Signal Management – Industry viewpoint

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   - Administrative burden
   - Regulatory action triggered by PSURs
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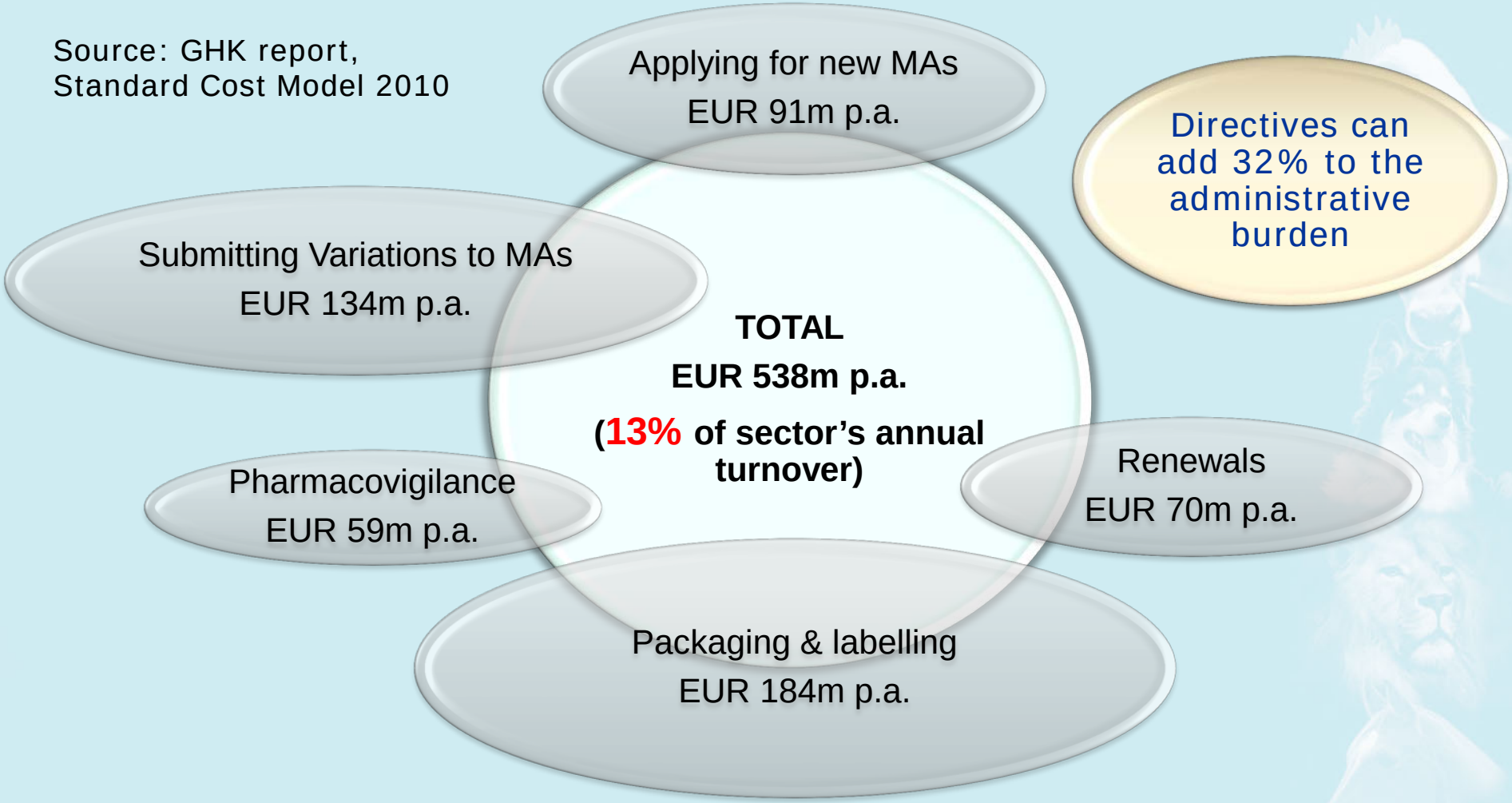
1. Experience

Administrative burden is fast growing

- EPEC/GHK Impact assessment data 2010
- What's missing in the 2010 data?
- Administrative burden 2015

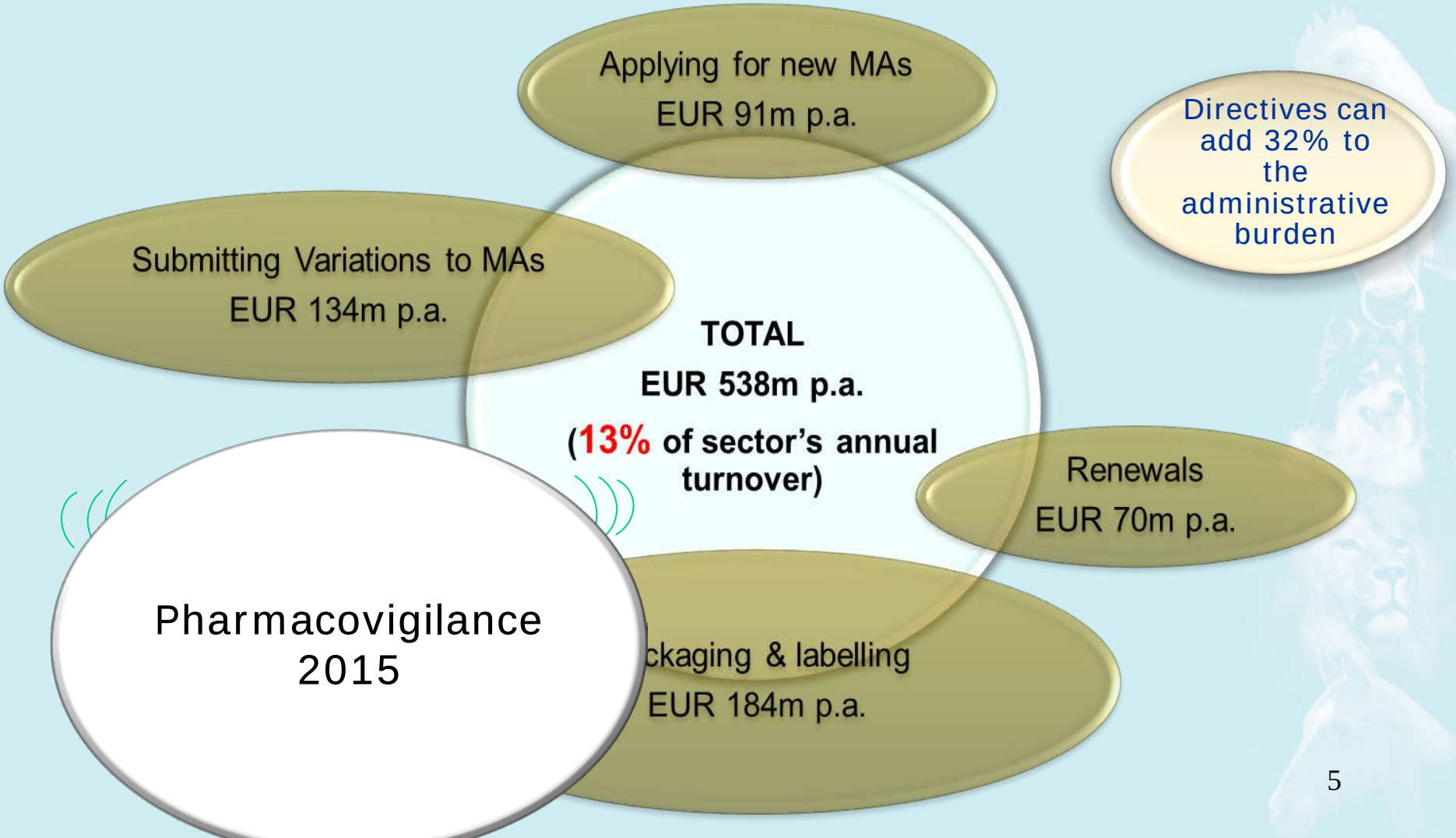
EPEC/GHK Impact assessment data 2010 – Administrative burden

Source: GHK report,
Standard Cost Model 2010



MA = Marketing Authorisation

EPEC/GHK Impact assessment data 2015 – Administrative burden



EPEC/GHK Impact assessment data 2010 – what's missing? 1/2

Included in the calculation (Standard Cost Model - SCM):

- AE reporting
- Serious AE reporting
- PSURs
- For 300 companies and using the same cost/hour

What's missing?

- **PhV Data-base -** substantial costs for:
  - set up
  - validation
  - maintenance
  - updates for new requirements/tools (e.g. statistical tools for signal management)
  - Capacity for increased numbers of cases
    - increased reporting
      - VMD (UK) reports a doubling of volumes
      - Time spent by company personnel (field reps and technical services staff)
    - increasing geographical scope, new country requirements
  - Either
    - full time internal IT support or
    - user-license fees and maintenance fees
  - Increased PhV resource requirement
  - Access to literature databases

EPEC/GHK Impact assessment data 2010 – what's missing? 2/2

More…

- **Activities**
  - Inspections and audits – costs of personnel, time, flights/hotels etc for auditors
  - Training: cost and time for QPPV and staff
  - Increased PhV resources requirement
- **Documentation**
  - Written Procedures: Detailed Description of Pharmacovigilance System (DDPS)/SOPs/Forms/etc.
  - Contracts: PhV exchange agreements with distributors etc.
- **Costs**
  - Change of Qualified Person PhV (QPPV) or DDPS – Variations
  - Accounts staff – payment of invoices

IFAH-Europe impact assessment data package, estimated 2010

Summary of days per annum (& FTEs) attributed to pharmacovigilance tasks

Main task	Estimated total days per year
1. Detailed description of the pharmacovigilance system	48
2. DB management	120
3. Inspections	30
4. Case handling (AE and serious AE)	250
5. Prepare PSURs	500 (50 PSURs)
Total days p.a. (FTEs)	**948 (4.3)**
Cost for average company	**€803,000**
Cost for 300 companies	**€240 million**

Nearly 50% of SCM*

It is urgent to tackle this together and cut this figure down!

*Standard Cost Model

1. Experience

Very small % of PSURs lead to regulatory action

- Only 6% for CP
- Overall <<6% and probably <1%

i.e. >99% of PSURs are generated and assessed without triggering regulatory action

1. Experience

- Experience from Human sector:

→ Signal detection and PSURs systems in parallel is huge burden

2. Objectives of the new legislation for VMPs

Objectives of the new legislation

- Reduce administrative burden
- Efficient and effective system

→ Will bring benefits for both MAHs and Authorities

Proposal from the Commission

- Move from routine PSURs(*) to Signal *Management*

→ Industry is very supportive

→ Big concern from Authorities on reporting in the future but Signal Management includes reporting (see next slide)

Note:

(*) P stands for periodic

3. Signal Management

What is Signal Management?

Signal Management is a system covering:

- Signal detection
- Signal validation
- Signal confirmation
- Signal analysis and prioritisation
- Signal assessment
- Actions
- *Reporting*

→ Reporting yes but Risk-based reporting!

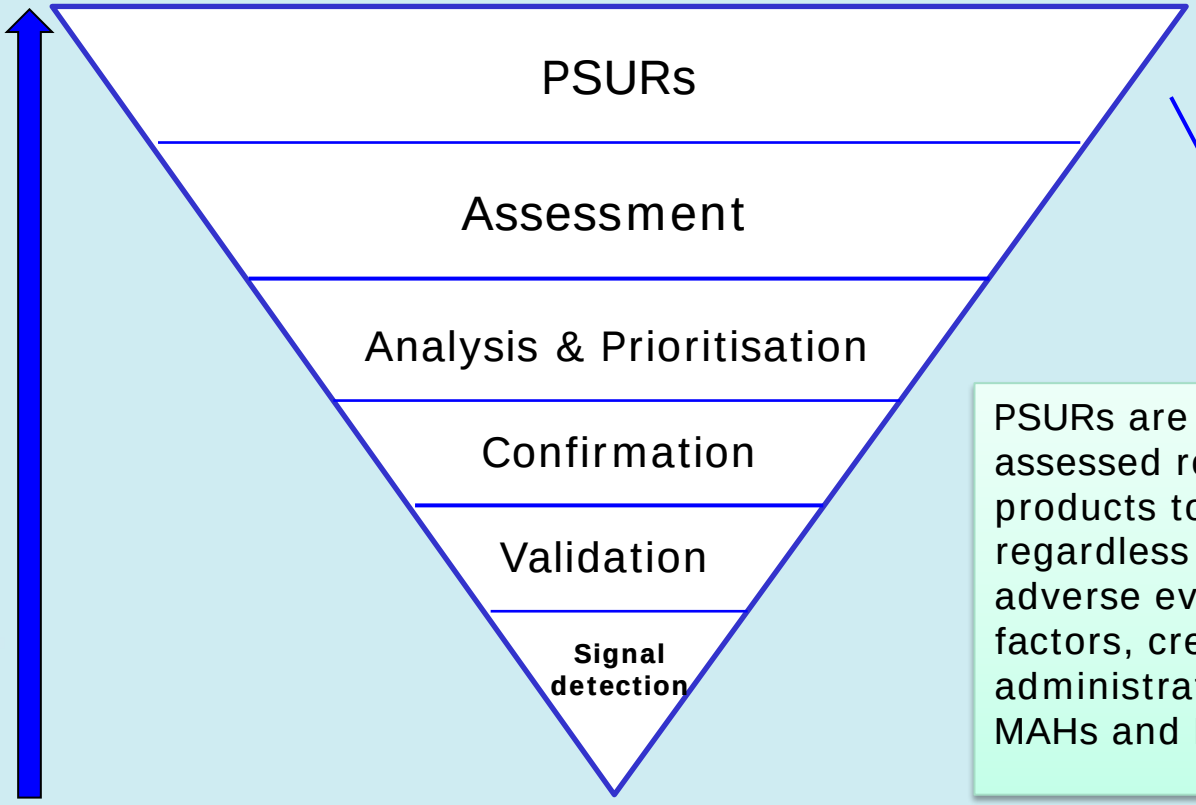
4. Future vision

FUTURE VISION

- Future Regulation: high level – no details
- Details in the implementing acts
- Change of emphasis:
  - Signal Management system
    - ✓ Risk-based evaluation
    - ✓ Risk-based reporting

Change of emphasis

TODAY: periodic reporting = significant administrative burden & not targeted approach

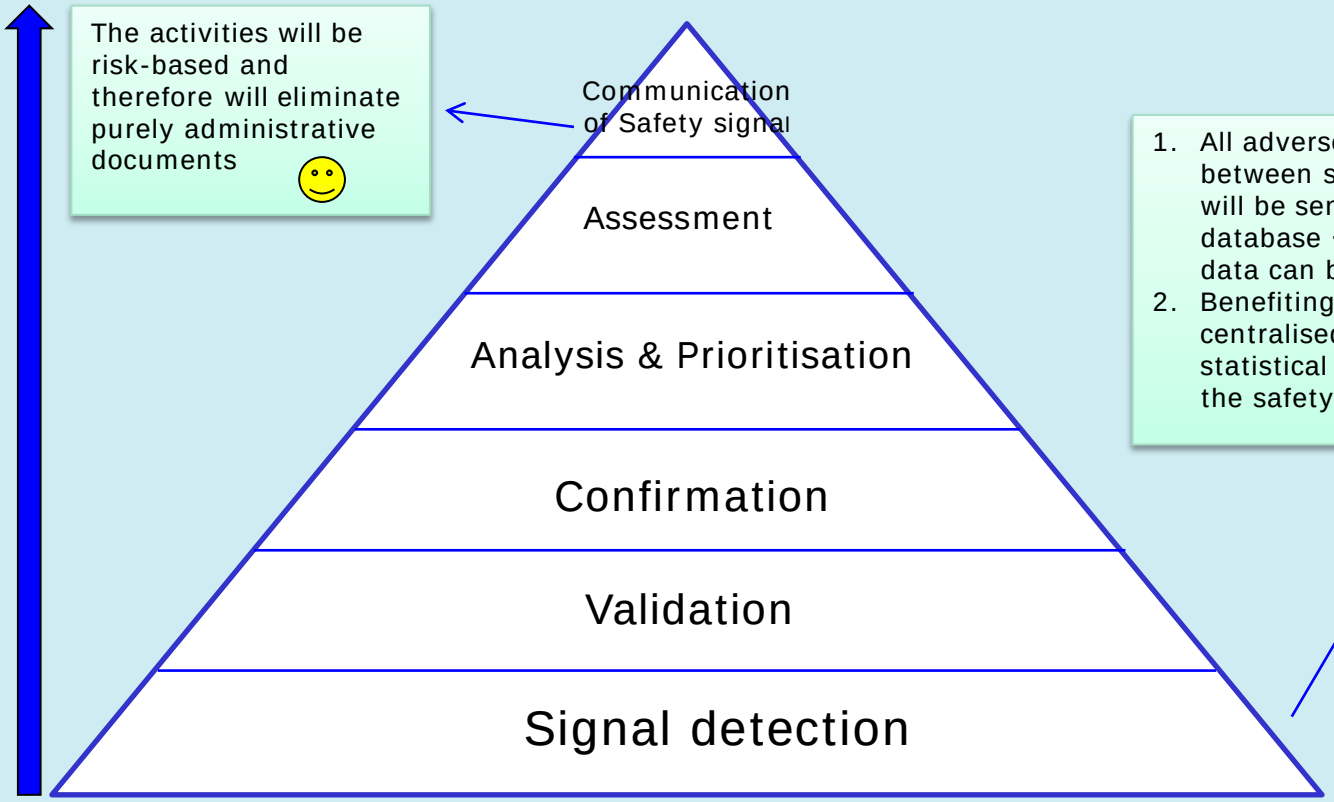


PSURs are produced and assessed routinely for all products to the same cycle regardless of sales, number of adverse events or other risk factors, creating a significant administrative burden on both MAHs and Regulators.

Change of emphasis

TOMORROW: Signal management process = RISK – BASED surveillance*

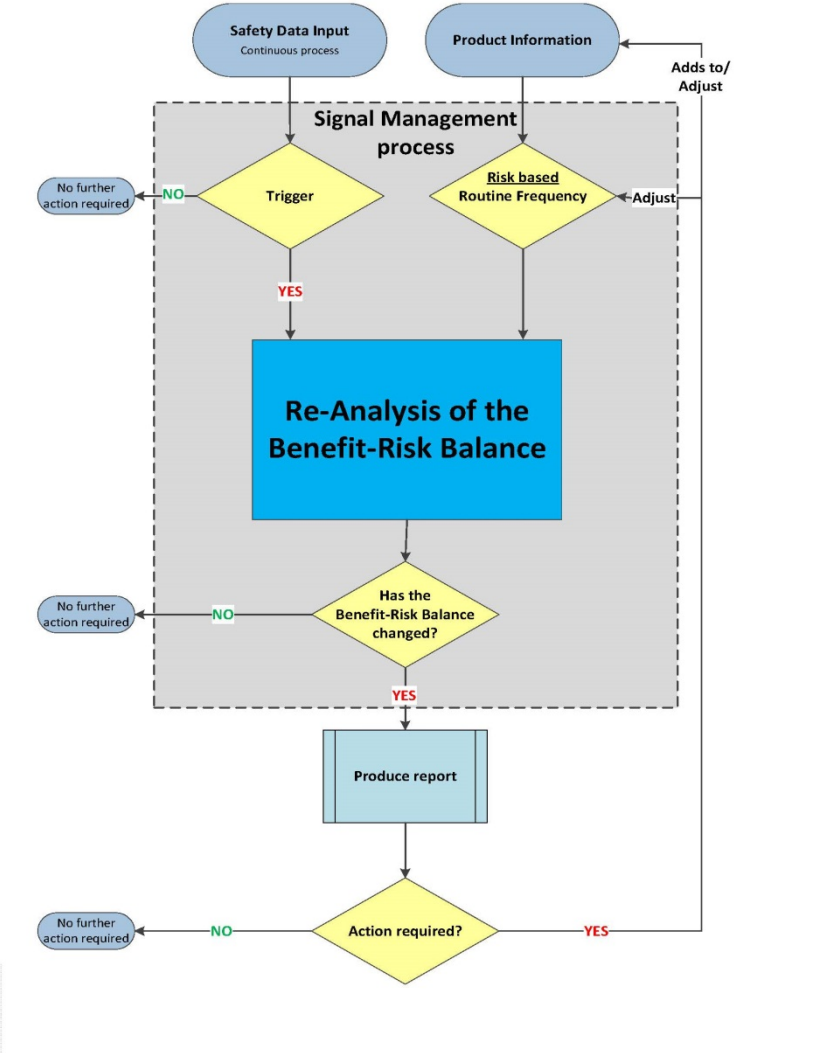
The activities will be risk-based and therefore will eliminate purely administrative documents



1. All adverse events (no distinction between serious and non-serious) will be sent to a single Union database → increased volume of data can be analysed.
2. Benefiting from the availability of centralised data → more accurate statistical analysis which will improve the safety of medicines

*The adoption of risk-based surveillance will result in efficient utilisation of limited PhV resources of both regulators and MAHs while at the same time increasing focus on areas where significant changes in benefit-risk balance are most likely to occur. Hence, facilitating most rapid/effective mitigation of significant risks.

4. Future vision



4. Future vision

Industry supports:

- Risk-based; focussed; no administrative reporting
- Single EU PhV database
  - ✓ one point of data entry; (no national databases)
- Signal management process
  - ✓ Signal detection, follow-up
  - ✓ Risk-based evaluation
  - ✓ Risk-based reporting

Industry does not want:

- Signal management + other systems running in parallel

5. Proposals

What is needed?

- COM proposal: Dialogue with MAH during signalling and trending and before action is taken → WIN-WIN

- Work together on developing the future system to ensure
  - Minimisation of administrative burden
  - needs of all stakeholders are addressed
  - all opportunities for increased efficiency are taken
  - can evolve with new technologies/approaches

  → WIN-WIN
- Retain compatibility with VICH / global PhV vision
  - Definitions – need for global harmonisation
  - Open regulatory framework

Europe IFAH
Representing the European Animal Health Industry

Thank you for your attention!