REIMBURSEMENT SYSTEM UNDER CONSTRUCTION – Poland ver. 2.0

by Jakub Adamski

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Me, myself and I

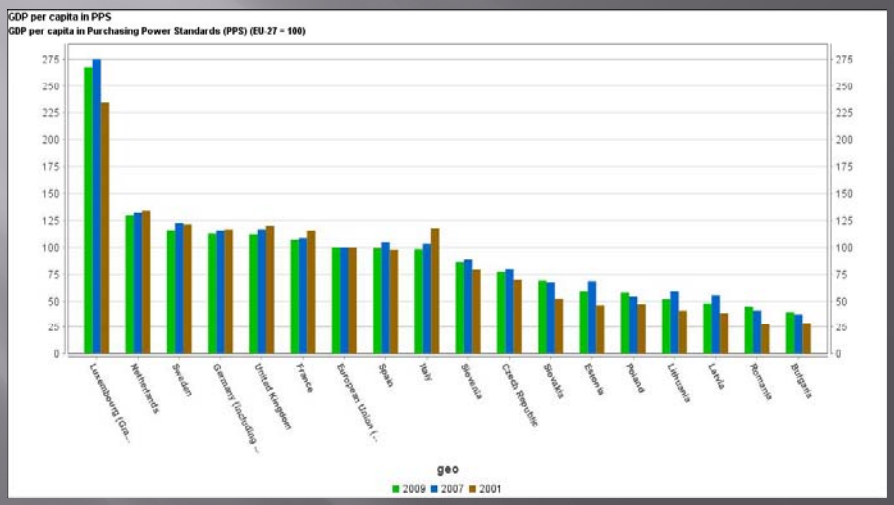
- Lawyer
- Chief Expert at the Ministry of Health
  - participation in European Commission and Council working groups
  - member of the EUCERD
  - coordination of works of the Rare Diseases Team
  - cooperation with pricing agencies of the MS
- Networking (PPRI, PHIS, PIPERSKA)
- Some publications

Overview

- Economic background
- The challange
- The tricky part…
- … in detail

Economic background

Down there? Seriously?

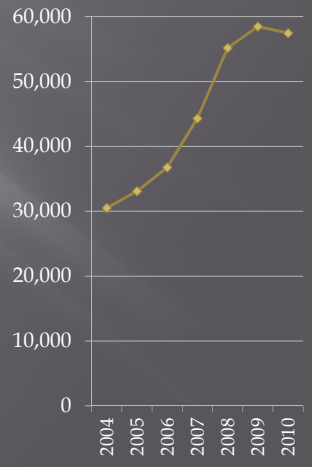


Source: Eurostat

Basic facts…

- Sole national public payer
  - Bismarck system
- Health contribution
  - 9% deducted from salaries
  - ~11% Unemployment rate

NHF expenditure in PLN Mio.



More numbers…

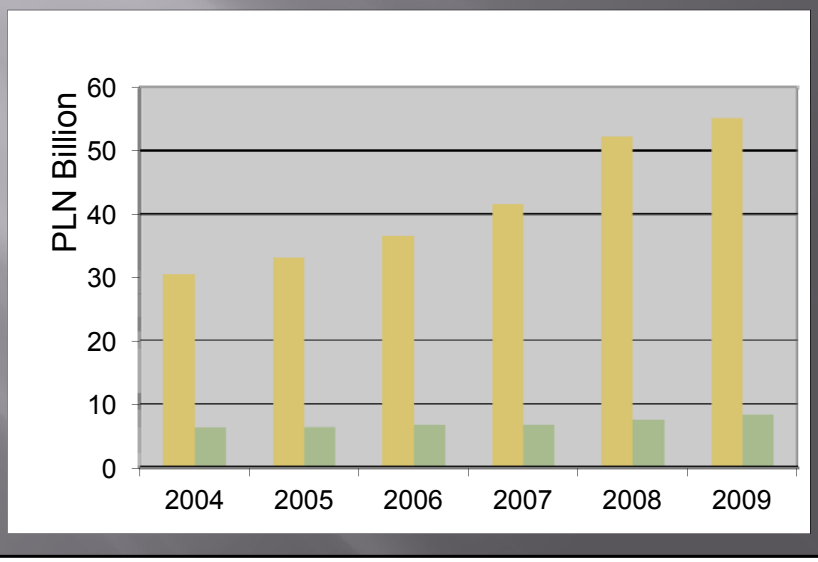
- ~31 bn PLN – value of the pharmaceutical market in Poland in 2011
  - ~4% projected yearly increase 2011-2013
- ~10 bn PLN – public expenditure on drugs
  - 32% – patient co-payment level
- 1 EUR = 4,3 PLN

The other 'why'

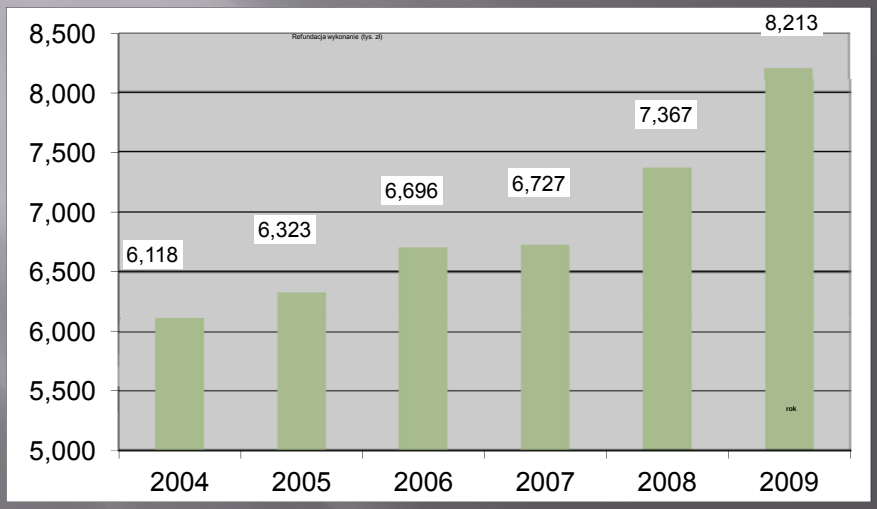
- Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems
- Infringement procedure 2005/4974 since December 2005
  - Reasoned opinion of the European Commission on the implementation of the Directive on 29 June 2007

The challange

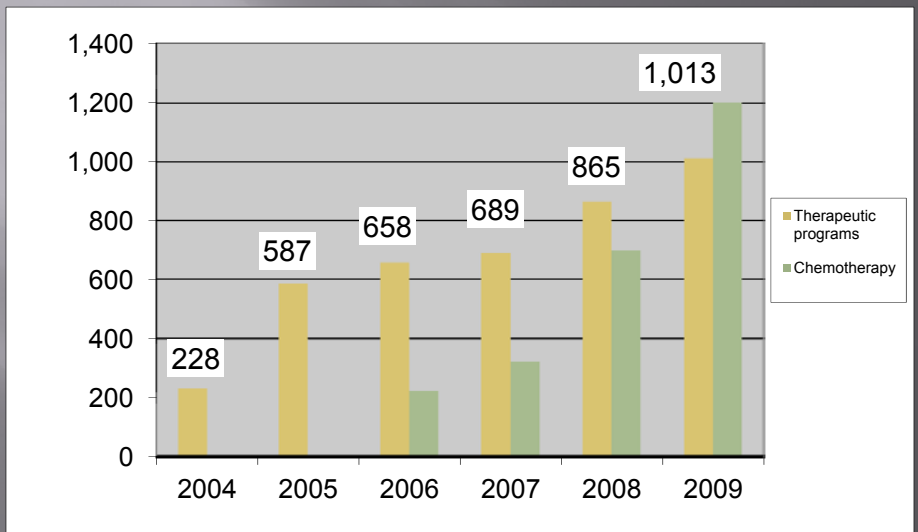
Total reimbursement budget vs reimbursement in pharmacies



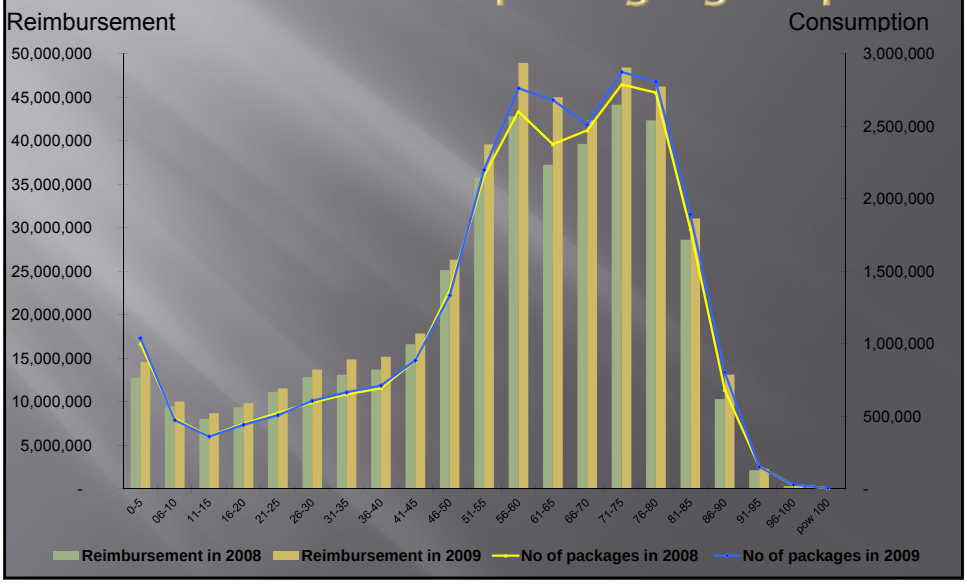
Reimbursement in pharmacies in PLN Mio.



Therapeutic programs vs chemotherapy in PLN Mio.

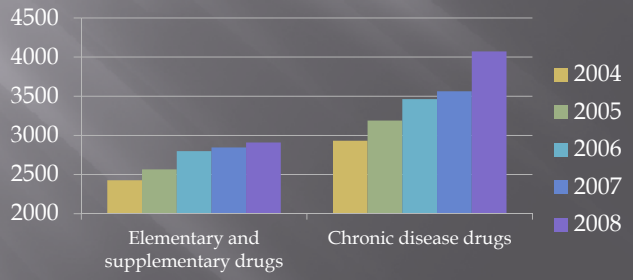


Drug consumption and reimbursement per age groups



More trends…

- Value of the reimbursement is growing
- Share of drugs for chronic diseases is growing fastest
- Highest share of drugs for chronic diseases in the reimbursement value



The question is…

How would you cope with it?

To sum up…

- Actions have to be taken to fully implement the Transparency Directive
  - Court of Justice may impose a fine of up to ***792 k EUR/a day***
- New challanges have to be taken into account
- Patient-oriented approach
- Particular interests of stakeholders have to be considered

And please DO remember that we have limited funds…

The tricky part

It has to be done…

Key aims of the Act…

- To transform the reimbursement system to better answer the patients' needs and diminish the financial burden on them
- To ensure financial sustainability of the system and increase participation of public funds in costs of reimbursable products
- To rationalize the expenditure on reimbursement
- To implement the Transparency Direcitve

Unified and transparent reimbursement procedure

- Pharmacies
  - Drugs
  - Foodstuffs for particular nutricional use
  - Medical devices
- Drug programmes
- Chemotherapy

By way of announcement…

- Instead of 4 reimbursement regulations of Minister of Health…
- Only 1 announcement published every 2 months
- Easier, faster, clearer…

Even more numbers

- More than 4000 drug presentations on the reimbursement lists
- 417 active substances
- 186 active substances in groups with only one brand drug
- 150-200 applications submitted quarterly
- 43 chronic diseases

Reimbursement procedure

- New bodies
  - Economic Commission
  - Transparency Council
- By way of decision
  - Seperate for an every single product
  - Reimbursement criteria in the law
  - Reasoned
  - Appealable

Pharmacy reimbursement

- Reimbursement level criteria
- Limit groups and their bases
- By way of announcement

Suprisingly… reimbursement rates don't change

- Free of charge
- Flat rate
- 50% co-payment
- 30% co-payment

- Surcharge above the limit

Reimbursement level criteria

- Reimbursement level criteria based on cost of treatment to miminum wage for work ratio
- Economic criteria established to:
  - Limit the financial barriers in access to medicines
  - Protect people with the lowest income against the economic effects of an expensive and longlasting therapy

Common limit group

- Drugs with the same INN or different INNs but similar therapeutic effects if they have the same indications in which they are reimbursed and have a similar effectiveness

Reimbursement limit

- To increase patients' access to drugs with a lowest co-payment the reimbursement limit will be based on a drug's marketshare
  - At the moment it is the cheapest drug by default

Cost-containment measures

- Total reimbursement budget
- Negotiations and risk-sharing schemes
- Fixed prices and mark-ups

Price negotiations

- Prices and conditions of reimbursement of all reimburable products are negotiated
- Reimbursement decisons will be made for a limited time only
  - Negotiations will be carried out again every 2-5 years to verift the legitimacy of the reimbursement status and price
- The Choice

Total reimbursement budget

- Poland has one of the lowest expenditure on health care per capita in OECD and one of the highest percentage of pharmaceutical expenditure
- To keep the pharmaceutical budget under control it will be calculated as 17% of total budget for health care services
- This is to ensure sustainable access to other health care services (doctor visits, hospitals treatment)

Pay-back

- In case of exceeding the planned budget responsible entites will be obliged to pay back a part of their reimbursement in proportion to their share in excess spendings
- This sums will be corrected by a multiplier derived from drug's price

Risk-sharing schemes

- The agreements to protect the National Health Fund's budget from excessive or not expedient expenditure
- At the same time these schemes allow for boosted reimbursment of expensive and innovative therapies
- This may include
  - Making the price conditional on sales of a drug
  - Making the reimbursement conditional on effectiveness of a drug
  - Making the statutory ex-factory price conditional on ensuring partial supply of a drug with a rebate
  - Making the statutory ex-factory price conditional on a partial pay-back of reimbursement

Fixed prices and mark-ups

- The Act obliges entities to use exact prices and mark-ups stated in the announcement of the Minister of Health
- This is to protect the National Health Fund's budget from abuses in distribution chain, which lead to uncontrolled increase in prescription and thus to excessive reimbursement

Generic substitution

- Pharmacy is obliged to inform patients that they have a cheaper equivalent drug (priced at the limit price)
- Pharmacy is obliged to have the drug on stock
- Pharmacy is obliged to dispense the drug on a patient's request

Calculation of retail mark-ups

- All drugs in a given limit group will have the same retail mark-up calculated according to a price of drug within the limit
- This is to ensure better pharmaceutical care in pharmacy

And a cherry on top…

- First generic drug to be introduced in a limit group will have to have a price not higher than 75% of the original drug
- When the patent protection is off an original drug has to decrease its price by at least 25% even if no generic drug is introduced

Benefits to patient

- Limiting the economic barrier in access to drugs
- Limiting the economic effects of chronic diseases
- Introduction of cost-minimalization mechanisms
- Allowing for introduction of new pharmaceuticals

And why?

- Medical needs for treatment with innovative technologies
- Inaccessibility of patients to high-cost, innovative drugs
- Impossibility of using reimbursement policy tools like the lists of reimbursed drugs
- Necessity of application of uniform criteria for qualification of patients for a therapeutic program and treatment with innovative technologies enabling to monitor related expenses of the payer
- Special requirements for health care providers (relevant number of specialists or medical facilities etc.)

In-patient care

- The statutory wholesale prices of pharmacy drugs are binding for hospitals
- Maximum margins in the in-patient sector
- Some other maximum prices will be set by way of announcement

The last one

Thank you for your attention

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