



PHARMACEUTICAL DEVELOPMENT, THERAPEUTIC ACCESS, AND STRATEGIC PREPAREDNESS: NEW PATHS FOR PUBLIC HEALTH

A multi-country high-level policy dialogue

in the context of the State of Health in the EU Voluntary Exchange

Date: November 25, 2022 (Friday), h 10.00-16.00

Place: Rome, LUISS University (Viale Romania 32) – hybrid, in person and via TC

Format: Policy dialogue between high level Italian experts, policy makers and stakeholders, international experts from the OECD, the EU Commission, and the European Observatory on Health Systems and Policies. Experts will be asked to make some preliminary comments on the issues at stake, followed by ample time for interactive discussion with national experts.

Policy context: The recent experience gained during the Covid-19 outbreak points at the need to consider apt preparedness against incoming pandemics, as well as unexpected health crises. New forms of pharmaceutical strategic autonomy for both R&D and supply chains must be secured, pursuing availability and affordability of therapeutics. Reliable and predictable legal frameworks play a fundamental role by means of both *ex ante* regulation and *ex post* market disciplining interventions, also in view of securing better public procurement. From a broader perspective, public health administrations will also need to consider increasing industrial and regulatory convergence in the biotech sector, driven by a One Health approach.

Goals: This voluntary exchange pursues a high-level policy dialogue among relevant institutional actors to examine essential components of the national pharmaceutical systems and policies, also in view of improving preparedness for future health emergencies. Open discussion on selected relevant topics aims at fostering encounters of ideas and support new coordinated actions, based upon a better understanding of country's health profile within a sound international context analysis.

Target Audience: AIFA top management, high-end operative offices of the Ministry of Health, the Ministry of Economy and Finance, the Ministry for Industrial Development, the Ministry for University and Research, selected representatives of pharmaceutical departments of both central and regional public administrations, representatives of the Italian competition authority, selected stakeholders from the pharma/biotech sector, selected academicians.

AGENDA

Each speaker will address her topic with a short speech (ca. 15 min), followed by open dialogue between experts and participants both in presence and via TC

Session 1. Crisis response and preparedness: lessons from pandemics

Moderator: Dimitra Panteli (Eu Observatory)

10:00-10:15

Representative of the Italian Ministry of Health
- opening remarks

10:15-10:45

Ana Maria Henao-Restrepo (WHO) - TC

Clinical trials integration and the Covid19 experience

10:45-11:15

Rino Rappuoli (Italian Anti-Pandemic Hub)

Need for preparedness: R&D through public platforms

11:15-11:30 – coffee break

11:30-12:00

Francesco Branca (WHO)

The Joint Plan of Action on One Health

Session 2. Market dynamics and disciplines: horizon scanning

Moderator: Eliana Barrenho (OECD)

12:00-12:30

Luca Arnaudo (AIFA)

Decentralizing advanced pharma-tech for supporting sustainable access

12:30-13:00

Dimitrios Florinis (EC – DG SANTE)

Joint pricing negotiations: on the EU JPAs and existing regional experiences

13:00-13:30

Peter Schedereit (EC - DG COMP)

Market regulation and competition: recent caselaw and developments

13:30-14:30 – light lunch

Session 3. Global way(s) ahead

Moderator: Daniele Mascia (LUISS)

14:30-15:00

Marco Zibellini (Farindustria)

On pharmaceutical innovation, global value chains, and national security

15:00-15:30

Nicola Magrini (AIFA)

Public health institutions as incubators for pharma access and innovation

15:30-16:00

Aaron Kesselheim (Harvard University) - TC

On public health, innovative and accessible pharmaceuticals: a broader view