European Federation of Pharmaceutical Industries and Associations

How can pharmaceutical industry contribute to measuring impact?

Session 5: Way forward and next steps

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Presentation

About EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing &bringing to patients new medicines that will improve health and the quality of life around the world

Our Vision

"We support a vision of outcomes-driven, sustainable healthcare systems in Europe. **We want systems that provide patients with equal and early access to the best and safest medicines; that support innovation while balancing realistically benefit and risk**; that empowers citizens to make informed decisions about their health and ensure the highest security of the medicines supply chain. Such a vision will also assist policymakers in sustaining Europe's economic growth and competitiveness, by balancing healthcare budgets and helping to provide for a healthy and productive workforce. It also offers the most effective approach to deliver the innovative medicines needed to tackle current and potential health threats."

How can the industry contribute?

- **Key principles/ thoughts from EFPIA members**
  - Need to first establish “what does success look like?”
  - Play to industry strengths
    - Manage many projects, so used to defining success factors and data gathering and can help with methodology
    - Plan/ Roadmap to success needed – industry involved throughout
  - Use existing data (KPIs, KQIs) where possible to reduce burden and facilitate multi-stakeholder data sharing
  - Be realistic about what industry can contribute as one of several stakeholders

Outline of presentation – Align with PRAC strategy

1. Effectiveness of risk minimisation actions
2. Effectiveness of specific PV processes – requirements / framework
3. Enablers of effective PV including stakeholder trust and engagement - enablers (now)
4. Method identification and development – and future view

1. Effectiveness of risk minimisation actions (1/3)

- *Systematically compile results of effectiveness of risk minimisation studies performed by companies to understand*
  - *Types of data collection, study designs and evaluation methods, criteria to design successful risk minimisation, effects of different types of risk minimisation efforts*
- These data should already exist as MAHs are required to submit information on measurement of effectiveness to EMA or Member States
- Can this information be collated and looked at in aggregate across the categories for key themes and identification of areas worthy of further information gathering
- Data should inform next steps including Plan/ Roadmap. Further targeted questions could be asked of industry e.g.
  - Brief examples of risk minimisation activities, good and bad experiences?
  - What were the challenges in development, set up, performing? Joint studies? Generics?
  - Did/ does it work well or not?
  - If not, why not?
  - Any learnings?

1. Effectiveness of risk minimisation actions - Thoughts on shift from risk to benefit risk (2/3)

- The PV legislation shifted focus from risk to benefit-risk (BR), with multiple BR documents/activities

- Industry could provide feedback – likely to be more qualitative than quantitative
  - Has this shift to on-going BR monitoring had a positive impact?
  - Is there evidence for this?
  - Is there information missing to determine whether impact has been positive?
  - Have there been any withdrawals?
  - Can industry collaborate to generate consistent evidence, can EMA/ NCA contribute?

Effectiveness of risk minimisation actions - Thoughts on shift from risk to benefit risk (3/3)

- Could targeted studies be used to look at particular issues that would allow learning to be extrapolated?
  - For example US Federal Interagency Steering Committee for Adverse Drug Events proposal to assess progress on the National Action Plan for Adverse Drug Event Prevention (ADE Action Plan)
- Can we learn from other countries/areas e.g. US?
  - Ongoing work to standardise REMS tools & assessments?

2. Effectiveness of specific PV processes – requirements/ framework

- *Strategy focuses on PV processes e.g. spontaneous reports, signal detection, signal management*
  - *No current systematic way to measure*
  - *e.g. time to identify a new risk, time from identification to action*
  - *Study of different processes in PV will support continuous improvement*

- All companies will routinely collect KPIs, KQIs internally on PV processes as part of quality system requirements
- Currently no data are collected across the industry
- EFPIA members propose that a 3rd party could be used to collect and collate data across companies and trends, standards, resource implications and best practice could be identified and shared
- Industry could propose topic areas and meaningful data for collection
- Intention would not be for all companies to participate but all types of company should be represented e.g. large & small, generics, vaccines, consumer products etc.

3. Enablers of effective PV

including stakeholder trust & engagement

- *Engagement and trust of patients and HCPs in medicines regulation*
  - *Data on key stakeholder response to risk minimisation need to identify concerns or misunderstandings*
- Transparency is key to success
  - Monitor number of hits of key publically available documents?
- Important here for efforts to be coordinated to avoid HCPs and patients being bombarded with surveys from all stakeholders
- Greater collaboration within industry could be helpful but not always easy. Examples
  - Bisphosphonates & osteonecrosis of the jaw?
  - Hepatitis C treatment and Hepatitis B reactivation?
  - Methylphenidate RMP
- Identify barriers to industry collaboration – can 'non-competitive' safety information be defined?
  - Sharing of label and RMP updates for generic products?
  - US ANDAA draft rule

4. Method identification and development – future view (1/3)

- *No current accepted methods for measuring how PV activities translate into health outcomes*
  - *Further method identification and development for impact studies needed*
  - *Methods for modelling health impact of PV decisions based on epi parameters will be explored*
  - *Key sources EHRs, drug utilisation data, patient registries*

- Since introduction of new PV legislation there has been very beneficial collaboration between industry and EU Regulators e.g. GVP Module V and MLM discussions
  - Industry platform meetings allowing issue to be raised and addressed through dialogue – this should continue

4. Method identification and development – future view (2/3)

- Industry would like to be at the table to contribute to design and methodology of proposed impact studies

- PV legislation has an emphasis on the Quality System
  - Has there been positive impact?
  - Is this something we should measure?
  - If so, how can this be measured? Is there an opportunity for industry to work with regulatory authority inspectorates to identify and communicate best practices
    - Inspectorates hold wealth of information but only findings shared not best practices

4. Method identification and development – future view (3/3)

- Standardisation and robust methodology is needed, items from chapter 5 of the Escher report* to be considered, in particular:

1. **What is measured**:

   E.g. activities in a process, e.g. case processing, resources required, e.g. costs of case processing, outputs e.g. number of cases in a time period and outcomes – societal benefits as a result e.g. averted morbidity/ mortality

2. **Baseline** – or how to determine a surrogate: literature, pre legislation, other country?
3. **Actual impact**: compliance is not impact, but what do you measure and when should you measure it? How is an SmPC update linked to health benefits?
4. **Success**: defined ideally before an instrument is implemented
5. **Data** required is fragmented across stakeholders – more sharing/ transparency needed
6. **In addition**: independent platform, all stakeholders engaged and with equal weight

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Thank you!