



AVAILABILITY | ACCESSIBILITY | AFFORDABILITY
OF MEDICINES & MEDICAL DEVICES

3A CONFERENCE

29 | 30 APRIL 2021 **IN VIRTUAL FORM**

PRELIMINARY PROGRAMME

DAY 1: 29 APRIL | 08:30 - 16:45 GMT

WELCOME ADDRESS AND OPENING REMARKS

Marta Temido, Portuguese Minister of Health

HIGH LEVEL SPEAKERS

Ursula Von der Leyen, President of the European Commission (tbc)

António Costa, Portuguese Prime Minister (tbc)

Tedros Adhanom Ghebreyesus, Director-General WHO

KEYNOTE SESSION

09:00 – 09:10 | Portuguese Presidency priorities on access to medicines and medical devices
Marta Temido, Portuguese Minister of Health

09:10 – 09:20 | European Health Union and the Pharmaceutical Strategy for Europe
Stella Kyriakides, European Commissioner for Health and Food Safety

09:20 – 09:30 | European Parliament perspective on access to medicines and medical devices
Pascal Canfin, ENVI Committee Chair (tbc)

PANEL I: AVAILABILITY OF MEDICINES AND MEDICAL DEVICES | **Moderator:** Christa Wirthumer-Hoche, AGES, AT

09:30 – 09:45 | Addressing shortages: preliminary results from the Commission study
Andrzej Rys, European Commission

09:45 – 10:00 | Taking forward the structured dialogue on security of supply chains
Nuno Simões, INFARMED, PT

10:00 – 10:15 | A common understanding for a list of critical medicines and medical devices
Noël Wathion, EMA (tbc)

10:15 – 10:15 | Q&A

10:40 – 10:50 | BREAK

PARALLEL BREAKOUT SESSIONS

10:50 – 11:40 | **Stakeholders solutions to medicines shortages**
Moderator: *Kristin Raudsepp, SAM, EE*

PARALLEL BREAKOUT SESSION 1:

National experience on shortage's management

Rapporteur:

*Xavier De Cuyper
FAMHP, BE*

PARALLEL BREAKOUT SESSION 2:

Shortages management plans to avoid availability problems

Rapporteur:

*Sinisa Tomić,
HALMED, HR*

PARALLEL BREAKOUT SESSION 3:

Hospital Pharmacists solutions for availability problems

Rapporteur:

Aida Batista, EAHP

PARALLEL BREAKOUT SESSION 4:

Consumers and patients' perspectives on medicines shortages, the case of small volumes and limited use medicines

Rapporteur:

Monique Goyens, BEUC



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11:40 – 12:00 | Breakout sessions' conclusions

12:00 – 12:25 | Q&A

12:25 – 13:30 | LUNCH

PANEL II: INNOVATION AND ACCESSIBILITY OF MEDICINES AND MEDICAL DEVICES TO PATIENTS

Moderator: Karl Broich, Bfarm, DE

13:30 – 14:00 | HMA-EMA joint strategy 2025

Emer Cooke, EMA | Svens Henkuzens, ZVA, LV

PARALLEL BREAKOUT SESSIONS

14:00 – 14:50

PARALLEL BREAKOUT SESSION 1:

Access to medicines for special populations: Orphan and Paediatric Regulations & Revision of the system of incentives

Rapporteur:

Koenraad Norga Chair PDCO (tbc) and Violeta Stoyanova-Beninska, Chair COMP

PARALLEL BREAKOUT SESSION 2:

Unmet medical needs: medicines and medical devices research in view of patients and health systems needs

Rapporteur: Marco

Greco, President, European Patients Forum (EPF) (tbc)

PARALLEL BREAKOUT SESSION 3:

How the repurposing of old medicines may add new value on patients' access to new therapies

Rapporteur:

Cesar Hernandez, AEMPS, ES

PARALLEL BREAKOUT SESSION 4:

Generation of evidence for a better patient access & Health data space and big data: shared data for a better communication and coordination

Rapporteur:

Peter Arlett, EMA (tbc) and Nikolai Brun, DKMA, DK

14:50 – 15:10 | Breakout sessions' conclusions

15:10 – 15:40 | Q&A

15:40 – 15:50 | BREAK

PANEL II (CONT): INNOVATION AND ACCESSIBILITY OF MEDICINES AND MEDICAL DEVICES TO PATIENTS

Moderator: Maria Lamas, AEMPS, ES

15:50 – 16:05 | The new regulation of medical devices: State of play – Are we ready?

Ana Eva Ampelas, European Commission

16:05 – 16:20 | Will the new regulation promote accessibility of MD: Coordination, complexity and stringency vs. the need for regulatory flexibility

Thomas Wejs Moller, Chair CAMD

16:20 – 16:35 | The technological, scientific and regulatory convergence between medicines and medical devices (digital technologies, companion diagnostics, combination products)

Niall MacAleenan, HPRA, IE

16:35 – 16:50 | Q&A



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DAY 2: 30 APRIL 09:00 – 12:30 GMT

PANEL III: AFFORDABILITY OF MEDICINES | *Moderator: Rui Santos Ivo, INFARMED, PT*

09:00 – 09:15 | Developing an “affordability” agenda under the pharmaceutical strategy for Europe to keep the sustainability of Health Systems | *Sylvain Giraud, European Commission*

09:15 – 09:30 | Effective ways of investing in health and patient access | *Pedro Pita Barros, Nova SBE*

09:30 – 09:45 | Sustainability of healthcare systems: What costs? What value? | *Francisco Ramos, ENSP*

09:45 – 10:00 | Q&A

10:00 – 10:10 | Break

ROUNDTABLE

10:10 – 11:55 | **Collaboration and priorities for accessibility and affordability**

Moderator: Marcel van Raij, MoH, NL

| The perspective of National Competent Authorities
Momir Radulovic, JAZMP, SI | Nicola Magrini, AIFA, IT

| The perspective of the Industry
*Nathalie Moll, Director General, EFPIA,
Christoph Stoller, MfE
Serge Bernasconi, Medtech Europe (tbc)*

| The perspective of patients & health professionals
*Yannis Natsis, EPHA
Annabel Seebohm, CPME*

11:55 – 12:20 | Q&A

CLOSING SESSION

12:00 – 12:15 | Closing remarks
Diogo Serras Lopes, Portuguese Secretary of State for Health