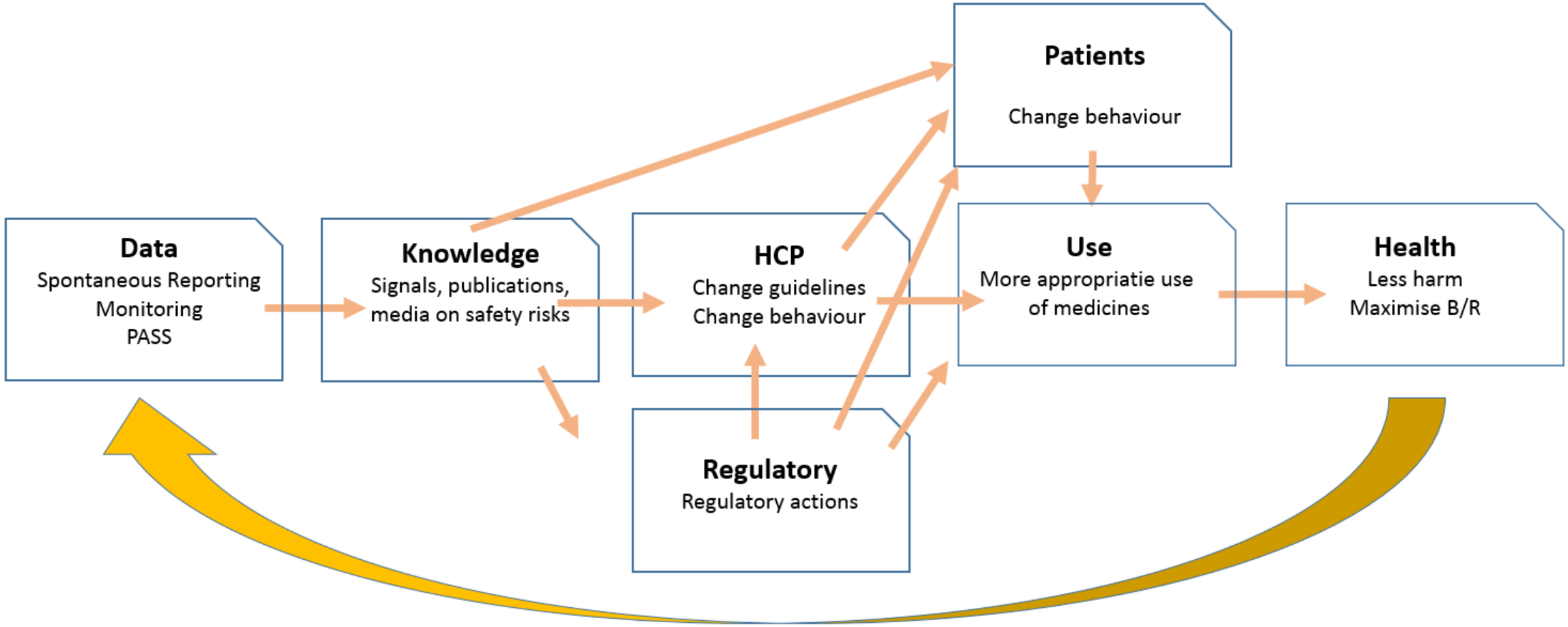
- The recommendations can give input for the revision of ENCePP Guide on Methodological Standards in Pharmacoepidemiology

Start with deliverables

1. Inventory of pharmacovigilance activities to be taken into account for impact measurement, including a description why these activities have been chosen

2. Review of methodologies of studies measuring the effectiveness of risk minimization measures included in the EU PAS Register (only those with published protocol and results) and a reflection on methodological limitations and gaps

Scheme of the pathways of PV

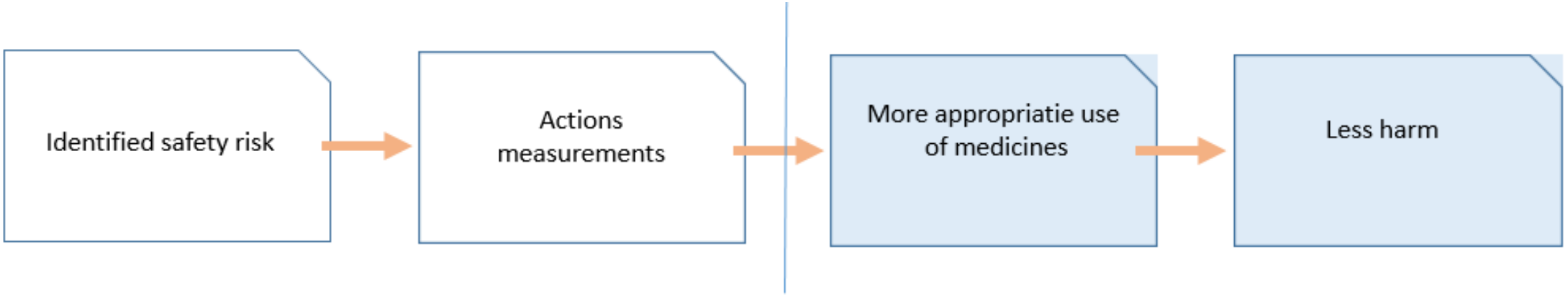


Considerations

- PV activities are to some extend intertwined
- PV activities can be complementary
- Measure the outcomes of each link in the PV pathway separately is difficult
- Knowledge on safety of medicines has a broad possible usefulness in clinical practice
- It is difficult to measure many of these positive and useful PV activities and their impact on health, and for some even impossible
- If we want to measure impact of PV activities, the best approach is to focus on identified safety risk with high public health burden and/or those for which there is potential in reducing harm

Focus on

- suspension /withdrawal of a medicine
- restriction of the indication
- patient screening for groups at risk
- contra-indications
- prevention of drug interactions
- pregnancy prevention plans
- prevention of drug interactions-additional risk minimisation e.g. educational material



Although it is preferable to measure the reduction of harm, it will not always be possible.

Measuring the effect on more appropriate use of medicines is a good indicator. Because identified risks outcomes are already based on the PV scientific knowledge, harm reduction is to be expected, and might be predicted.

Next steps

1. Perform a search of the EU PAS register for studies measuring the impact of pharmacovigilance activities to look at the methodologies used and identify gaps in the knowledge base
2. Perform a literature review on pre-specified examples of an identified safety risk where regulatory actions have been taken to look at the methodologies used and identify gaps in the knowledge base. Evaluate how well the available information fits the pathways
3. Review of the methodologies of studies measuring the effectiveness of RMM
4. Develop methods for modeling health outcomes of pharmacovigilance activities, based on epidemiological parameters and identification of relevant data sources.