

# EU Big Data Stakeholder Forum – Stakeholder perspective – Pharmaceutical industry - AESGP



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Association of the European Self-Care Industry (AESGP)

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# Priorities

Ensure a regulatory framework is “fit for purpose” and takes into account the specificities of non-prescription medicines



Foster big data usage for a broad variety of products including non-prescription medicines



Acting on the ten key recommendations

Deliver a sustainable platform to access and analyze healthcare data across the EU

Data quality & representativeness

EU Network skills

Governance framework

Create an EU Big Data stakeholder implementation forum



# Opportunities/risks

## BENEFITS

Data is coming from real life and wider population

Substantiating Rx to OTC switch

Support the benefit-risk review of older non-prescription medicines

Generate insights to better understand people behaviors and treatment needs

No systematic collection of OTC data in non-prescription setting (eHRs, registries, pharmacy databases...)

Regulatory acceptability for new indications / information and benefits/risks evaluation

Existing framework is not fit for purpose for OTC medicines

Specific expertise required

Big change of paradigm

Data privacy

## HURDLES

# Areas for collaboration/engagement



Guidance in terms of study design and methodologies tailored to OTC medicines would be of tremendous help

Continuous dialogue : all stakeholders are on a learning curve and can learn from one-another.

Interoperability is key for efficient and easy Real World Data usage

thank you!

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