

Pharmaceutical Legislation

Highway to innovation

RSNN ANNUAL WORKSHOP
June 6th 2023

Program starts at 13:30h

Scan for the program:



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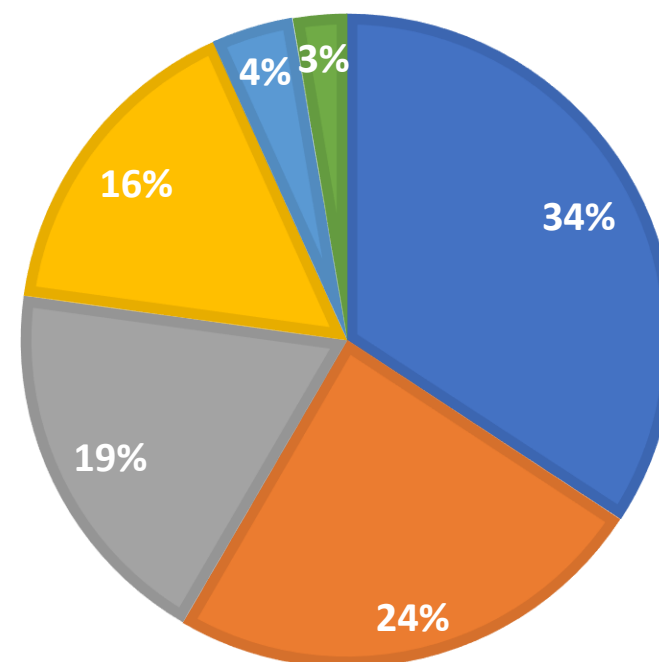


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BACKGROUND PARTICIPANTS

■ Industry ■ Other ■ Academia ■ Regulator ■ Patient ■ HCP



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TIME	PROGRAM
13:30	Welcome Chair: Marjon Pasmooij (CBG/RSNN)
13:40	Pharmaceutical innovation, regulation and regulatory innovation: a pathway perspective Jarno Hoekman (Utrecht University)
14:00	The role of specialist medical societies in building the European Health Space Elizabeth Macintyre (President of the European Hematology Association and President Elect of the Biomedical Alliance in Europe)
14:20	The Role of Innovation in Future General Pharmaceutical Legislation – European innovative industry's perspective Sini Eskola (EFPIA)
14:40	EMA's perspective on key provisions designed to stimulate innovation Tony Humphreys (Head of Regulatory Science and Innovation Task Force – EMA)
15:00	Opportunities vs challenges for patients and future expectations Viviana Giannuzzi (Head of Research Department – Fondazione per la Ricerca Farmacologica Gianni Benzi onlus; Founding Member – APS Bottega del Sorriso)
15:20	Coffee break

EU Pharmaceutical Reform

Builds
on the
**Pharmaceutical
Strategy** for
Europe (2020)

Supports
EU citizens and
industry

Addresses
**long-standing
challenges
and public
emergencies**

Marks a
**European
Health Union
milestone**

6 Key political objectives

No Single Market
ACCESS

Shortages and
Security of supply
AVAILABILITY

Budgets
AFFORDABILITY

Competitive
regulatory framework

Environmental
Sustainability

Combat
AMR

Single market of medicines in the EU

A 4-part package

Chapeau communication

New Regulation

- Specific rules for the most innovative medicines such as orphans, antimicrobials
- Rules on shortages and security of supply
- EMA governance

New Directive

- Placing on the market of all medicines
- Authorisation and labelling requirements
- Strong incentives for access



Council Recommendation on AMR