STATE INSTITUTE FOR DRUG CONTROL – CZECH MEDICINES AGENCY

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Highly innovative drugs in the Czech Republic:

retrospective analysis of impact on early market entry, regular reimbursement system entry and public pharmaceutical expenditure

Highly innovative drugs - definition

Very severe disease

Unmet medical need

Significantly better clinical effectiveness or safety

Highly innovative drugs – reason

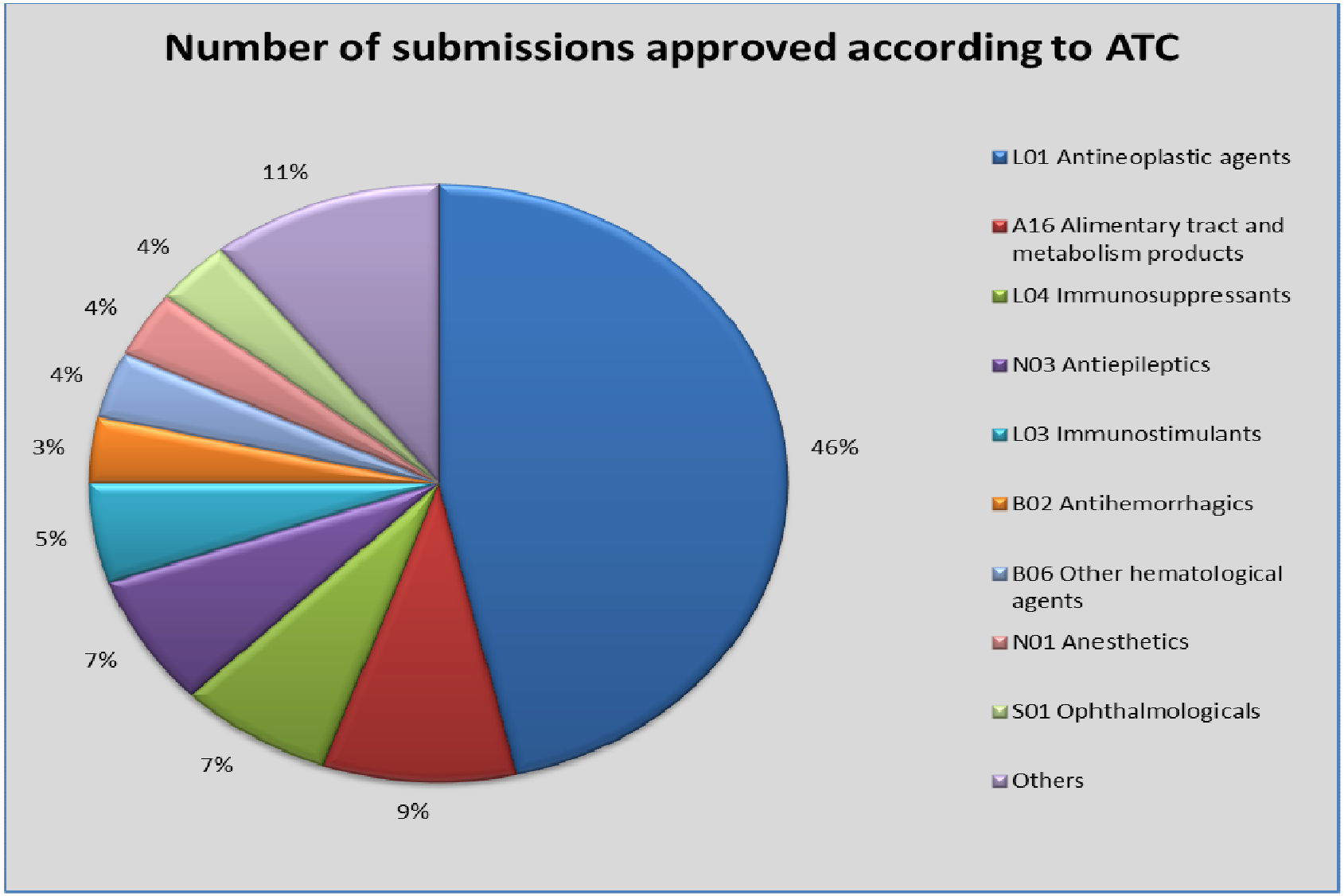
- Early entry to the market
  - Final ICER and budget impact do not play a role in the decision on temporary reimbursement
  - Compulsory agreement between payers and MAH
- Possibility to prove clinical and cost effectiveness
  - More data on effectiveness and safety in real world
  - Payers certainty about the real budget impact
- Patients‘ access to the treatment
  - Often HID are on Czech market earlier than in other European countries
- Meeting the unmet need
  - Can not be taken into account in standard cost effectiveness analyses

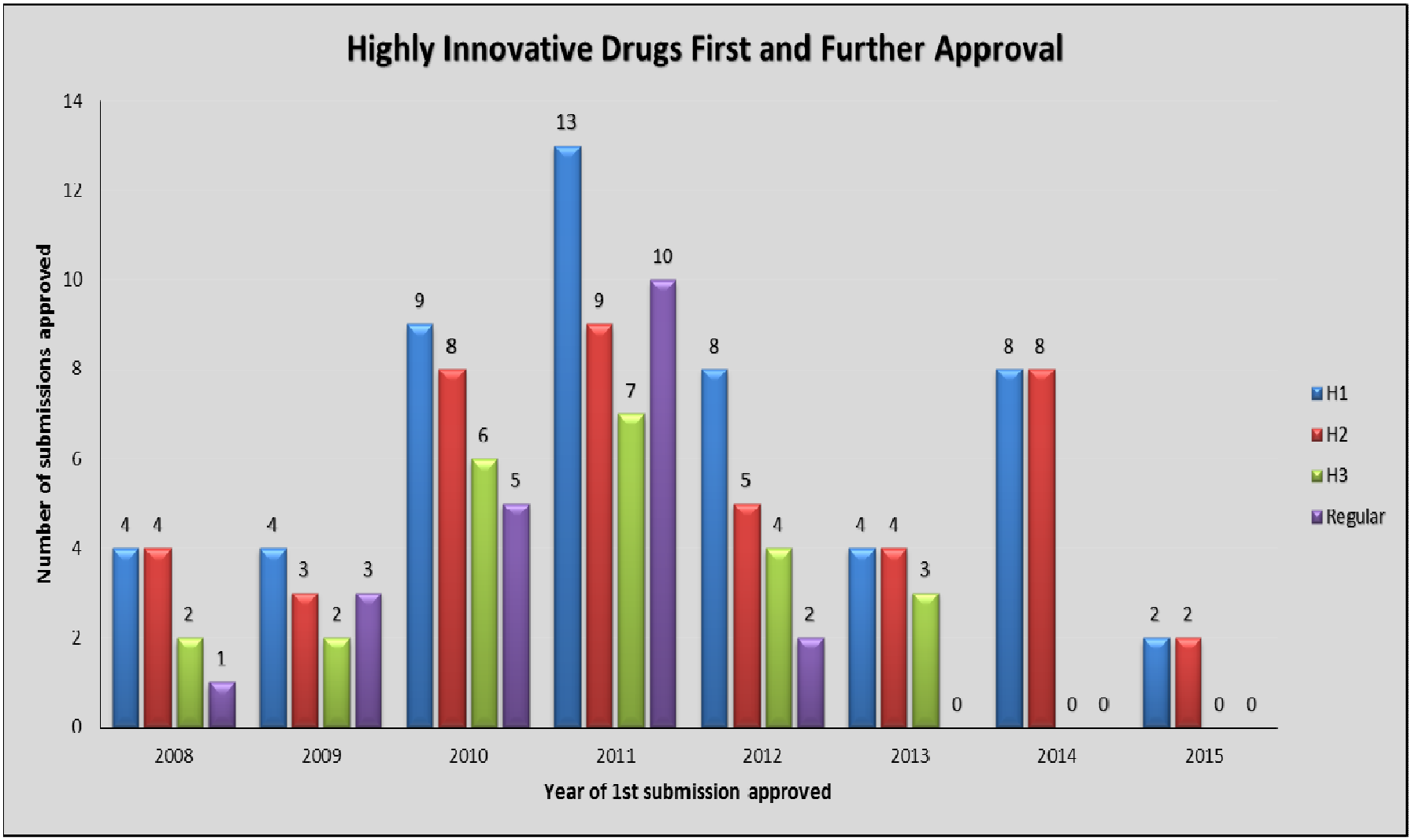
Highly innovative drugs – procedure

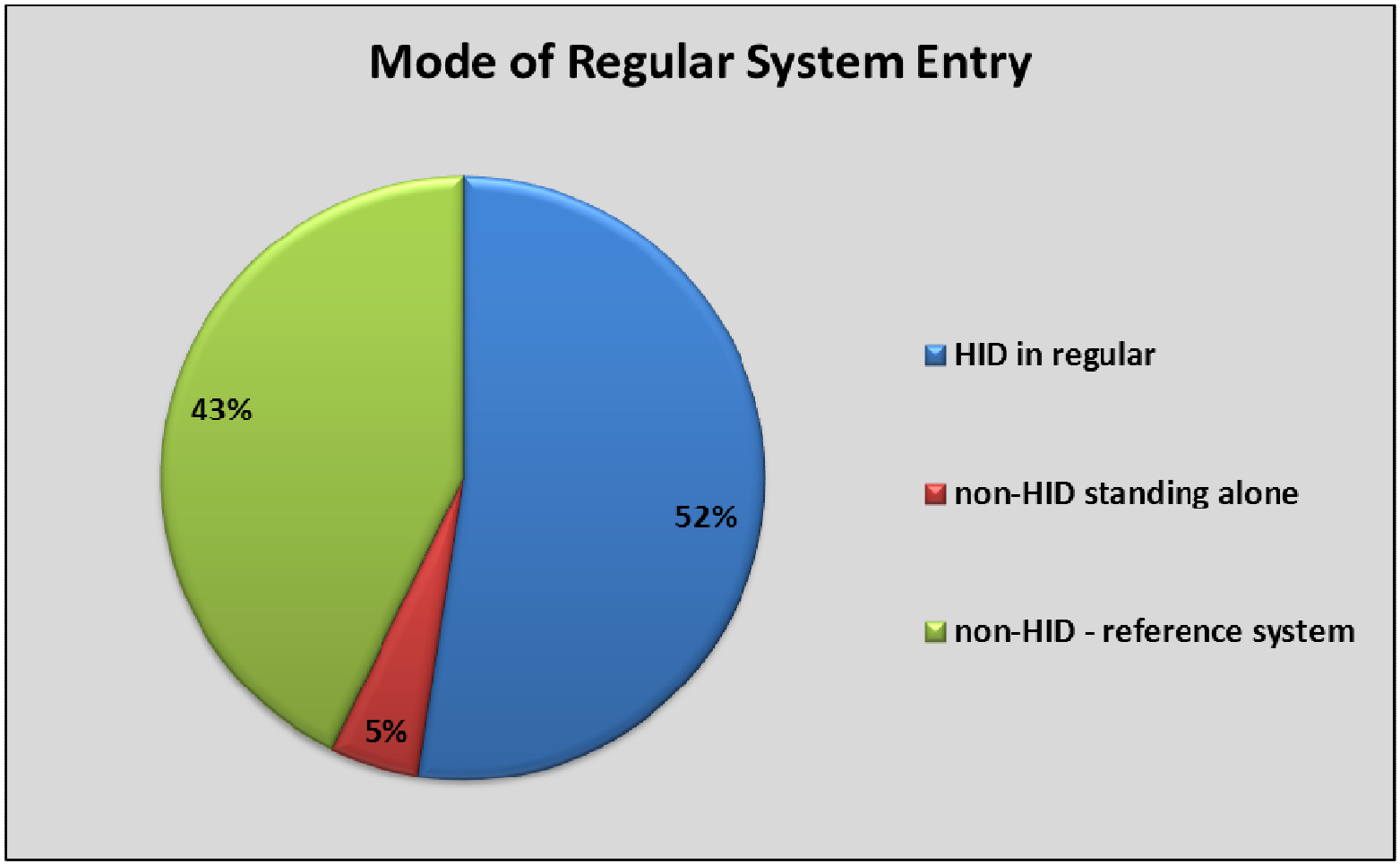
- SUBMISSION – voluntary scheme
- ASSESSMENT – clinical effectiveness and safety, meeting highly innovative criteria
- ASSESSMENT – cost effectiveness and budget impact – without impact on the decision on reimbursement
- APPROVAL - Temporary reimbursement 24 + 12 months
- CLINICAL DATA COLLECTION – mandatory after approval – druh registries
- REASSESSMENT – after 24 months and at time of entry to the regular reimbursement system

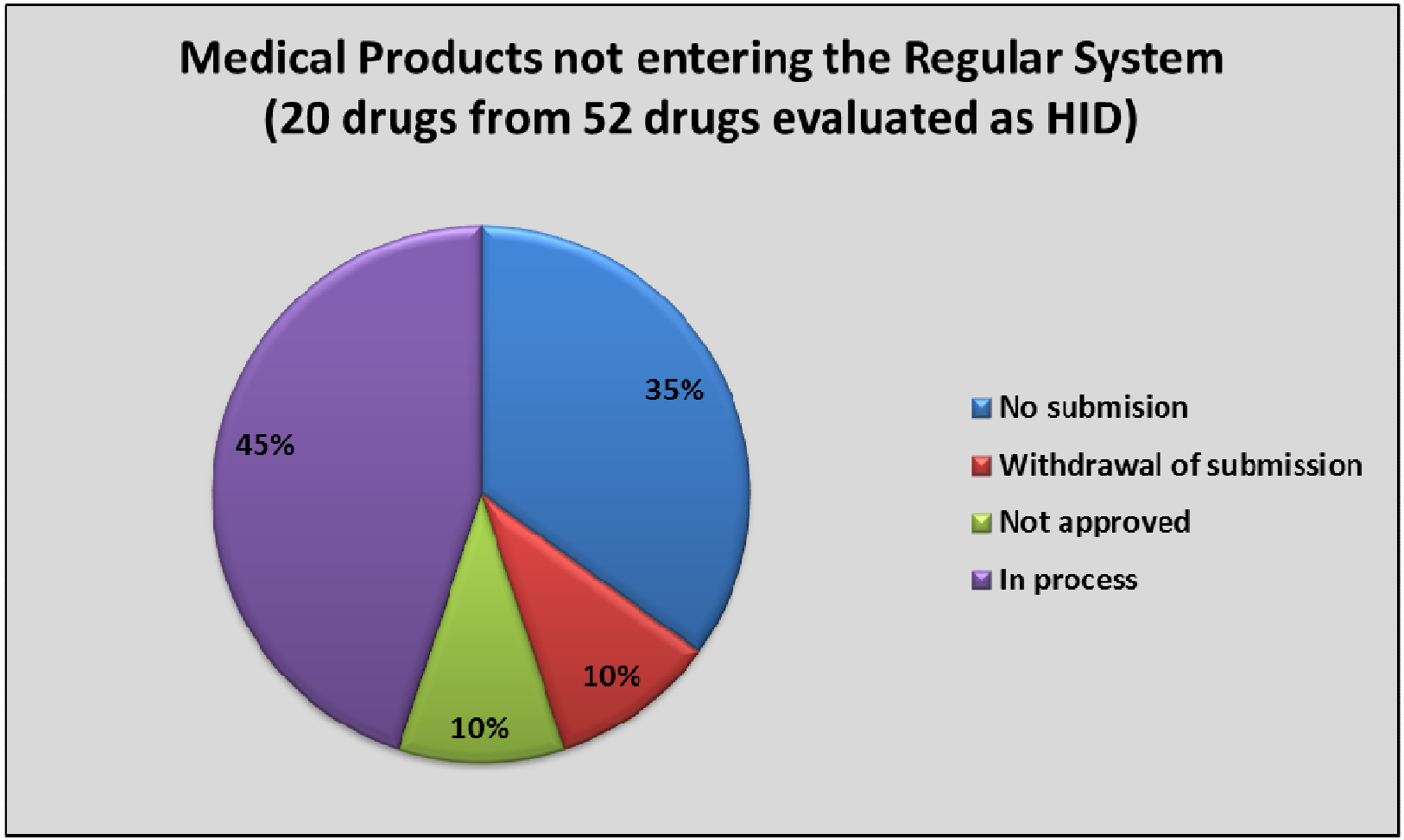
Highly innovative drugs- retrospective analyses

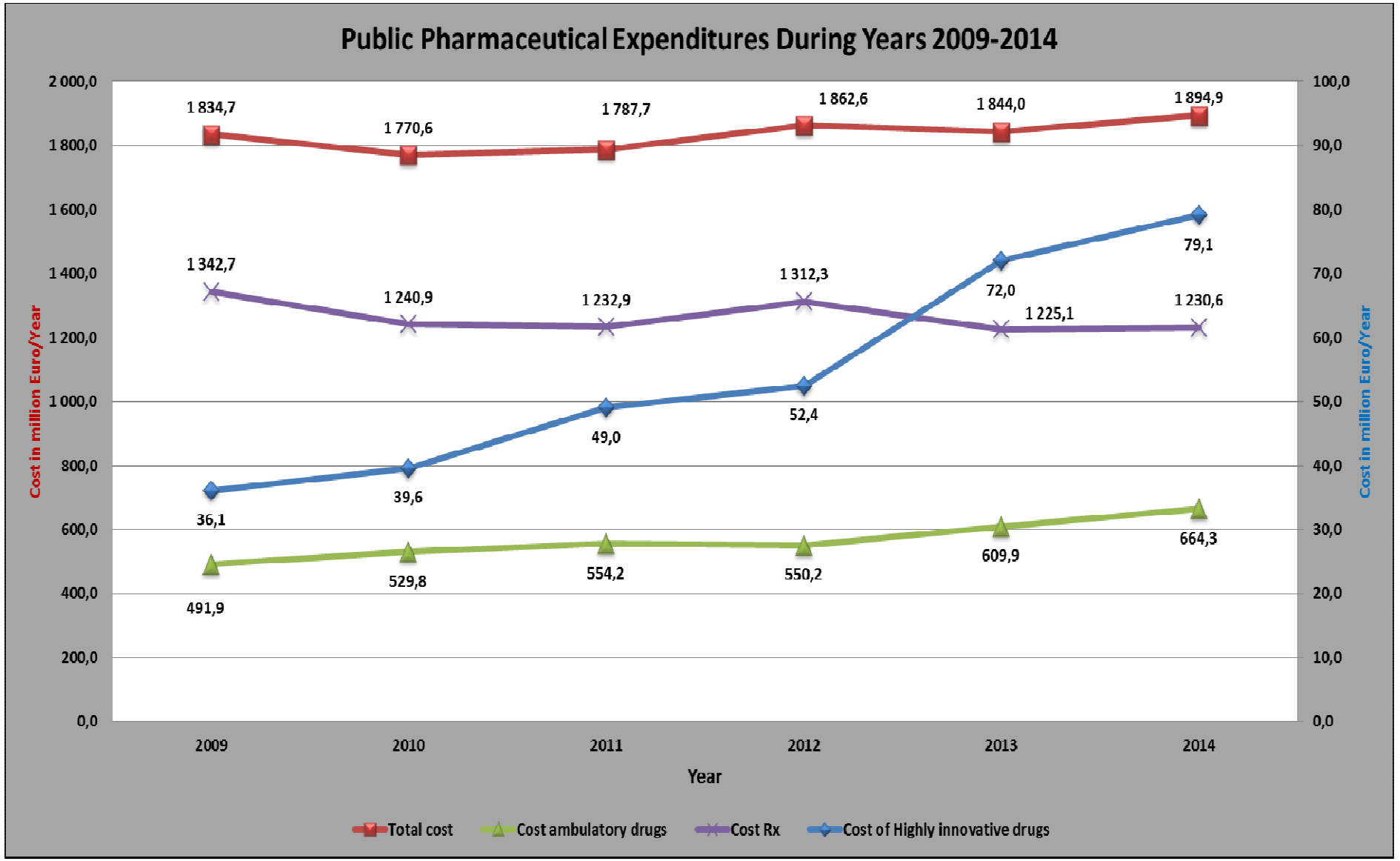
http://www.merule-expert.com/











Highly innovative drugs. vs. orphans

- No specific legislation for orphan drugs
- the term HID does not mean orphan drug
- Many orphan drugs are highly innovative but not all
- Problems with high costs and insufficient real-world data

Pharmacoeconomics - part I

- Mandatory pharmacoeconomic analysis for reimbursement
- Budget impact analysis
- Cost-effectiveness analysis (no WTP treshold set in the Czech legislation)

Pharmacoeconomics - part II

- Temporary reimbursement:
  - usually incomplete analysis (lack of data from real clinical practice)
  - indicative results (not crucial for reimbursement)

- Permanent reimbursement:
  - complete analysis (clinical studies data vs. real clinical data)

Highly innovative drugs - conclusions

- **Early entry to the market**
- **Unmet meed**
- **Highly expensive therapy (between 2009 - 2014 the expenses increased by more than 50%)**
- **Discussion about data from real clinical practice**
  - small number of patients
  - patient registries (ownership of data, differences between clinical studies and registries)

Thank you for your attention

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