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Reimbursement of Medical Devices in Romania – 2026

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AGENDA FOR TODAY:

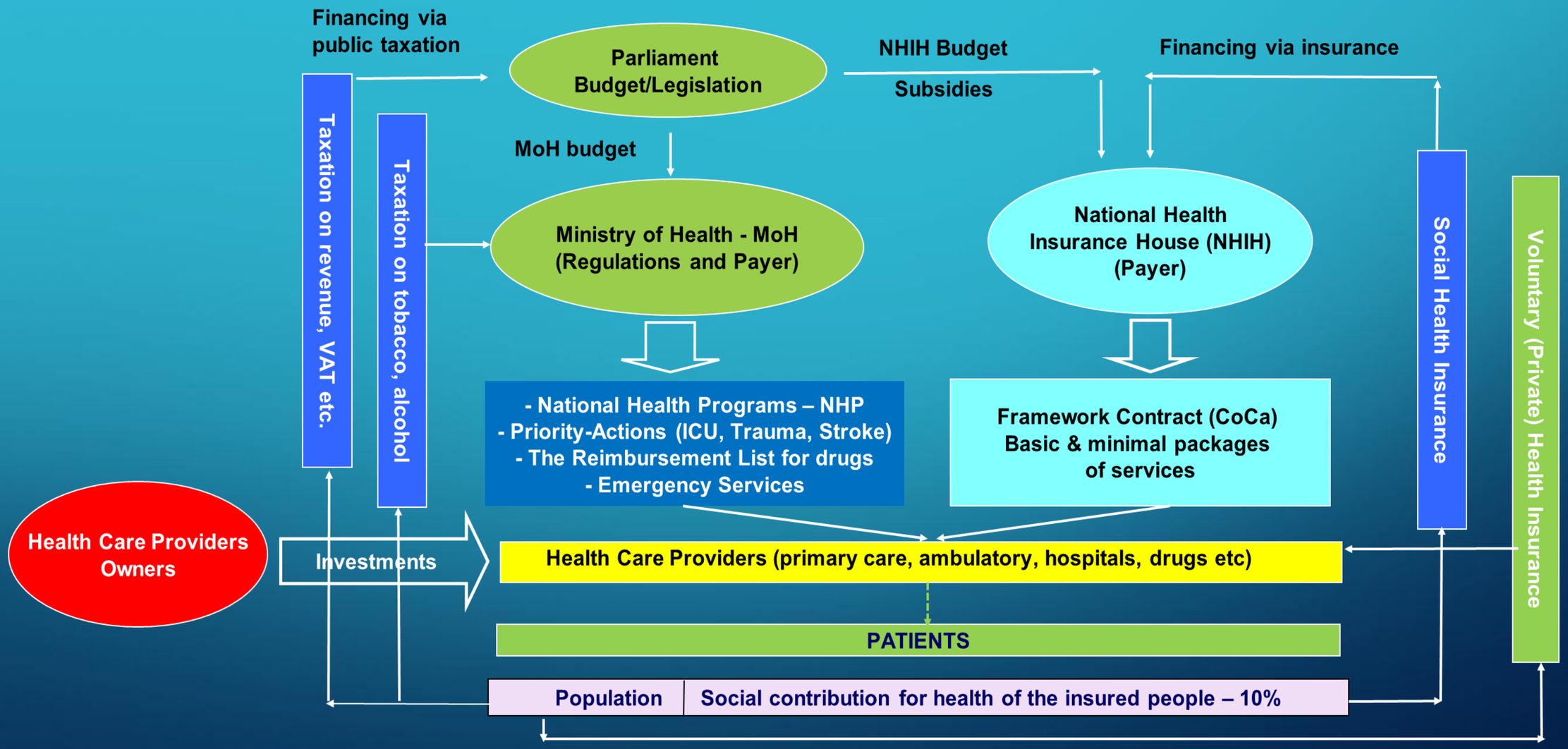
- Financing and delivery model & data on Romanian health care system
- Access to Medical Devices
- Reimbursement of MD in Romania
- Directions for the future access and reimbursement in Romania

ROMANIAN HEALTH CARE EXPENDITURES BRIEFLY (EUROSTAT DATA 2022):



- Population: around 19 million
- Total Health Care Expenditures: 5,8% of GDP
- Expenditures per inhabitant: 858 Euro
- Expenditures in Purchasing Power Standard (PPS) per inhabitant: 1.613 Euro
- Public funding accounts for around 77% of total expenditures
- Private funding accounts for around 23% of total expenditures
- Romanian Health Care System:
  - ✓ Mixture of public and private funding
  - ✓ Mixture of public and private providers (hospitals mainly public owned, ambulatory and ancillary services mainly private owned)

FINANCING OF HEALTH CARE IN ROMANIA & THE MAIN ACTORS



TOTAL EXPENDITURES BY TYPE OF PROVIDER (EUROSTAT DATA 2022):

ICHA11_HP (Labels)	2022 (%)
Hospitals	45,13
Retailers and other providers of medical goods	25,55
Providers of ambulatory health care	16,33
Providers of ancillary services	5,82
Providers of health care system administration and financing	3,17
Residential long-term care facilities	1,54
Rest of economy	1,40
Rest of the world	0,85
Providers of preventive care	0,18

PUBLIC FUNDING OF THE HEALTH CARE SYSTEM (1)

- **Social Health Insurance (SHI)** is a compulsory scheme run by NHIH (National Health Insurance House) and its local offices = 78% of total public funds for health
  - NHIH revenues come from:
    - ✓ Insured people contributions (10% of income goes for health contribution)

      (Around 6 mil. contributors and over 18 mil. Beneficiaries!!!)
    - ✓ Claw-back taxation of Drugs
    - ✓ Subsidies from the State Budget
- **SHI** is an unique National Payer who contracts via its Regional Officies with all types of health care providers, public & private (primary care, ambulatory services, ancillary services, hospitals, rehabilitation etc.)

PUBLIC FUNDING OF THE HEALTH CARE SYSTEM (2)

- **Ministry of Health** is financing the health care system using several mechanisms:
  - ✓Direct reimbursement of several expenditures in areas like Public Health, Forensic Medicine, Emergencies System etc.
  - ✓National Health Programs: curatives or public health.
    - ✓Reflect some health specific priorities and are dedicated to all Romanian citizens
    - ✓Covers some specifics MD or drugs in different areas: Oncology, Diabetes, Orthopedy, Cardio-vascular Diseases, Rare disease etc.
    - ✓Could be accessed by both public and private providers
  - ✓Priority Actions (AP): covers specific priorities only in Public Hospitals (e.g. Trauma, Stroke, Intensive Care, Heart Attack etc.)

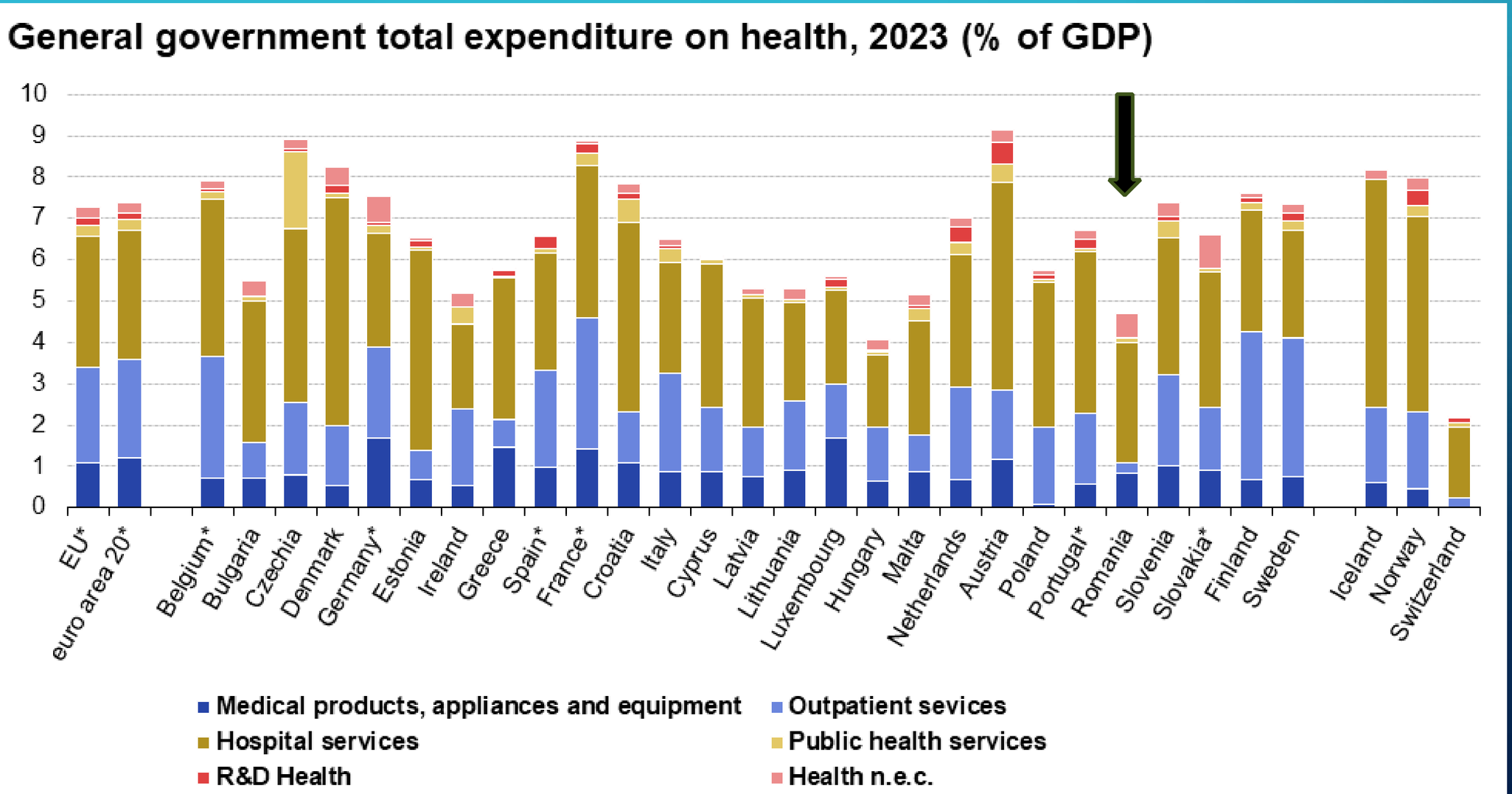
PUBLIC FUNDING OF THE HEALTH CARE SYSTEM (3)

- **Local Administration (City Hall)** could add supplementary funds for their owned providers of health care

- **Local County (Regions) Administration** could add supplementary funds for their owned providers of health care

- Grants:
  - ✓ UE Resilience Funding
  - ✓ UE Funds for Health – Romania has a specific financing programme for health in the financial cycle 2021-2027
  - ✓ Other types of local or UE grants

SHARE OF DIFFERENT EXPENDITURES IN EU



* provisional

Source: Eurostat (gov_10a_exp)

eurostat

PRIVATE FUNDING OF THE HEALTH CARE SYSTEM

- Private sources of funds include:
  - ✓ Co-payments of the insured persons (e.g. % from the price of a covered drug)
  - ✓ Contributions of the insured persons (e.g. a certain amount in a private hospital; a certain amount for an external prothesis)
  - ✓ Out-of-pocket for not covered services/products
  - ✓ Voluntary Health Insurance (private). Total market is > 100 mil. Euro
  - ✓ Health Subscriptions. Total market is >500 mil. Euro
  - ✓ “Grey” payments (under-the-table)

ACCESS TO MARKET FOR MEDICAL DEVICES (1)

- MD Regulations at EU level (#2017/745 & 746) transposed in Romanian local legislation:
  - ✓Government Ordinance #46/2022 for EU #2017/745
  - ✓Government Ordinance #137/2022 for EU #2017/746
- The Compethent Authority is ANMDMR (National Agency for Drugs and Medical Devices from Romania):
  - ✓Verify application of EU MD Regulations (#2017/745 & 746)
  - ✓Develop and apply specific measures for control of medical devices
  - ✓Give the approval for all distributors of MD in Romanian market

ACCESS TO MARKET FOR MEDICAL DEVICES (2)

- For the moment there is **no formal HTA (Health Technology Assessment) for MD**
- HTA EU Regulation #2021/2282 will be applied also in Romania for MD
- For:
  - ✓ the Lab tests &
  - ✓ Radiology

  provided as ambulatory services reimbursed by NHIH,
- the **List of services and the reimbursement price are** defined by NHIH and the Specialty Commissions of the MoH (providers of MD/technology could propose new services)

ACCESS TO MARKET FOR MEDICAL DEVICES (3)

- MoH and NHIH decides:
  - ✓ what generic services &
  - ✓ what devices are part of the National Health Programs or Priority Actions (AP) like Hip prosthesis, diabetes pumps etc.)

- NHIH or MoH do not specify any brand technology included in NHP or AP

- For NHP and AP the acquisitions are done at hospital level (public tenders in public hospitals)

PUBLIC TENDERS FOR MEDICAL DEVICES

- All MD (consumables, devices, equipment etc.) acquired by hospitals using tenders are regulated by the Public Acquisitions Law
- Hospital Acquisitions:
  - ✓ usually done based **on the lowest price**
  - ✓ legislation allows for **Value Based Procurement (VBP)** – seldom use

VBP BEST PRACTICE EXAMPLE:



- Ministry of Health and National Office of Centralized Acquisitions run two national tenders in 2024/2025 to equip with devices around 2.500 family physicians' offices

→

- ✓ Price was only 40% of the evaluation grid
- ✓ Other criteria (training, warranty, battery life etc.) were used to reflect better the value – 60% on the evaluation grid

PRICING FOR MEDICAL DEVICES

- No price regulation on MD (like the Pricing Rules for the pharmaceuticals)
- NHIH establish a **reference price** on some MD for ambulatory/rehabilitation utilization (hearing aids, prothesis/orthesis etc.):
  - ✓ the patient could pay the difference between the reference price and the price of the MD
- NHIH also establish **the prices of medical and ancillary services in ambulatory** offices
- **Access for some new MD/technologies is restricted due to clinical guidelines/therapeutic protocols** (which are regulated by MofH)
  - ✓ The guidelines/therapeutic protocols sometimes do not include the respective MD/technologies

REIMBURSEMENT FOR MEDICAL DEVICES (1)

Type of Provider	Examples of MD	Reimbursement mechanism
Ancillary ambulatory care	Devices for Labs, Medical Imagistic, Nuclear Medicine etc.	• **NHIH List of tariffs** with covered ancillary services • Capital investment
Hospitals	Materials, medical devices, implants, equipment etc.	• DRG • Day-Hospitalization • **National Health Programs (NHP)** for Orthopedy, Radiotherapy, Diabetes, Hearing Prothesis etc. • **Priority Actions (AP)** for ICU, trauma, stroke • Capital investment • Own hospital revenues (Out of Pocket, local administration, Voluntary Insurance etc.)

REIMBURSEMENT FOR MEDICAL DEVICES (2)

Type of Provider	Examples of MD	Reimbursement mechanism
Primary / Ambulatory care	Equipment/medical devices in the provider office	• Part of medical services • Capital investment
Dialysis	Specific materials, devices and equipment	• Part of payment per dialysis episode
Rehabilitation	Prothesis/Orthesis and other devices	• **NHIH List with Reference Prices** for each type of device • Possible patient co-payment
Emergency Care	Medical devices for ambulances/ER, stretchers, cats	• Running expenditures • **Priority Actions (AP)** for trauma, heart attack, stroke etc. • Capital investment

DIRECTIONS FOR FUTURE MD ACCESS/REIMBURSEMENT

- Implementation of EU HTA Regulation, including Managed Entry Agreements for MD (after the “localization” of the EU HTA Regulation for drugs)
- Emphasis on Value-Based Procurement and better/clearer market consultation regarding MD acquisitions
- Development of a Public Registry with all MD in use in Romania
- Operational leasing for MD in public hospitals (?)

DIRECTIONS FOR FUTURE MD ACCESS/REIMBURSEMENT

- Introduction of specific reimbursement mechanism for high-value MD (e.g., robotics)
  - ✓Reimbursement for specific robotic surgery expenditures and equipment's maintenance introduced in 2026 and in process of operationalization
- More regional & national tenders for MDs (National System for Emergency etc.)
- New Public Procurement Act to be introduced in EU for public tenders
- Development of specific training for the staff of hospitals about public acquisitions

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Thank you!

Q & A