

Intergroup Hearing – Pharmaceutical Legislation

Thursday 10 July, 10.30 - 12.00 European Parliament, Strasbourg

Conference room N3.1

Topic	Speaker	Timing
Introductory Remarks (20 Minutes)		
1. <i>Introduction from co-chairs – Intergroup on Cancer & Rare Diseases</i>	<ul style="list-style-type: none"> • MEP Tomislav Sokol (HR, EPP) • MEP Vlad Voiculescu (RO, RE) • MEP Tilly Metz (LU, Greens/EFA) • MEP Stine Bosse (DK, RE) • MEP Alessandra Moretti (IT, S&D) 	20 Minutes (4 min per co-chair)
SECTION 1: Regulatory Incentives - Modulation, Access to Innovation & Addressing Unmet Medical Needs (55 Minutes)		
<ul style="list-style-type: none"> • <i>Modulation of Incentives for orphan medicinal products</i> • <i>The ‘first in child’ approach</i> 	<ul style="list-style-type: none"> • Dr. Virginie Hivert, Head of Therapies and Access, EURORDIS – Rare Disease Europe • Prof. Gilles Vassal, European Society for Paediatric Oncology (SIOPE) 	10 minutes
<ul style="list-style-type: none"> • <i>Regulatory Incentives and Access to Innovation</i> 	<ul style="list-style-type: none"> • Tina Taube, Director, Market Access & OMP Policy Lead, EFPIA (online) 	5 minutes
<i>Questions & Answers</i>		5 Minutes
<ul style="list-style-type: none"> • <i>Moving incentives from drug-focus to</i> 	<ul style="list-style-type: none"> • Denis Lacombe, Chief Executive, European 	15 minutes

<p><i>patient focus: safeguarding the Parliament's amendments on treatment optimisation</i></p> <ul style="list-style-type: none"> • <i>Unmet medical Need: the importance of repurposing</i> • <i>Definition of UMN and capability to support innovation and research from insurers/payers perspective</i> 	<p>Organisation for Research and Treatment of Cancer (online)</p> <ul style="list-style-type: none"> • Lydie Meheus, Managing Director, Anticancer Fund (online) • Yannis Natsis, Director, European Social Insurers Platform 	
Questions & Answers		10 Minutes
SECTION 2: Governance of the European Medicines Agency (15 Minutes)		
<ul style="list-style-type: none"> • <i>European Medicines Agency – preserving a gold standard in patient and healthcare professional involvement</i> 	<ul style="list-style-type: none"> • Claudia Louati - Head of Policy - European Patients' Forum • Dr. Tomasz Grybek, CEO Foundation of Borys the Hero, member EMA Paediatric Committee (PDCO) (online) 	10 Minutes
Questions & Answers		5 Minutes
Conclusions and Next Steps (5 minutes)		10 Minutes