EXCEPTIONAL HIGHER ALLOWED PRICE OF MEDICINES IN SLOVENIA. DOES HTA FIT IN?

Eva Turk
National Institute of Public Health, Slovenia
Stanislav Primožič
Agency for Medicinal Products and Medical Devices of the Republic of Slovenia

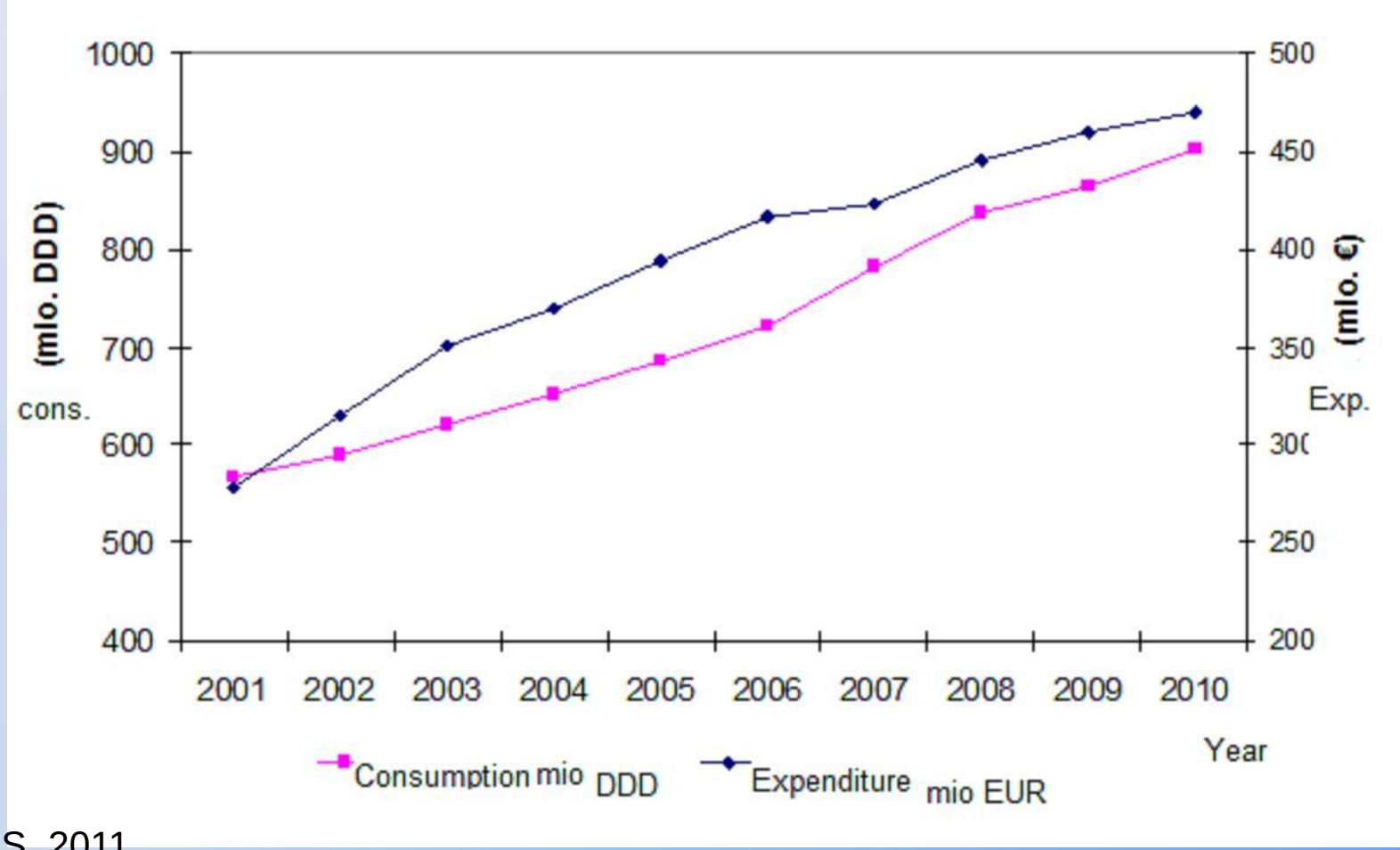
HTAi 2011, June 27-29, 2011

eunethta

General Overview

- The maximal allowed price (MAP) for medicines at the wholesale level is determined by the use of external reference pricing model (AT, FR, DE).
- The regulations define the criteria and procedures for setting the ceiling prices (MAP or exceptional–higher-allowed-price (EHAP)
- Small market, vulnerable; 3429 medicines reimbursed from public budget, 5-15-fold less compared with other EU countries

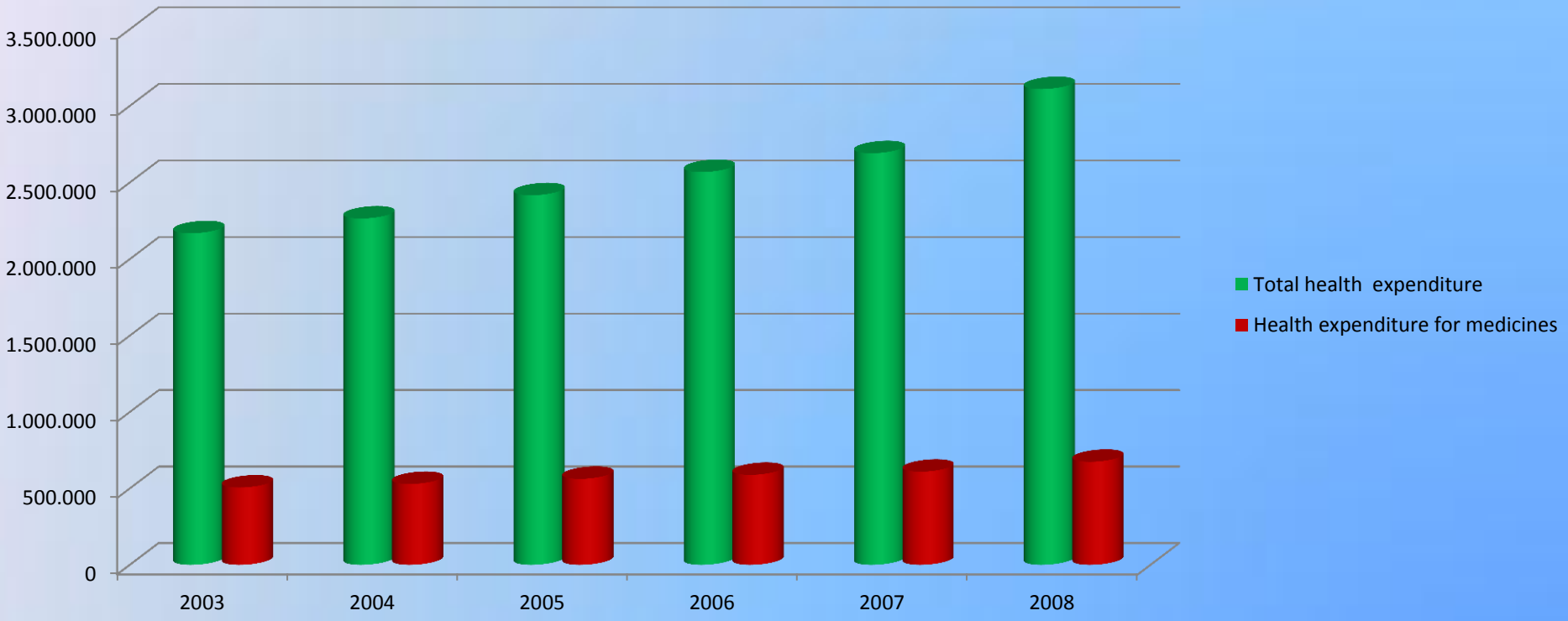
Consumption of medicines in Slovenia



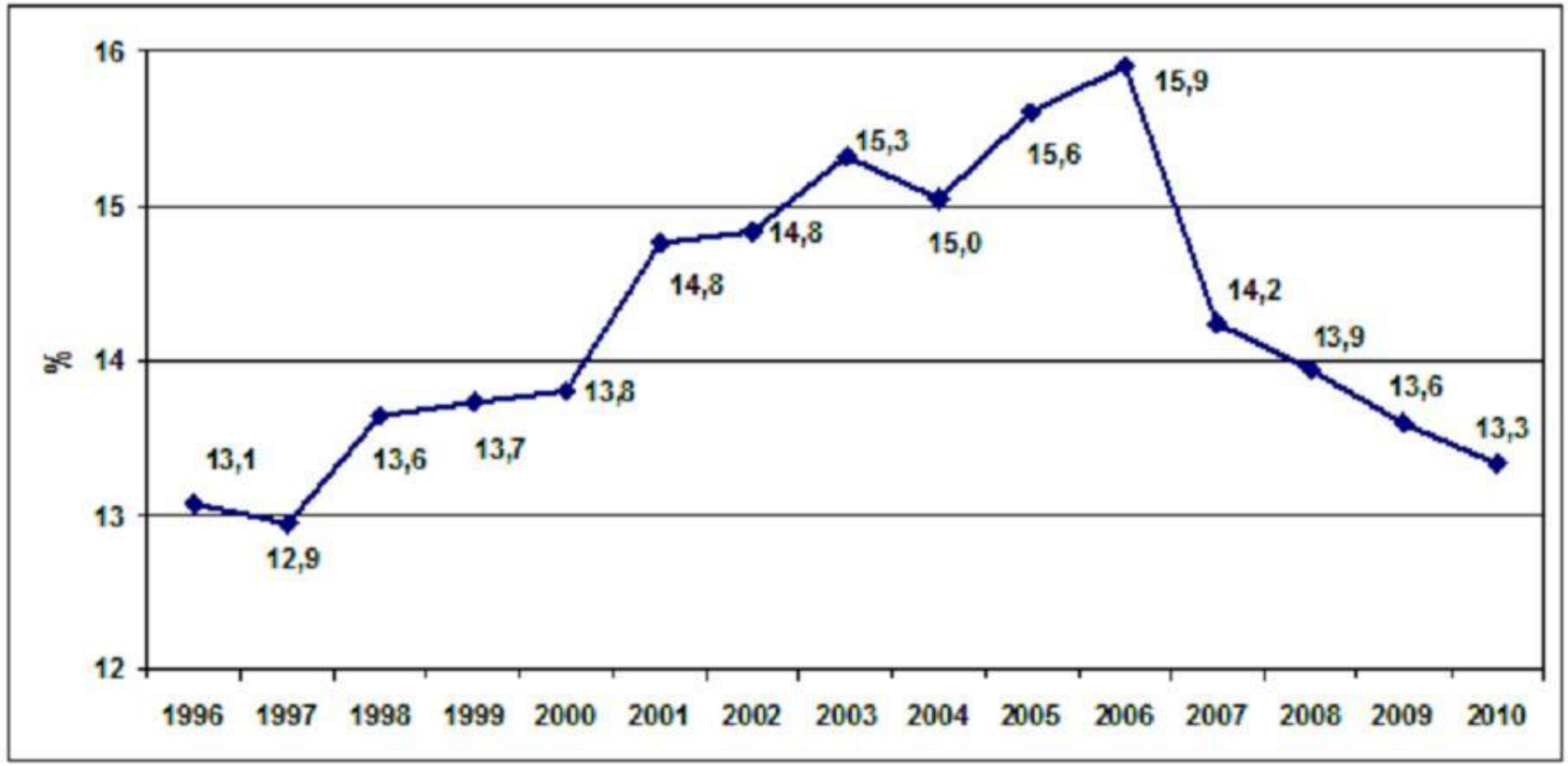
HIIS, 2011

Expenditure for medicines as % of THE

22-23% percent

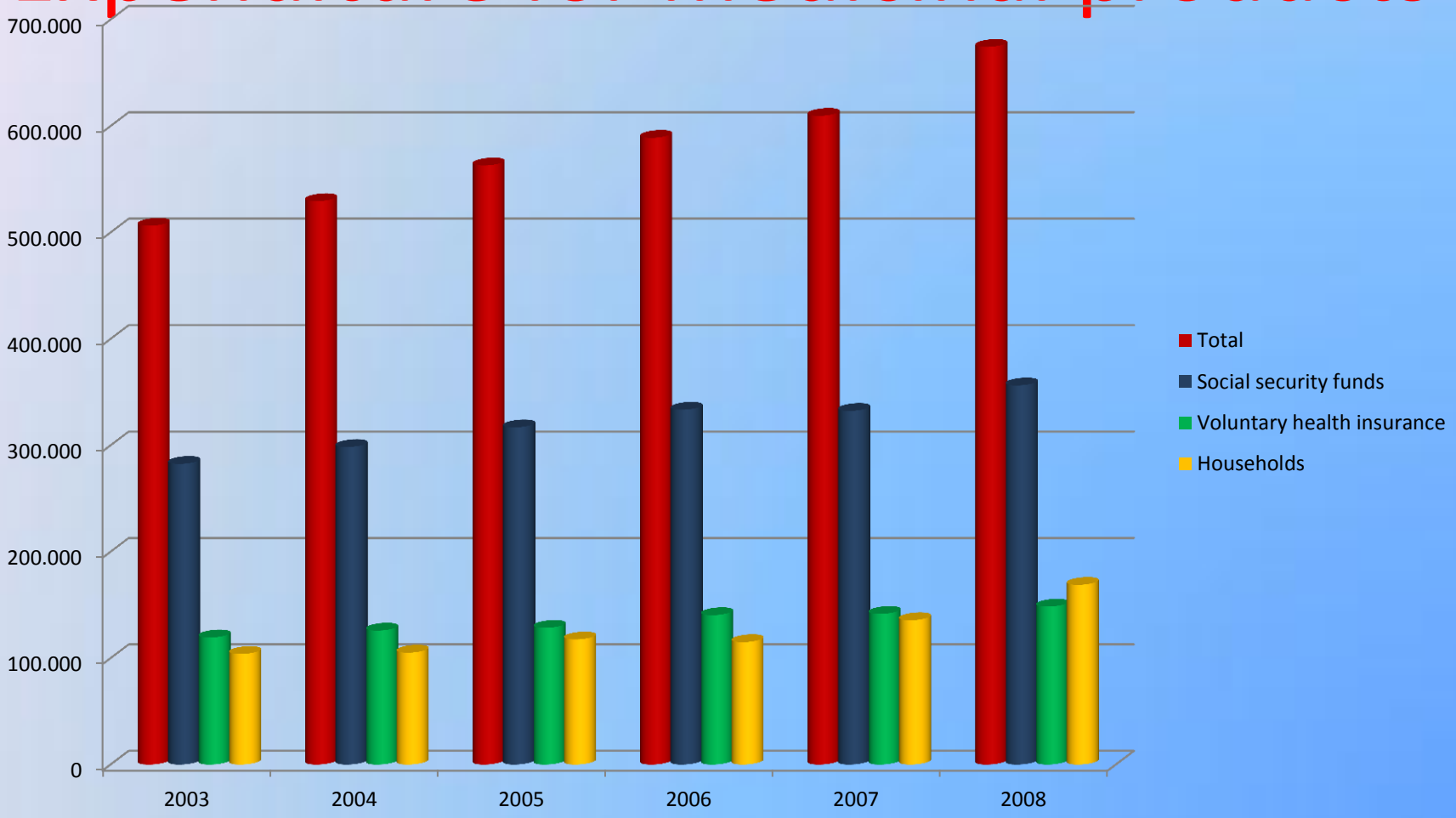


The share of expenditure for medicines out of the total HIIS expenditure 1996-2010



HIIS, 2011

Expenditure for medicinal products



When EHAP?

- The medicine does not have an agreed price between the Health Insurance Institute of Slovenia and the applicant (nor is in a process for reaching an agreement)
- No same active substance, dosage form and same strength, with a lower price than proposed EHAP is on the market
- No treatment with the same therapeutic indication and the same pharmacological mechanism, lower price than the proposed EHAP is on the market
- The value of total annual turnover in all its dosage forms and strengths did not exceed 400,000 € for the previous calendar year (if over 400,000 € - only for medicines where no substitution is possible) ;
- The value of total annual turnover did not exceed 100,000 € in the previous calendar year provided that the value total annual turnover in the preceding year does not exceed growth index of 150 on the annual basis.

An application for an EHAP shall include:

- Justification that the maximum price does not allow supply for the market in Slovenia (including information on the actual costs charged for other medicines and as a basis for claiming an EHAP);
- Information calculating maximum wholesale price of medicines- B1 form
- Calculation of the proposed EHAP- B2 form
- Information on sale of this medicine in Slovenia for the last 3 years
  - to file an application with the medicines on the market a shorter period than requested, or just coming on the market, indicating the expected sales volume;
- Data on producer prices and wholesale prices of the same medicine publicly funded in other EU Member States and EEA – B3 form
- Pharmacoeconomic analysis and/or Budget impact analysis, based on Slovenian data or economic evaluationa from EU MS which can be applied to Slovenia
- Assessment of relative therapeutic value of appropriately designed or pharmacoepidemiological data include the relevant data for Slovenia;

If the medicine does not exceed 50,000 € per year during the previous calendar year, no economic evaluation needed.

A	ZAVEZANEC:								Številka izdaje:					
B	ZADEVA:	OBRAZEC B2 ZA IZRAČUN IZREDNE VIŠJE DOVOLJENE CENE ZDRAVILA NA DEBELO							Lauer-Taxe - CD ROM					
C									Lauer-Taxe - spletni vir (datum vpogleda)					
D									Vidal CD - ROM					
E		Datum priprave podatkov:							Erstattungskodex (publikacija ali spletni vir)					
F									Warenverzeichnis (spletni vir)					
1	Šifra zdravila	Lastniško ime predlaganega zdravila, jakost, oblika in pakiranje	ATC	Število osn.enot	Veljavna IVDC	Originator - Generik	Primerj.cena na osn.enoto	Primerjalna cena	Odstotek primerj.cene	PEC	Delež veletrgov. %	Predl. IVDC	Index	Datum prisotnosti na trgu
2	1	2	3	4	5	6	7	8=7*4	9	10=8*9/100	11	12	13=12/5*100	14
3														

4	*Primerjalna država*	*Lastniško ime primerjalnega zdravila, jakost, oblika in pakiranje*	*Število osn.enot*	*Cena iz publikacije*	*Primerjalna cena **	*Primerjalna cena na osn.enoto**
5	16	17	18	19	20	21=20 / 18
6	Avstrija 1					
7	Avstrija 2					
8	Francija 1					
9	Francija 2					
10	Nemčija 1					
11	Nemčija 2					

B2 form

Legenda:

PEC - proizvajalčev element cene zdravila na debelo

NDC - najvišja dovoljena cena zdravila na debelo

* podatek za primerjalne države

Podpis odgovorne osebe:

NAVEDBA CEN ZDRAVILA V DRŽAVAH ČLANICAH EU/EGP OZIROMA V DRUGIH EVROPSKIH DRŽAVAH

Zavezanec:

Datum (dd.mm.LLLL):

Ime zdravila in pakiranje:

Delovna šifra:

Tabela a. Cene v državah članicah EU/EGP

DRŽAVA ČLANICA	proizva-jalčeva cena EUR	cena na debelo EUR	štev. enot*	količ.promet v 000 enot	opomba***
Avstrija					
Belgija					
Bolgarija					
Ciper					
Češka					
Danska					
Estonija					
Finska					
Francija					
Grčija					
Irska					
Islandija					
Italija					
Latvija					
Lihtenštajn					
Litva					
Luksemburg					
Madžarska					
Malta					
Nemčija					
Nizozemska					
Norveška					
Poljska					
Portugalska					
Romunija					
Slovaška					
Slovenija					
Španija					
Švedska					
Združeno kraljestvo					

Tabela b. Cene v drugih evropskih državah

DRŽAVA	proizva-jalčeva cena EUR	cena na debelo EUR	štev. enot*	količ.promet v 000 enot	opomba***
Albanija					
Andora					
Belorusija					
Bosna in Hercegovina					
Črna gora					
Hrvaška					
Kosovo					
Rep. Makedonija					
Moldavija					
Monako					
Rusija					
San Marino					
Srbija					
Švica					
Turčija					
Ukrajina					
Vatikan					

B3 form

* število odmernih enot v pakiranju

**aktualni letni količinski promet z zdravilom izražen v 000 prodanih enot-pakiranj zdravila

***zaporedna številka opombe; morebitne opombe zavezanci podajo na posebnem listu z označenimi zaporednimi številkami

Composition of EHAP Commission

- 12 experts (8 pharmacists, 2 MDs,2 economists) from:
  - Health insurance institute (3)
  - MoH
  - Agency for medicines and medical devices (2)
  - University clinical centre (2)
  - National institute of public health
  - Faculty of Pharmacy
  - General hospital
  - Health centre

Criteria defined

- The Commission's opinion to determine the EHAP
- public interest in health
- risk assessment for potential disruptions in supply of the drug with the economic rationale
- Decision valid for max 1 year (and then re-application)

Elements of HTA

Scoring 1-5

- Relative therapeutic value
- Cost-effectivenes (compared to other treatments)
- The balance of the proposed EHAP with prices in other EU countries, ie. Relevance
- The existence of specific factors important for the placement of the medicine into national health program

Is this good enough?

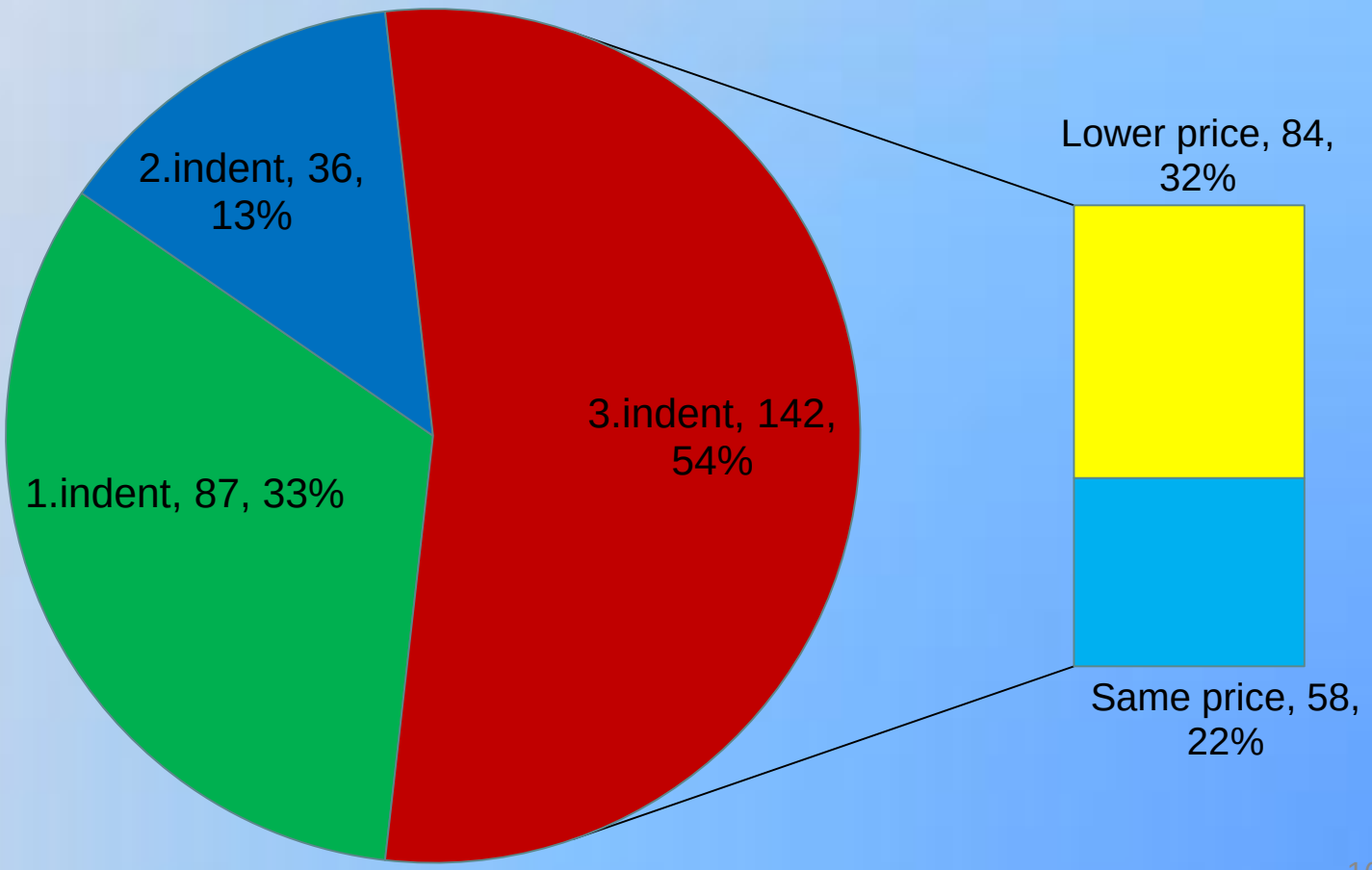
Possible recomendations of the commission of EHAP application:

- positive opinion, the proposed EHAP as proposed in the application
- positive opinion, however suggesting EHAP, lower than proposed in the application- using the algorithm
- negative opinion

Decision from the Agency includes:

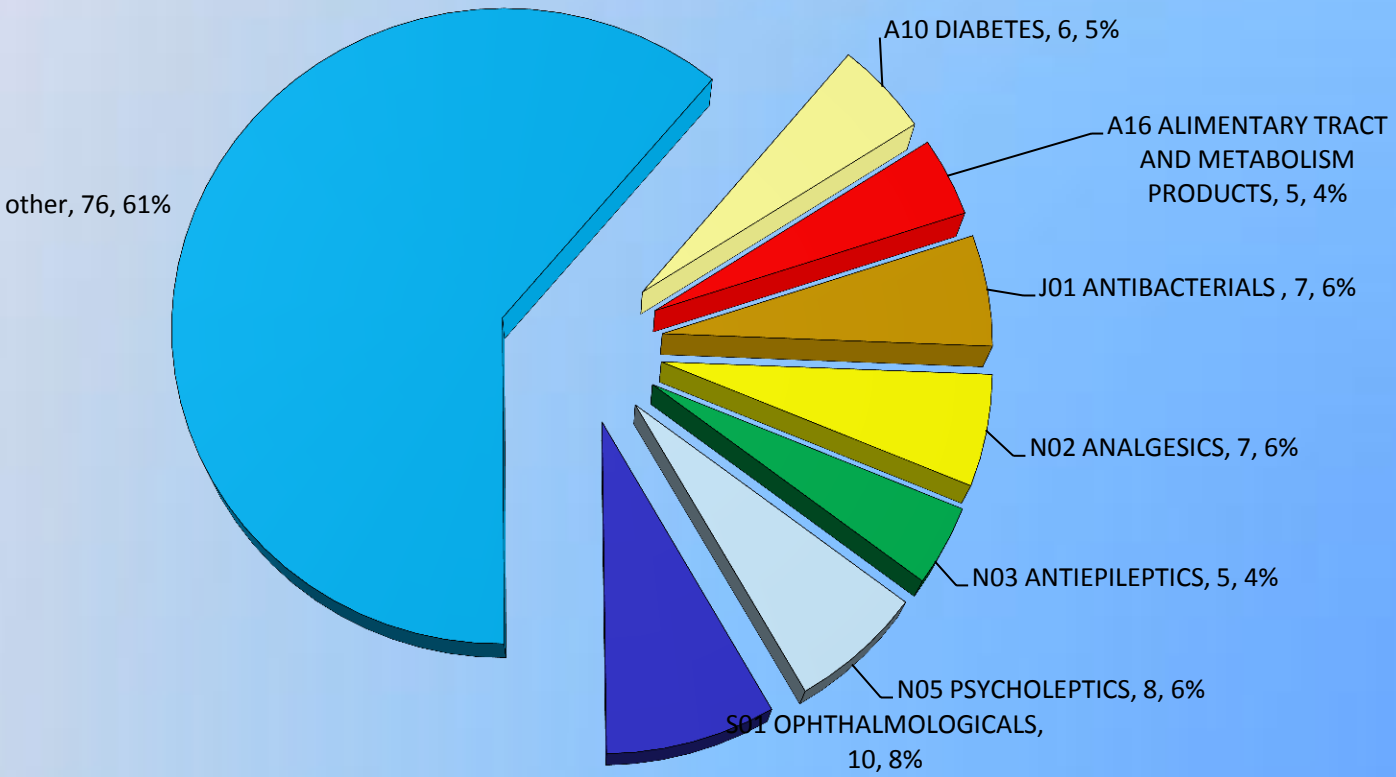
- determined EHAP
- Start of EHAP validity
- The period of validity of the price
  - up to 1 year, average: 9 months
- No extension of EHAP possible
- The new application should be made at least 3 months before the expiry

Granted EHAP



Number and % of active substaces on the 2nd ATC level with EHAP, 2010

Nr of active substances in EHAP: 123



Oražem, 2010

HTA in EHAP?

- Some elements of HTA present
- Well defined criteria?

But

- 70% of the applications incomplete (Almost no pharmacoeconomic evaluation; added therapeutic value rarely reported)

Thank you

Eva.turk@ivz-rs.si

eunethta