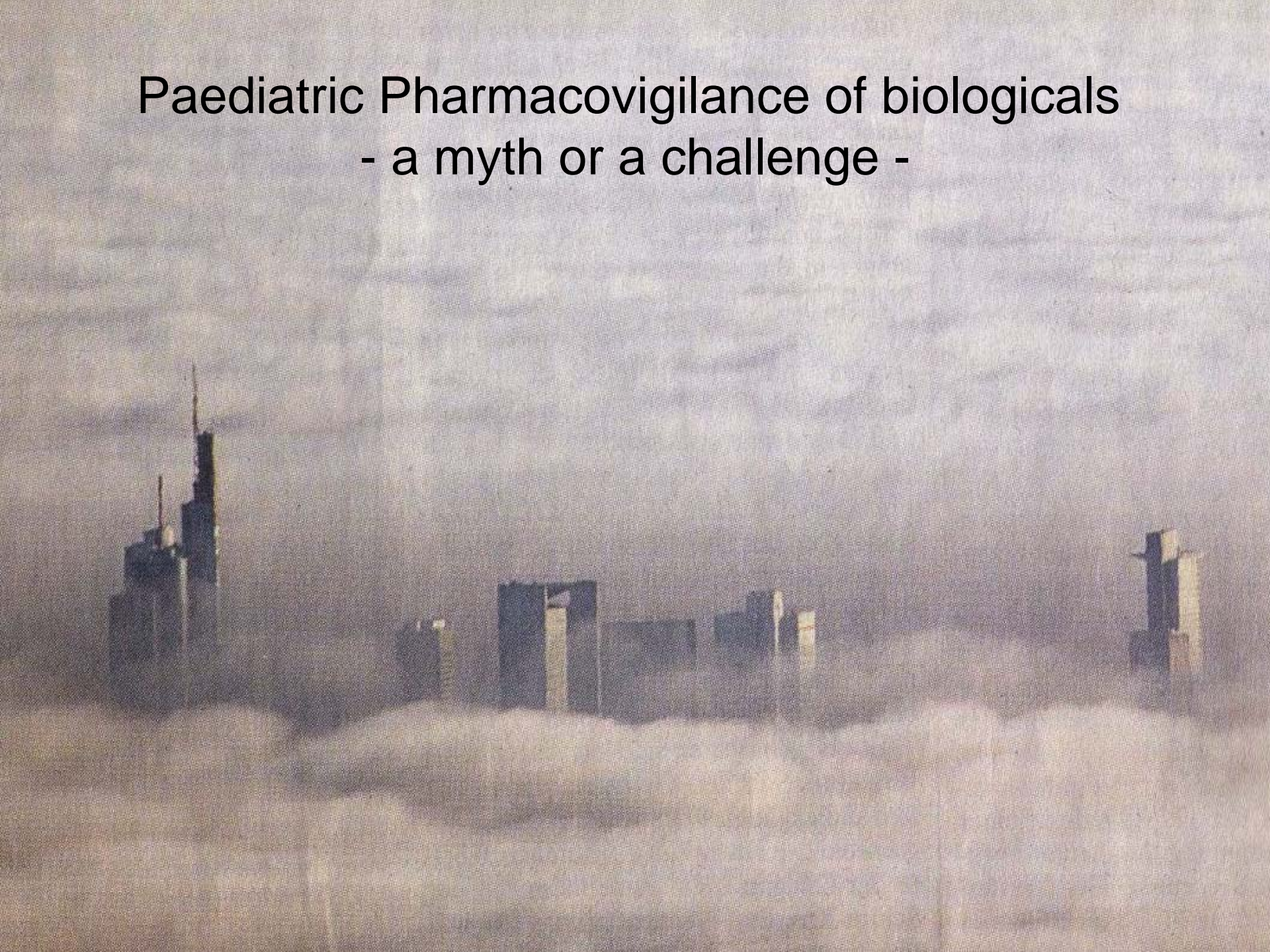


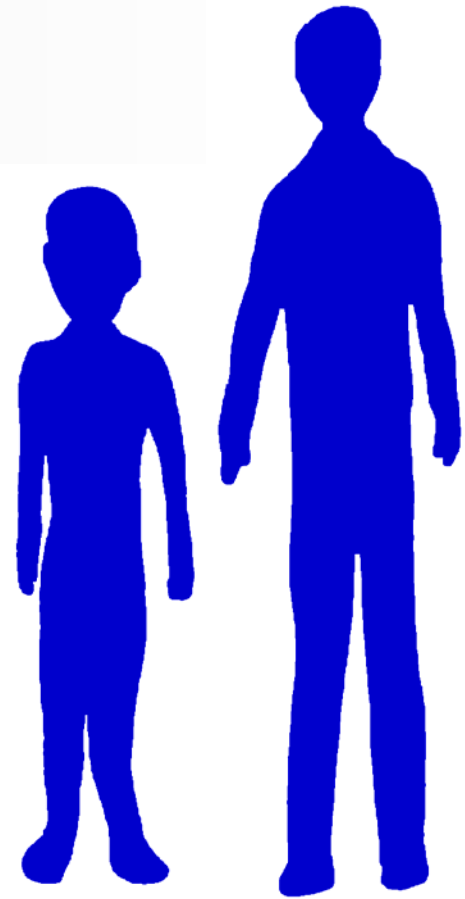
Paediatric Pharmacovigilance of biologicals - a myth or a challenge -



Paediatric pharmacovigilance of biological

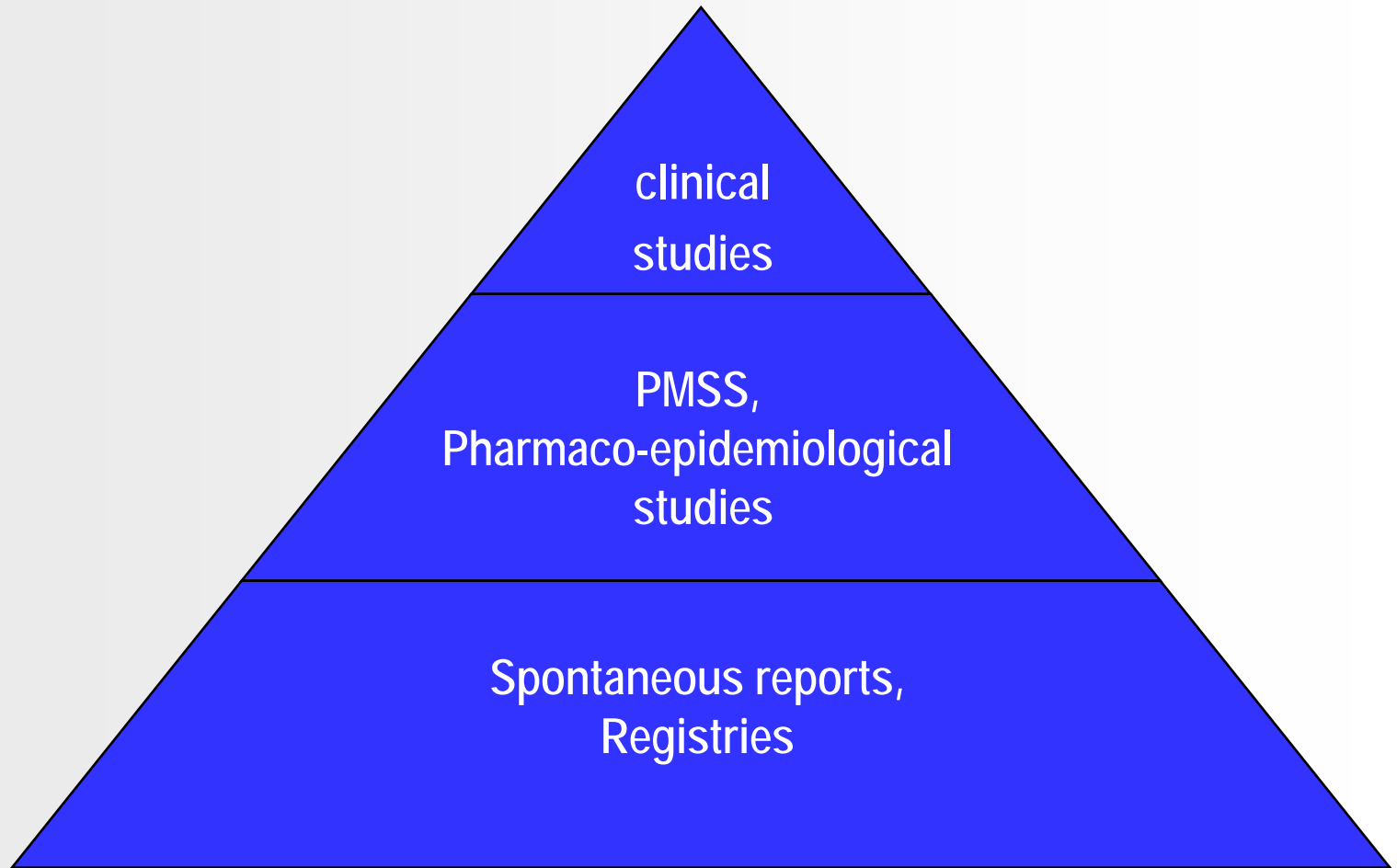
Challenge of Pharmacovigilance Planning

- **Multifactorial Pharmacovigilance**
- **small numbers to be treated**
- **Indication and dosage**
- **appropriate formulation**
- **Organ impairment**



Paediatric pharmacovigilance of biological

Pharmacovigilance aspects



Paediatric pharmacovigilance of biological

Pharmacovigilance aspects

Nice to have

clinical
studies

**Favorable and
Feasible**

PMSS,
Pharmaco-epidemiological
studies

**Possible
and
real life**

Spontaneous reports,
Registries



Paediatric pharmacovigilance of biological

Wish list for PhV in paediatrics

- Case definitions for adverse reactions in children
- Elaborating surrogate parameters and indicator Symptoms for ADRs to be specified in the EU-RMP
- Feasibility and responsibility for long-term follow up including registries and linked databases for aggregation of knowledge
- More interdisciplinary network of learned societies and regulators involving paediatric pharmacovigilance centres



Paediatric pharmacovigilance of biological

Wish list for PhV in paediatrics

- Case definitions for adverse reactions in children
data collection, analysis, presentation and assessment
- Elaborating surrogate parameters and indicator Symptoms for ADRs to be specified in the EU-RMP
Pathomechanism (in vitro studies, juvenile animal toxicology studies) and adult experience
- Feasibility and responsibility for long-term follow up including registries and linked databases for aggregation of knowledge
Post-marketing Phase IV studies as a part of the PIP – How long?
- More interdisciplinary network of learned societies and regulators involving paediatric pharmacovigilance centres
Education and awareness of collaboration of societies



Paediatric Pharmacovigilance clearing up

