DECISION MAKING PROCESS FOR PHARMACEUTICALS REIMBURSEMENT IN POLAND

negotiation committee, therapeutic guidelines and HTA efforts

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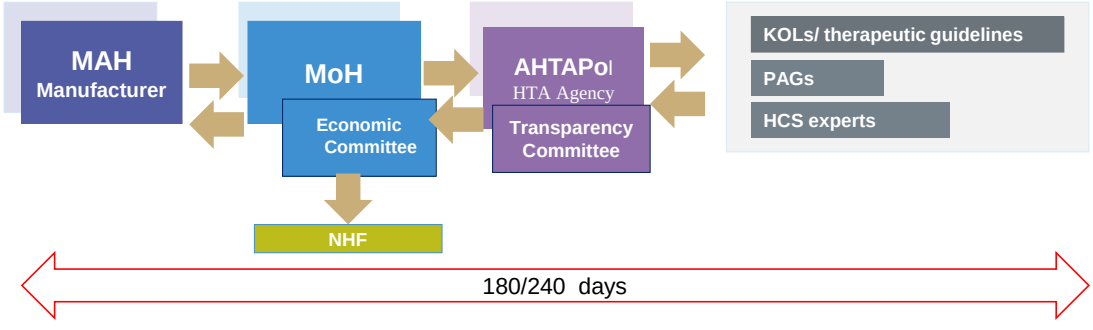
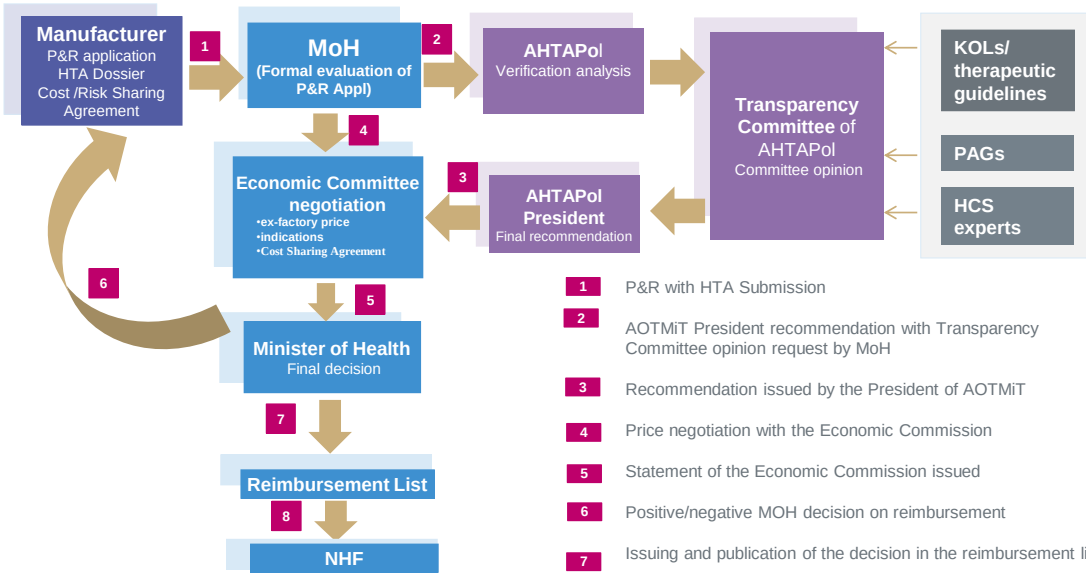
Market Access Director, Sanofi

Pricing & Reimbursement process for pharmaceuticals in Poland
key stakeholders



DECISION	▪ **MoH** is the final and the only decision-maker about taking new drug into the reimbursement system ▪ **Other institutions and bodies (AHTAPol/Economic Committee) play role of advisors (giving recommendations). MoH is setting official price and reimbursement conditions**
RECOMMENDATIONS	▪ **AHTAPol** is evaluating HTA reports and gives recommendations to MoH about clinical & economic value of the medicines ▪ Transparency Council is advisory body for President of AHTAPol team of experts from different institutions
IMPLEMENTATION	▪ **NHF** is keeping budget for health service and reimbursed drugs. NHF is financing drugs which are officially announced (reimbursement list) by MoH

Pricing & Reimbursement process for pharmaceuticals in Poland- **process flow**



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Pricing & Reimbursement process for pharmaceuticals in Poland: **main criteria**

HTA RECOMMENDATION (AHTAPOL)

- Indication to be reimbursed
- Way of reimbursement: part of existing or new limit group / drug program ?
- Clinical efficacy and safety/ relative effectiveness
- Cost-effectiveness ratios (ICER)
  - Vs alternative medicines
  - Rigid hurdle of C/E threshold = 3 GDP/QALY (130 kPLN)
  - Threshold price - set price that would not exceed the ICER
- Budget Impact from payer & patient perspective / with & without RSS
- HTA recommendations from other countries/ EU

ECONOMIC COMMITTEE OPINION (NEGOTIATION)

- **HTA RECOMMENDATION**
- Min & Max prices from 30 EU& EFTA countries
- Info about rebates, discounts in 30 EU& EFTA countries
- Comparator's costs of treatment and Budget Impact
- RSS – conditions/threshold price

MOH CRITERIA FOR REIMBURSEMENT DECISION

- **HTA RECOMMENDATION**
- **ECONOMIC COMMITTEE OPINION**
- Significance of the clinical status/health priorities
- Practical efficacy & safety
- The relationship of health benefits and risk of use
- Price competitiveness/
- Budget Impact/ RSS
- Reliability and precision of estimation

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AHTAPol in drug reimbursement process

role of HTA Agency in HCS

- **2005** – launching AHTAPol by the ordinance of MoH in line with Directive 89/105/EEC; capacity building under "Transparency of the National Health System Drug Reimbursement Decisions"
- **2009 – Act on Health Care Benefits** - confirmation of the place of HTA in the system by setting the rules of making decisions on coverage new health technologies under benefit basket and disinvestment
- **2012 – Reimbursement Act**: the important role of AHTAPol in HCS in Poland

tasks

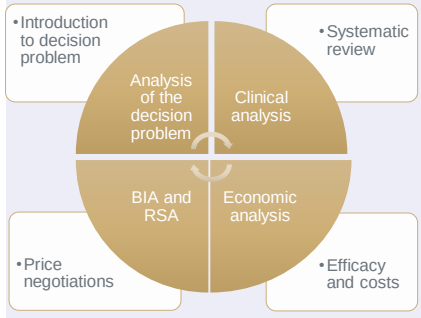
- HTA dossier assessment based o Polish HTA Guidelines and other regulations
- Recommendations to MoH
- Other tasks: tariffication of health services, health program evaluation …

implementation

- Verification analysis
- Transparency Committee recommendation
- Statement of AHTAPol President

HTA Agency

- **Scope of HTA analyses**



HTA guidelines in Poland (last update 2016)

http://www.aotm.gov.pl/www/hta/wytyczne-hta/

Decision problem analysis

- Determination of the scope and directions of the analyses
- Clear description of PICOS and measures of health outcomes
- Identification & justification all comparators

Clinical analysis

- Internal/external validity
- Direct & indirect comparison with current clinical practice in PL/ all available comparators
- Primary endpoints – or prove of surrogates impact on primary endpoints

Budget impact analysis and RSS

- RWE for size of population
- 2-3 years horizon with calculation of all costs – drugs & all other health care services
- Incremental costs – BIA with RSS and without RSS

Economic analysis

- All types of economic evaluations (CEA, CUA, CMA), perspective (e.g., patients, payer & combined), time horizon (long enough to reflect all important differences in costs & outcomes between the technologies being compared)
- Instrument (EQ-5D), source of utility data
- Deterministic/probabilistic sensitivity analysis and forms of results presentation
- Threshold 130 kPLN/QALY

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Economic Committee

committee

- 17 members of EC: 12 representatives of MoH & 5 of NHF
- Nominated by Minister of Health

tasks

- Reimbursement indications
- Price/ patient co-payment level
- RSS if needed

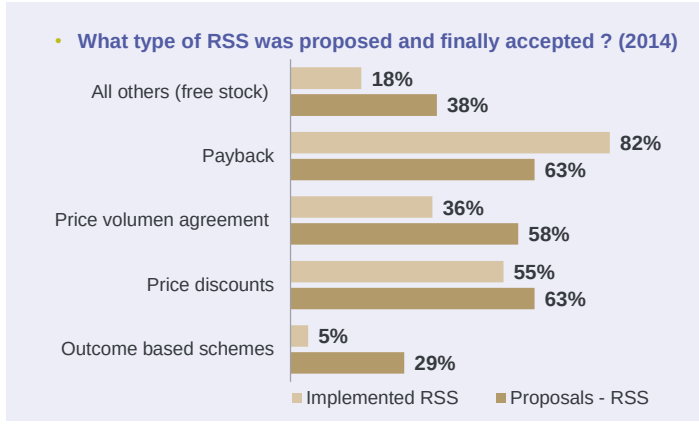
negotiation

- Criteria for EC negotiation are developed
- Team of 5 members of EC are negotiating
- Resolution as an result of negotiation

Risk Sharing Schemes – negotiated with EC

Risk-sharing instruments may apply to outcomes and financial based agreements

- Making the applicant's total sales amount dependent on the drug's outcomes (Payment-by-result)
- Making the price dependent on the applicant's assurance to supply the drug at a reduced price (Discounts)
- Making the price dependent on the drug's sales (PVA)
- Making the price dependent on partial repayment of the reimbursed amount to the public payer (Payback)
- Arrangement of other conditions improving access to or reducing cost of healthcare services (other)



In practice mainly financial based exists in Poland – as preferred one by Polish payer:

- 95% of RSS are finance based – only 20% of them are more complex (2-3 mechanism or/and with cap)
- 50% of reimbursement application for open care and about 80% for drug programs are with RSS

Source: Report "Impact of Reimbursement Law on access to innovation" Sequence, May 2014

HCS in Poland at a glance

Polish economy is growing but health is not priority

6TH POPULATION IN EU

Health System Indicators and Trend Over Previous Year		
Population (millions)	38.4†	↓
Population over age 65 (%)	15.5†	↑
Life expectancy	76.8†	↑

7TH ECONOMY IN EU:

- **GDP per capita PPP UD$ 25k (still only 69% of EU average)**
- **Economic Growth:**
  - **+19% vs 2008**
  - **GDP + 2.6% ('16), + 3.1% ('17)**

HCS trends

- **Growing macroeconomic challenges:**
  - **aging,**
  - **increase in life expectancy,**
  - **early retirement,**
  - **state budget deficit**
- **Epidemiologic trends:**
  - **cancer,**
  - **overweight,**
  - **diabetes,**
  - **dyslipidemia, asthma, dementia …**

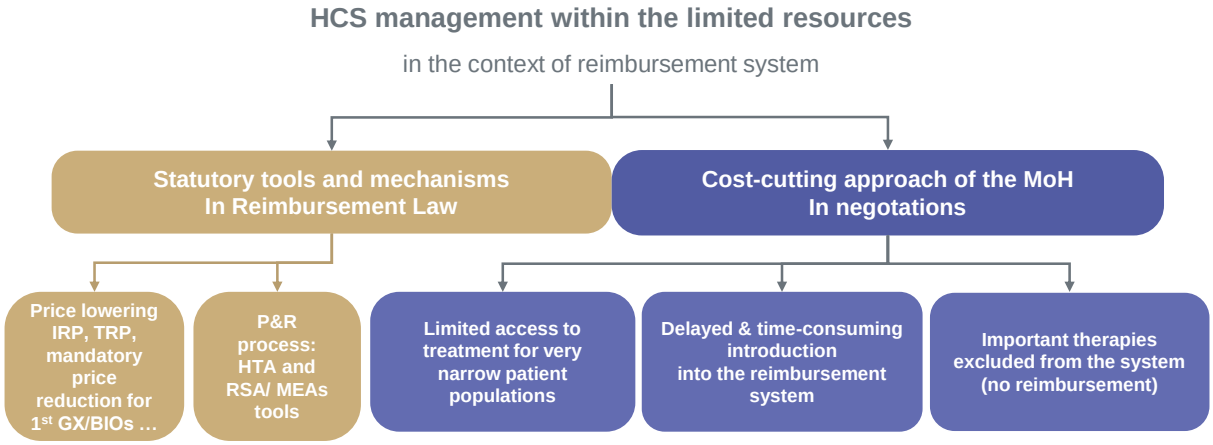
LOW INVESTMENT IN HEALTH

- **One of the lowest expenditure in EU in both HC total spending & drugs expenditure**

Health System Indicators and Trend Over Previous Year		
Health spend (% of GDP)	6.7Δ	↓
Public Health spend (% of GDP)	4.5	
Pharma spend (% of GDP)	1.34%‡	↓
Public Pharma spend (% of GDP)	0.45	

- **Out-of-pocket payments – 30%**

Cost-containment mechanisms in negotiations are used to keep limited budget and rationalize spending ….



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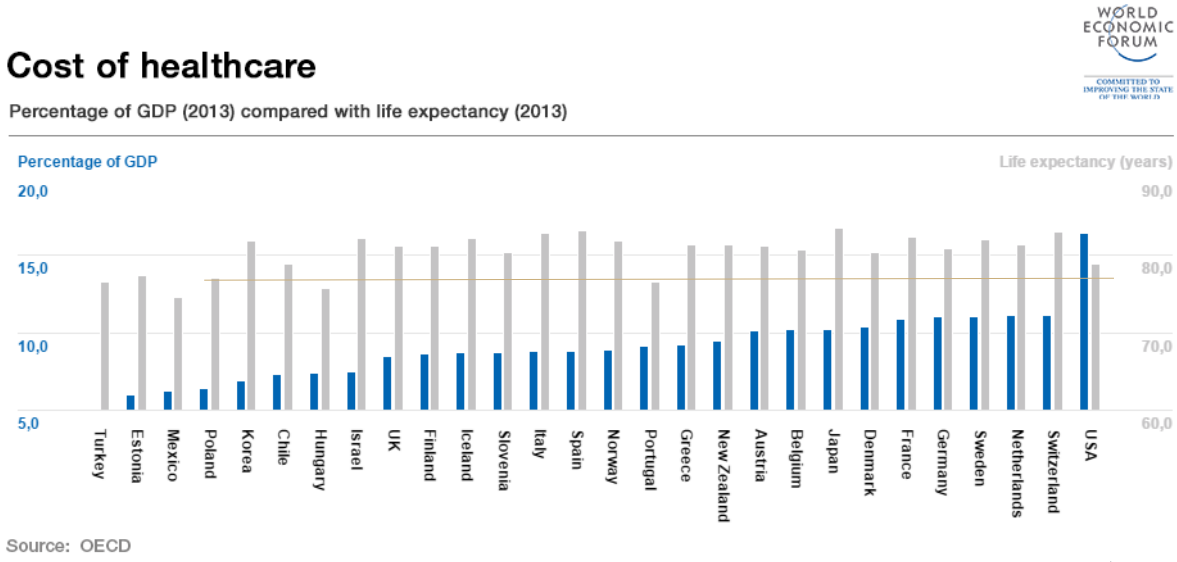
How to produce more health for less cost ?



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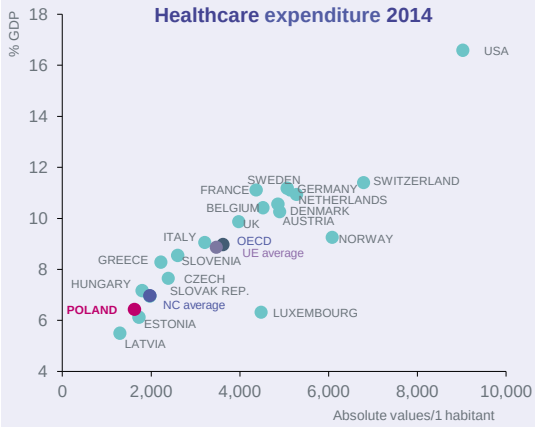
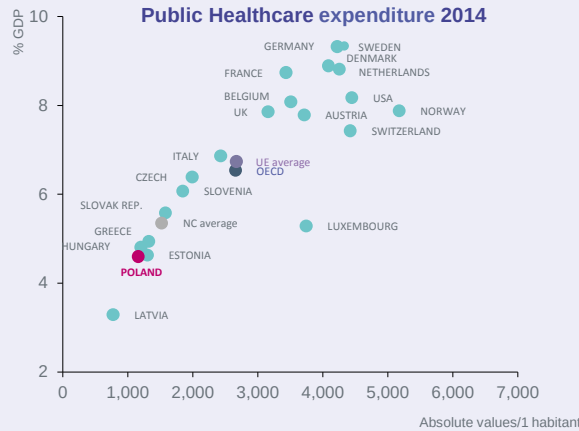
STAT

HCS in Poland is underfinanced

Poland is in tail of Europe regarding HC expenditures in relation to GDP



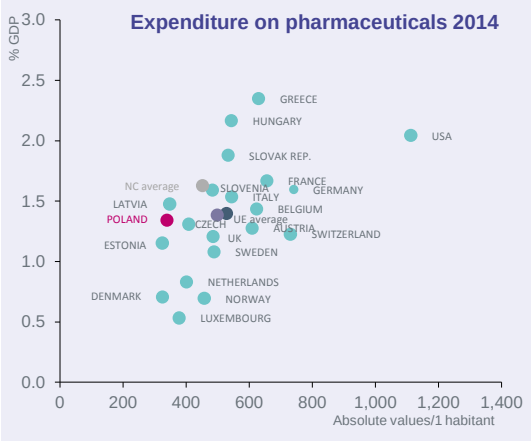


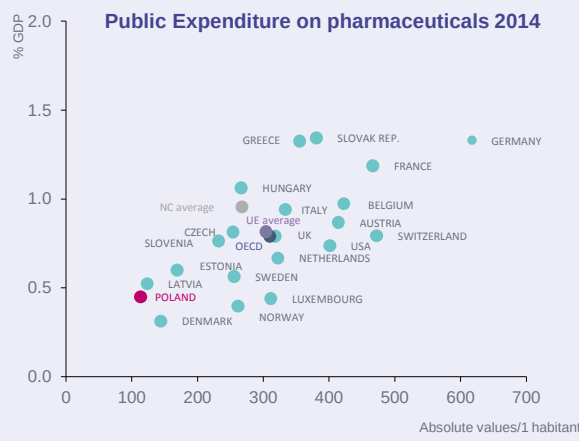
Source: OECD Data 2016

NC average: Czech Republic, Estonia, Slovakia, Hungary

Expenditure on drugs in Poland per 1 inhabitant is among the lowest in EU

Poland is on the lower end of the expenditure on pharmaceuticals





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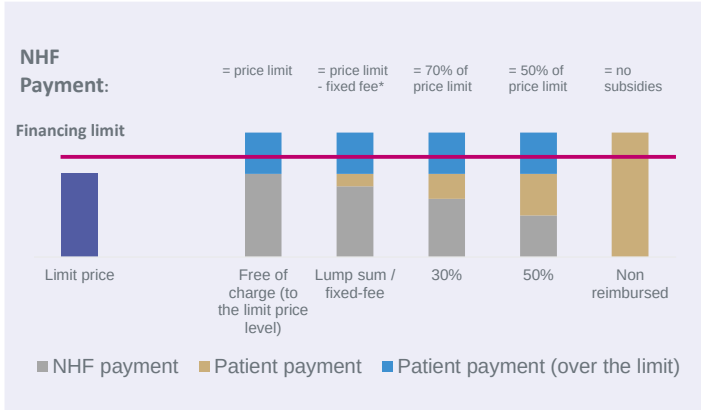
Patient co-payment is calculated based on the price limit & co-payment category

TRP

Patient reimbursement levels: FOC, fixed fee, 30%, 50% (based on therapy duration and monthly patient costs). Difference between the price and limit is paid by patient.

Regular reimbursement



Free drugs for Senior

- NHF payment remains the same as in the case of regular reimbursement
- Patient co-payment is refunded by the Ministry of Health from targeted grants
- Eligible patients (75+, GP prescription) always receive drugs included in the "S" list free of charge

** 3,20 PLN (0,76 EUR) fixed fee for 30 days of therapy or less*

Pricing & Reimbursement rules in a snapshot

CAP ON BUDGET AND PAYBACK MECHANISM

- Cap on drug reimbursement on 17% share of NHF expenses
- Claw back mechanism: to pay back 50% of spending over the limit

TRP LIMIT GROUPS & 4 REIMB. LEVELS

- TRP/Drugs are classified into limit/therapeutic groups
- Limit is the same (per DDD) for all products the group
- Copay at levels: FOC, flat fee, 30%, 50%
- Difference between price and limit is paid by patient
- TRP leads to high patient co-payments

OBLIGATORY PRICE CUTS POST LOE/ FIRST GX

- At least -25% for Original brand at LoE
- At least -25% for first generic.
- In case of reimbursement of the equivalent in given indications, the reimbursement limit is based on this equivalent.
- In case of reimbursement next equivalents, the reimbursement limit cannot be higher than price of the first equivalent

IRP

- Benchmark to 30 EU & EFTA countries
- IRP leads to one of the lowest drugs prices in Europe

FIXED PRICES AND MARGINS

- Prices of reimbursed drugs must be the same across all pharmacies
- Margins are fixed on all levels of distribution
- Prohibition of any incentives & penalization in case of broken rules
- Official price decrease is the only possibility to reduce patient co-pay in limit group

PRICE RE-NEGOTIATED EVERY 2/3 YEARS

- Reimbursement decisions are valid for 2 years for the first two applications and 3 years for the next
- Each reimbursement decision is proceeded by price negotiations

HTA

- Complex & highly demanding HTA process
- HTA mandatory: All comparators from current practice/ Comparative effectiveness for subgroups
- Local epi, QoL data
- Rigid hurdle of C/E threshold = 3 GDP/QALY (130 kPLN)

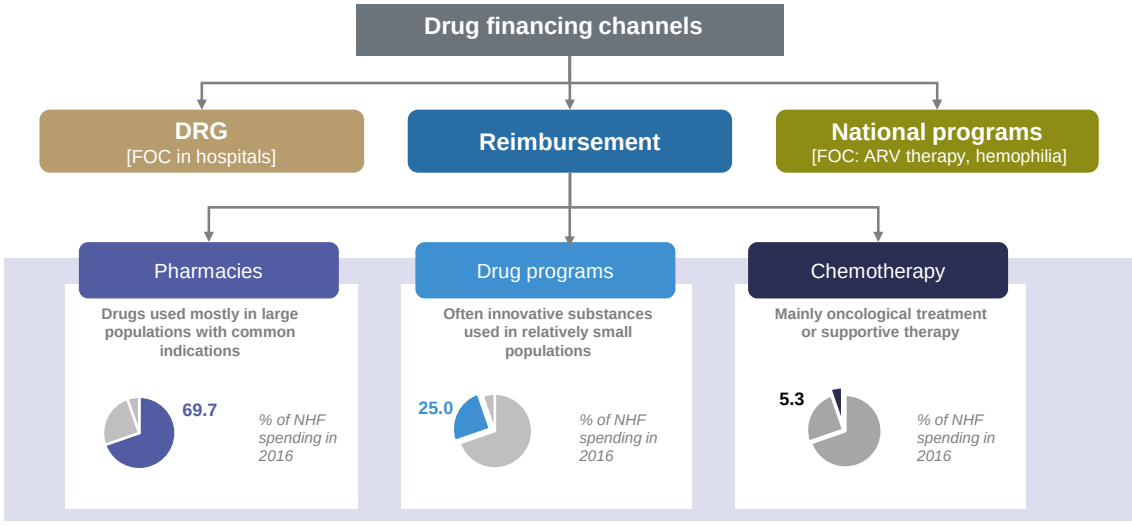
RISK SHARING SCHEMES

- Risk-Sharing Agreements for expensive drugs
- Mainly cost-sharing agreements up till now
- Drugs with RSS not included in Claw back

REIMBURSEMENT ACCRDING TO SMPC OR NARROWER

- MD cannot prescribe drug with reimbursement outside SMPC or outside more restricted reimbursed indications (limited groups are proffered in getting reimbursement)

Funding schemes of medicines in Poalnd



HCS in Poland at a glance

Poland guarantees citizens universal coverage, mainly funded through a mandatory public health insurance contribution levied by NHF

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SYSTEM TYPE

- General health insurance system providing obligatory social insurance to insured citizens
- Government provision and financing of care mostly through employee contributions (9% of gross salary)

FUNDING

- Public: NFZ collects (via ZUS - Social Insurance Institution and KRUS) mainly though mandatory employee contributions
- Private (30%): Mainly OOP payment and employer-based private insurance that covers healthcare.

COVERAGE

- Public insurance covers inpatient & outpatient care for all citizens, incl drugs in hospital & on reimbursement lists.
- Private health sector offers supplementary & complementary coverage.

DELIVERY

- Territorial self-governments have authorities that set policy priorities, resource allocation, service delivery
- Public & private healthcare providers may compete equally for a contract from NFZ to provide health services.

Sources: † United Nations Population Division (UNPD); Δ World Health Organization; ‡ Organization for Economic Co-Operation and Development (OECD)
Notes: OOP = Out-of-pocket; DR/Decision Resources (on-line: www.DecisionResourcesGroup.com

Monday, 6 November
18:15-19:15

- **F2: THE ESTABLISHMENT OF NEGOTIATION COMMITTEE, THERAPEUTIC GUIDELINES AND HTA EFFORTS IN CEE COUNTRIES**

- The objective of this panel is to present the benefits of the negotiation committee and the difficulties in the implementation phase, the criteria in decision making and how it will interact with HTA body. Current decision-making processes for pharmaceuticals will be described, emphasizing in therapeutic guidelines, reimbursement criteria and functions of negotiation committee. Additionally a proposal of the structure and the criteria of the decision making process of an HTA body will be presented.
- The proposal was developed by the ISPOR Greece Chapter Board of Directors in an effort to pave the way for the establishment of HTA process, which can lead to a sustainable health care system. This forum presentation could be also used as a guide by other CEE countries that are currently in the initiation phase of a Health Technology Assessment organization. *Presented by the ISPOR CEE Network*
- **Moderator: Magda Hatzikou, PhD**, Senior Health Economics Manager, Novartis Hellas SA, Athens, Greece
- **Speakers:**
- **Zoltan Kalo, MSc, MD, PhD**, Professor of Health Economics, Eötvös Loránd University (ELTE), Founder & CEO, Syreon Research Institute, Budapest, Hungary
- **Dragana Atanasijevic, MD, MSc**, President, ISPOR Serbia Chapter, and Consultant, HTA & Healthcare Quality Improvement, Belgrade, Serbia
- **Joanna Lis, PhD**, Adjunct, Faculty of Pharmacy, Department of Pharmacoeconomics, Medical University of Warsaw, and Market Access Director, Sanofi, Warsaw, Poland
- **Mary Geitona, MSc, PhD**, Professor, University of Peloponnese, Korinthos, Greece