

FAIRFIELD



POLMED
THE POLISH CHAMBER OF COMMERCE
OF MEDICAL DEVICES

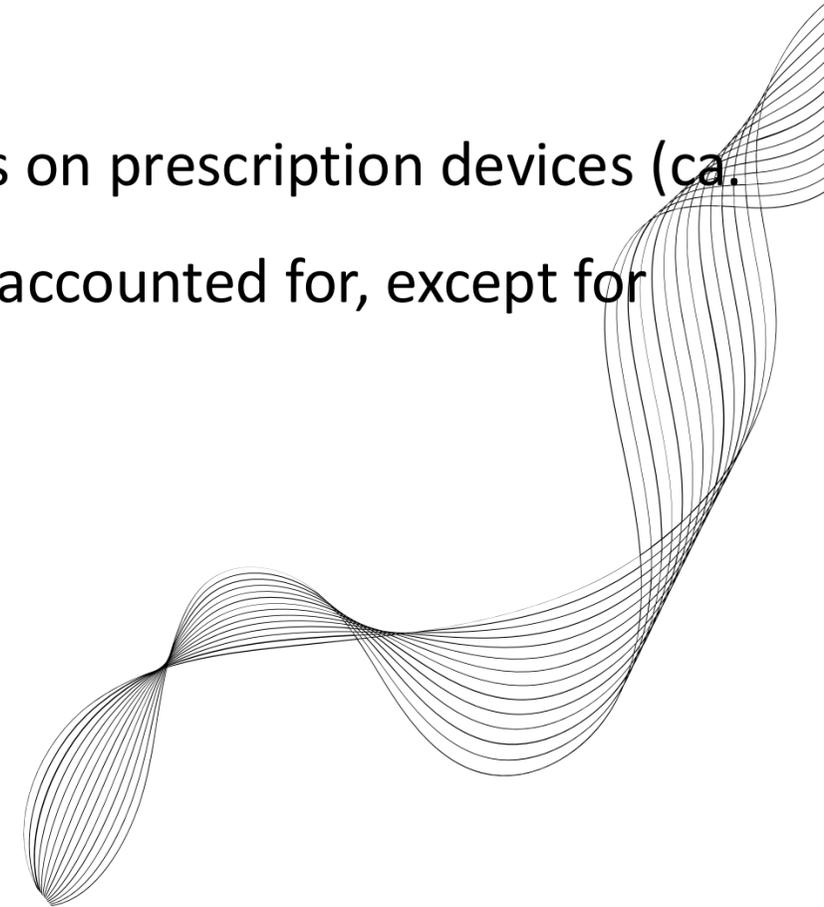
The Polish Medtech Market

Training webinar

Market value estimates

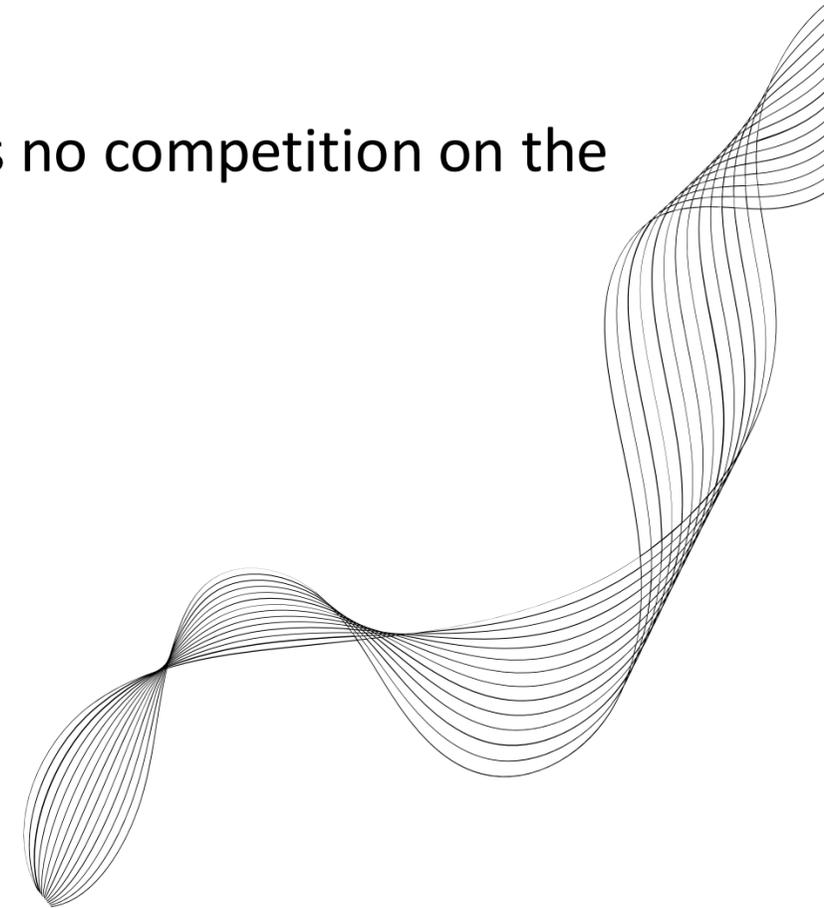
- ca. 4 - 5.5B EUR total market value estimates (2022)
- growing Polish production – ca. 2B EUR (2022)

- no good data on public spending on medical devices
- public spending is generally not accounted for, except for a small portion of expenditures on prescription devices (ca. 800M EUR) no good sources on market value; public spending on medical devices is not accounted for, except for small portion of expenditures



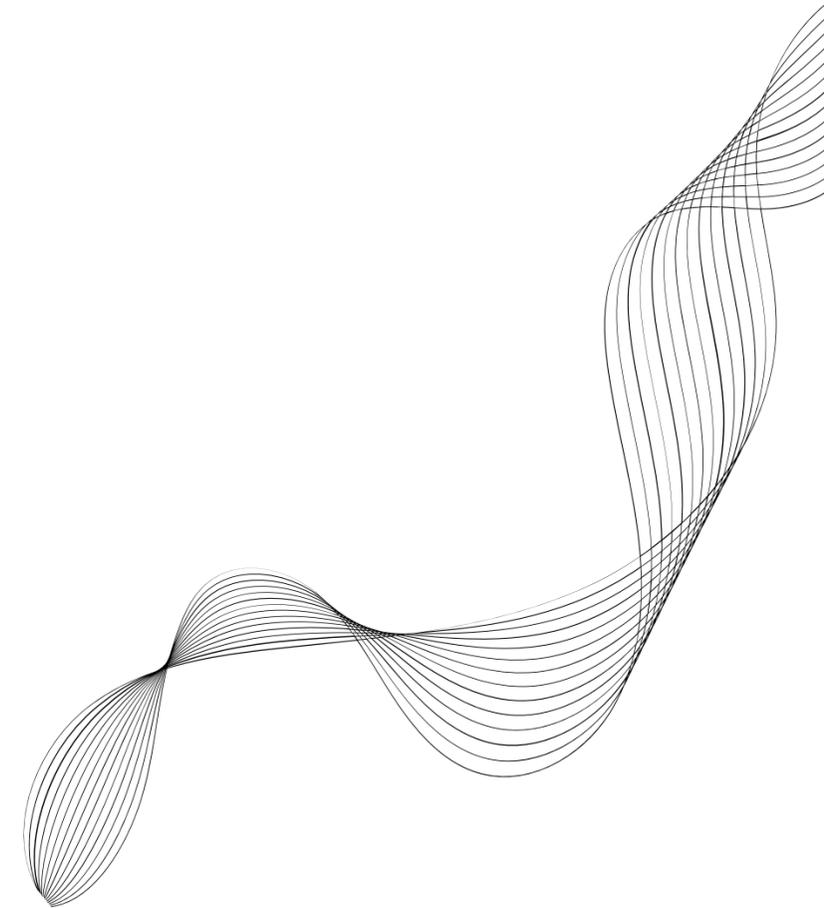
Statutory health insurance

- majority (36M) of population insured under mandatory insurance schemes (tax-like regulation), including 800K Ukrainians
- health insurance grants right to publicly financed healthcare services
- we have one big public payer & controlling body – National Health Fund („NFZ”); there is no competition on the public insurers market



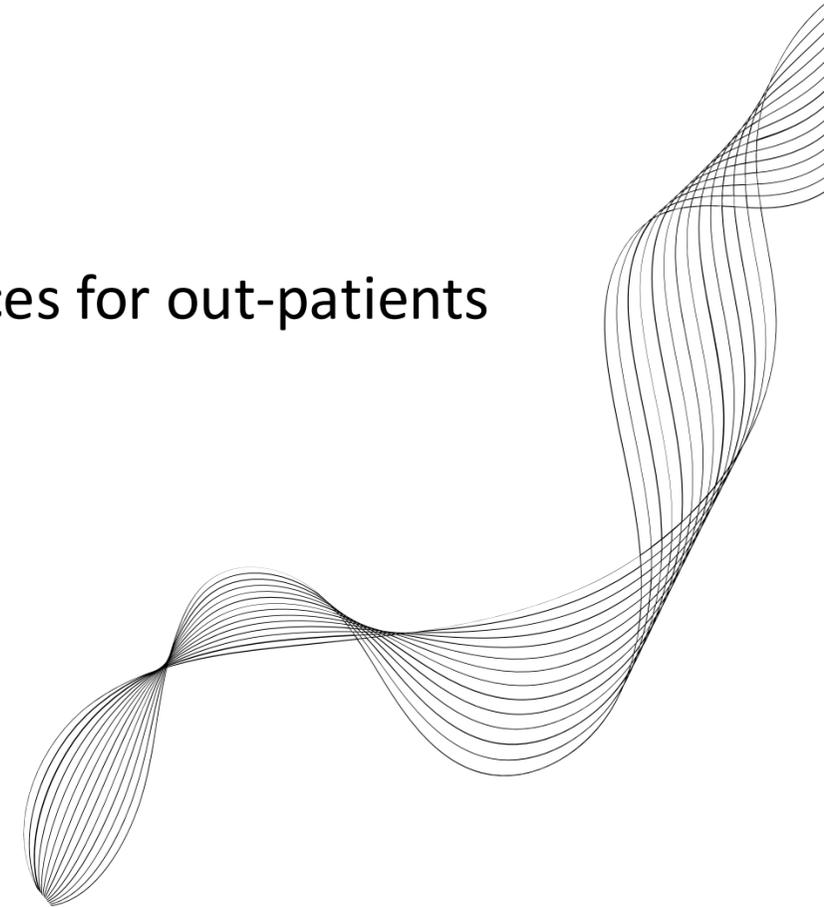
Private healthcare market

- both public and private hospitals are financed by NFZ
- private market for healthcare services involving use of high-cost & high-risk class medical devices (implants etc.) is practically non-existent
- private insurance schemes and private hospitals are however growing in the last years



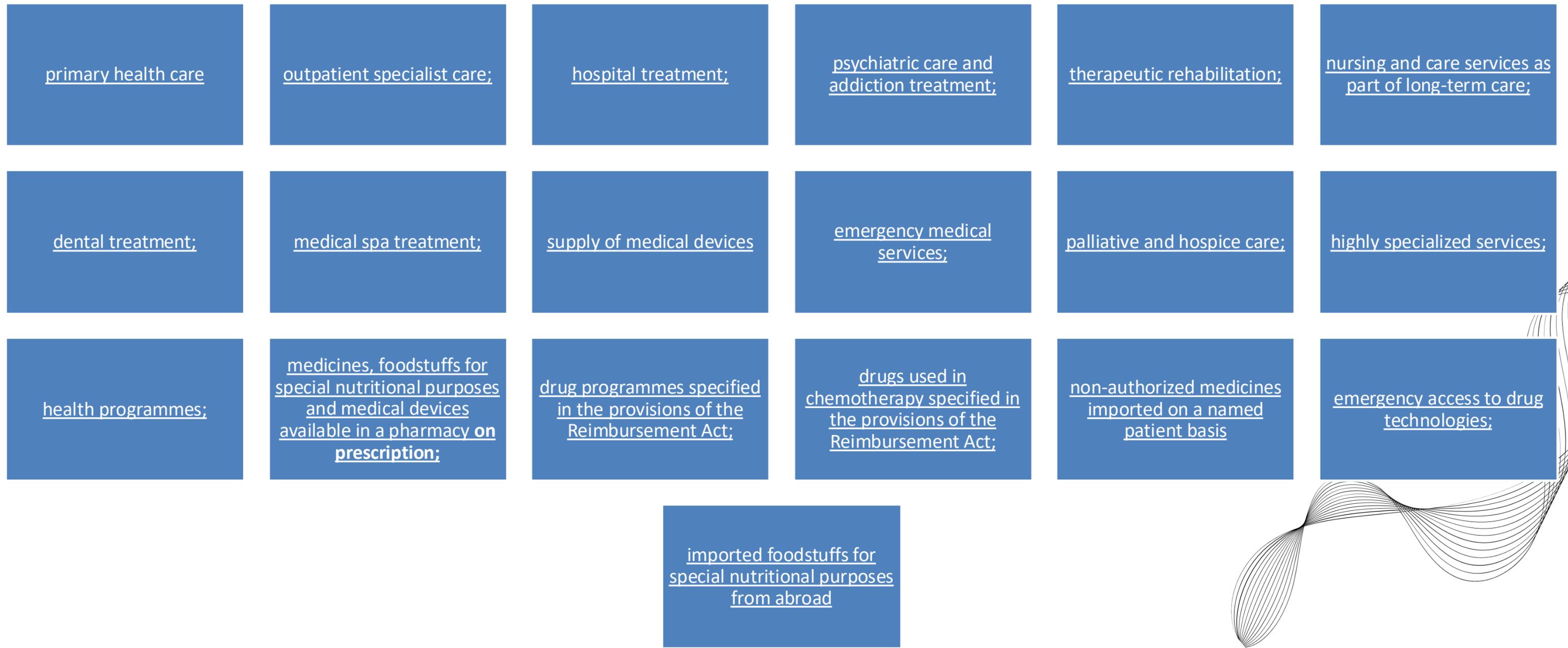
Principles of publicly fund healthcare system

- positive (white) list of publicly funded healthcare services
- healthcare services grouped into
- no co-payment for in-patients
- co-payment possible only in respect of prescription drugs and prescription medical devices for out-patients
- private insurance schemes and private hospitals are however growing in the last years



Principles of publicly fund healthcare system

- positive (white) list of publicly funded healthcare services
- healthcare services grouped into several „baskets“:



Three main pillars of public financing medical devices and IVDs

- public procurement at healthcare unit level + lump sum reimbursement for performance of healthcare services
- pharmacy reimbursement regulation – medical devices supplied in pharmacies against doctors' prescriptions
- generic reimbursement regulation – medical devices supplied in pharmacies or specialized retail stores against doctors' prescriptions



Pillar 1: financing at healthcare unit level

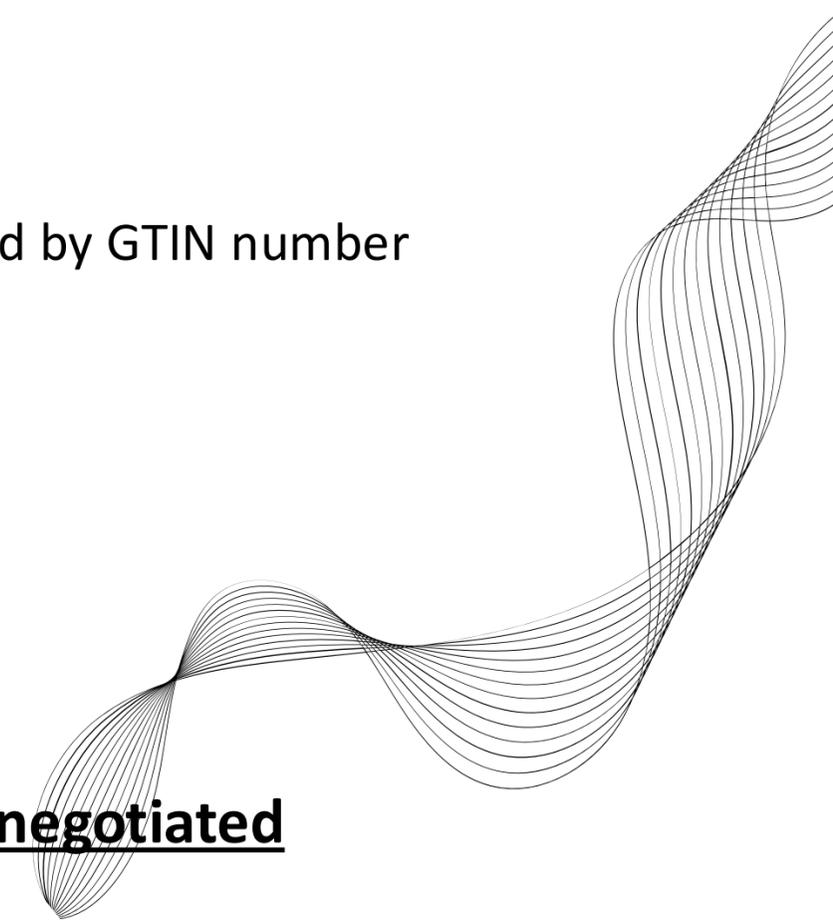
- healthcare units' (hospitals, out-patient clinics, infirmaries, hospices, medical spa etc.) services are financed under different, complicated schemes (DRG, Hospital Network etc.)
- the ultimate source of these schemes are legal acts enacted by the Minister for Health
- in almost all cases (99,99%) medical devices/IVDs are NOT subject to individual reimbursement and are financed as a part of the entire cost of an individual medical procedure
- healthcare units purchase medical devices by themselves and for themselves
 - no binding recommendations/requirements
 - units form a purchasing group on rare occasions
 - central purchasing is limited to several instances – such as central purchase of vaccines for general administration
 - no central purchases for medical devices – although this topic is present in the policy making discussions



Pillar 2: pharmacy reimbursement

- **this system is opened to all individual medical devices, however, as of now it only includes:**
 - wound dressings
 - glucometer stripes
 - insuline needles
- **product may be placed on the reimbursement list if:**
 - the manufacturer or distributor applies for individual reimbursement decision of a device identified by GTIN number
 - if a fixed price is agreed with special Ministry of Health's Commission for Negotiations
 - fixed manufacturing and retail prices + fixed wholesale margins are applied by all market operators
 - applicant undertakes to bear all legal liabilities resulting from the product enlistment

The reimbursement decision is valid through 2/3 years period – then prices must be renegotiated



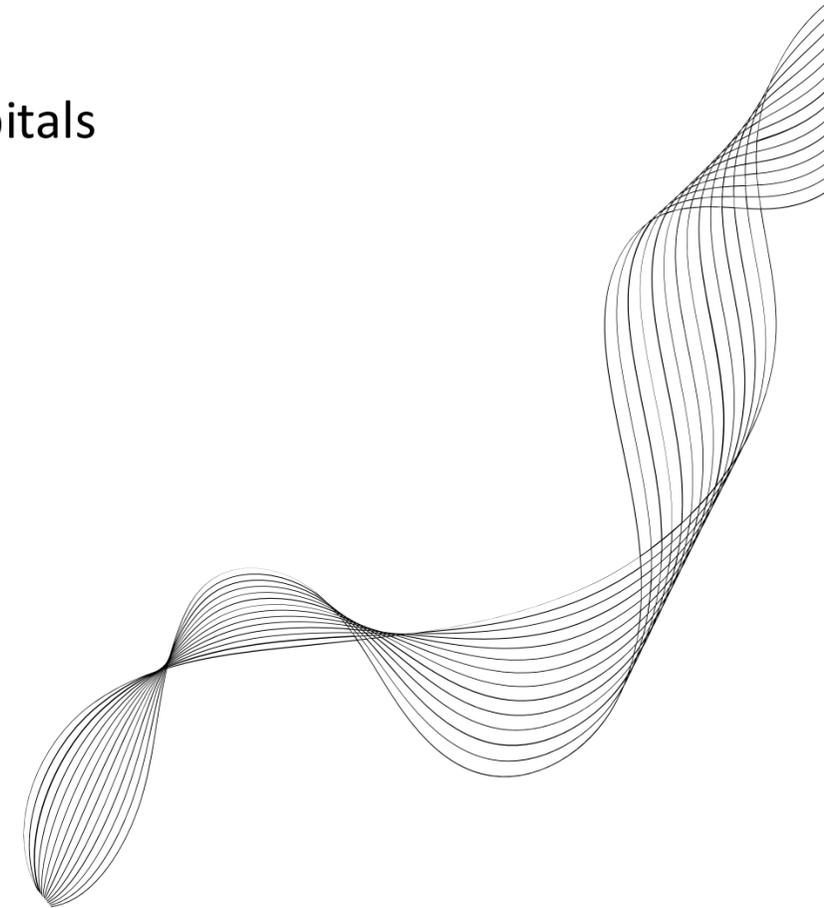
Pillar 3: generic reimbursement of medical devices

- **Minister for Health issues a legal regulation that lists types (generic) of medical devices that are subject to reimbursement within this pillar**
- **retail points (pharmacies or specialized retail stores), upon entering into contract with NFZ, may sell listed devices to patients who have obtained doctors' prescriptions**
- **the sales are effected at a discount (or even free of charge) and the remaining price is covered by NFZ**
- **no need to apply for any reimbursement decision on the supply part – only retail part of the market is subject to scrutiny**



Trade in medical devices

- **obligation to register in the Distributors' List held by the Polish CA – only if the distributor is incorporated in Poland**
- **no general legal obstacles in trade – however:**
 - disturbances in trade via pharmaceutical wholesalers
 - unfortunate debate whether non-pharmaceutical wholesalers may sell reimbursed products to hospitals



Cases

- I want to sell my innovative flow inverters to Polish hospitals. What should I do?
- I have hearing aids that might be a good option for Polish patients. Where could I sell them?
- I have an innovative med app that is addressed for children with ADHD – how can I get it to be reimbursed?
- My new surgery robot performs automatic appendectomy and does not require active surgeon.
How could I penetrate Polish hospital market?

