

Experience with external reference pricing in the Czech Republic

LENKA VOSTALOVÁ



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I hereby declare that in connection with that presentation, which I am author (co-author), I have no conflict of interest.



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Former status

Pricing






-  Ministry of Finance
-  Administrative proceedings
-  Published in price decree

Reimbursement

-  Ministry of Health
-  Categorization Committee
-  Decree on level and conditions of reimbursement

Current status - since January 2008:

Pricing and reimbursement

-  State Institute for Drug Control (SUKL)
-  Individual administrative proceedings – individual decisions
-  Fixed time limits
-  Possibility of appeal – Ministry of Health, administrative court
-  Pricelist of reimbursed pharmaceuticals updated monthly – incl. decisions made in previous month

External reference pricing is the basis for setting price limits of medicines and is used during decisions on reimbursement

Price regulation – Ministry of Health

Price decree valid since 20.3.2009

Reimbursable pharmaceuticals – regulated by:

- ☞ Maximum ex-factory price and degressive mark-up (topmost limits, real ex-factory prices and applied mark-ups can be lower)
- ☞ Only degressive mark-up: for ATC groups listed in price assessment (sufficient self-regulation of the market)


Non-reimbursable pharmaceuticals – no price regulation



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Price regulation – SÚKL

Defines maximum ex-factory price (topmost limit) – external reference pricing

- 
- ☞ Average of at least 3 ex-factory prices in reference basket countries (Estonia, France, Greece, Hungary, Italy, Lithuania, Portugal, Spain)
 - ☞ Company has an option to apply for the use of the lowest price of the generic instead of one or more prices
 - ☞ Average of the 3 lowest ex-factory prices in all EU countries
 - ☞ Ex-factory price of similar (therapeutically interchangeable) product in the Czech republic or EU



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Price regulation – comparison of prices for one product

[7]

- výpočet maximální ceny výrobce -

| země | ref. koš | datum | účinná | ATC | výrobce | silu | počet | cena | cena | cena | směnný | Alternativa | cena |
|----------------|----------|-----------|-----------|---------|---------|-------|----------|----------|-----------|------------|------------|-------------|--------------|
| | | | | | (kg) | (nebo | jednotka | Nalezená | výrobce | výrobce na | kurz (III- | (s) | výrobce |
| | | | | | | gener | k | cena | (balení, | jednotku | V/2008) | | (balení,nár. |
| | | | | | | | | | (kg) | (kg) | | | (m.) |
| Belgie | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 25,126 |
| Bulharsko | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 12,846 |
| Dánsko | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 3,368 |
| Estonsko | ano | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 1,606 |
| Finsko | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 25,126 |
| Francie | ano | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 25,126 |
| Holandsko | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 25,126 |
| Irsko | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 25,126 |
| Itálie | ano | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | 139,420 | 2122,54 | 2122,54 | - | 84,48 |
| Kyp | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 25,126 |
| Litva | ano | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | 270,450 | 1846,77 | 1846,77 | - | 253,78 |
| Lotyšsko | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 36,013 |
| Lucembursko | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 25,126 |
| Maďarsko | ano | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | 39502,000 | 3910,70 | 3910,70 | - | 39502,02 |
| Malta | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 25,126 |
| Německo | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 25,126 |
| Polsko | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 7,264 |
| Portugalsko | ano | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 25,126 |
| Rakousko | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 25,126 |
| Rumunsko | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 6,844 |
| Řecko | ano | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | 164,810 | 2596,83 | 2596,83 | - | 103,36 |
| Slovensko | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 0,783 |
| Slovinsko | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 25,126 |
| Španělsko | ano | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | 171,680 | 3019,57 | 3019,57 | - | 120,18 |
| Švédsko | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 2,684 |
| Velká Británie | ne | 14.7.2008 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | - | - | - | - | 31,905 |

AVERAGE OF EX-FACTORY PRICE IN REFERENCE BASKET COUNTRIES § 39a, (2), a) - průměr alespoň 3 zemí referenčního koše

Přifazení nebyl použit záměnitelný přípravek dle § 39a, odst. (2), a)

Identifikace přípravku

| alternativa | nová | kód | silu | ATC | výrobce | název | silu | jednotka | datum | vyvoztě | max. cena/kg |
|-------------|------|---------|-----------|---------|---------|-------|------|----------|-----------|---------|--------------|
| ne | ne | 0076204 | pacitaxel | L01CD01 | XXX | YYY | 30 | 1 | 14.7.2008 | Konečný | 2699,30 |



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Reimbursement regulation – SÚKL

Determines reimbursement price according to:

- The lowest EU-price = ERP
- Costs of other comparably effective (pharmaco)therapy = IRP (if lower than ERP)
- The price agreed between the manufacturer and the insurance company (if lower than previous mechanisms)
- The price resulted from price tender (if lower than previous mechanisms)



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Reimbursement price

- 👉 The same for one reference group – more products assessed together
- 👉 The lowest EU-price for daily therapeutic dose (or the average of 3 subsequent lowest prices)
- 👉 Prices searched in all EU countries (except MT)
- 👉 Guaranteed full reimbursement for at least one product in each the group defined by law -IRP

Common features in pricing vs. reimbursement regulation

- The same sources of information about prices in the EU
- The same deviation range of the pack size (deviation of $\pm 10\%$)
- The same exchange rate for conversion of prices to CZK

Challenges associated with ERP

- Product identification (brand names, marketing authorization holders, packages)
- Easier to search according to ATC code if possible

| COUNTRY | NAME OF PRODUCT | PACKAGE |
|----------------|--------------------|-----------------------------|
| CZECH REPUBLIC | PRESTARIUM NEO | POR TBL FLM 30X5MG |
| DENMARK | COVERSYL NOVUM 5MG | 30 STK |
| BELGIUM | COVERSYL 5 MG | 30 COMPRIMÉS PELLICULES x 5 |
| FINLAND | COVERSYL NOVUM | 30 TBL |

Challenges associated with ERP

- Validity of data and accuracy of calculations
 - EE – ministry – ACTOS TBL 15MGN28 – price 30,38 €
 - EE- raviminfo.ee -Pharmacy No.1 – price 35,95 €
-Pharmacy No.2 – price 35,25 €
- Product e.g. TRAMAL RETARD TBL 150MG N10 price found on commercial web site but not in ministerial database

Challenges associated with ERP

- Data updating and retention (web databases)
- Unable to prove the price at a later stage
- Frequent changes of foreign list prices (weekly, bi-weekly, monthly)

Challenges associated with ERP

- Price definition (price limits x real prices x reimbursement prices)
- discrepancy between the list price and real price on the market (tendency to adjust the real price to the reimbursement level – lower co-payment)

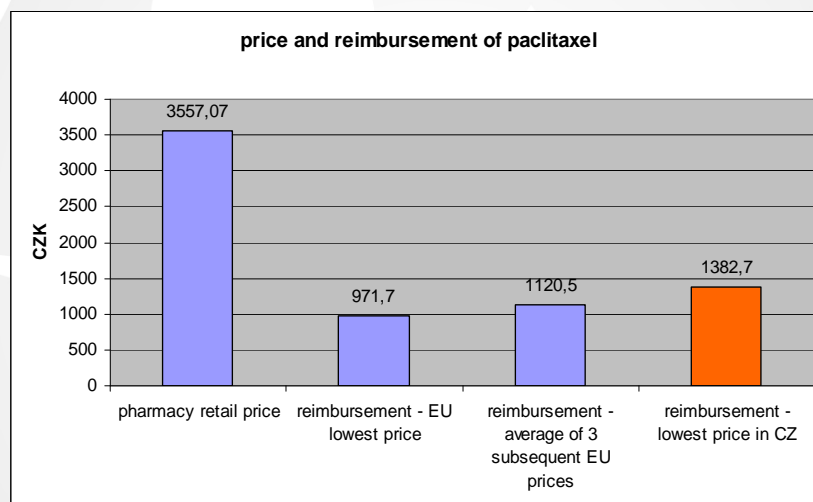
Challenges associated with ERP

- Relevant and comparable data (time-limited price discounts, direct-to pharmacy distribution, availability of the product on specific market)
- different pricing systems (price tenders - NL, free pricing – DK, SE)
- Price is listed, but the product is not actually traded

Advantages of ERP

- 👁️ Transparent way of price regulation
- 👁️ Predictability
- 👁️ Possibility to submit evidence (manufacturer, insurance fund)
- 👁️ Prevention of unjustified and very high prices

Specific situations – reimbursement increased by IRP [18]



Specific situations – anti-TBC therapy

- ☉ Law: EU-lowest price
- ☉ Reality: EU-lowest price = co-payment

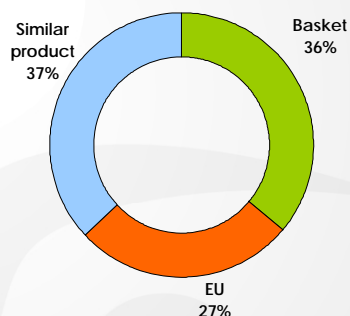


full reimbursement of anti-tuberculosis therapy
in accordance with the WHO
recommendation

Revision of maximum price limits in 2008 – process

| | |
|--|---|
| total amount of reimbursable pharmaceuticals | 8566 |
| regulation by maximum ex-factory price | 4112 |
| number of pharmaceuticals in the revision | 3937 1114 price increase 2823 price reduction |
| number of re-evaluated pharmaceuticals | 1669 |

How was price decided?



Revision of maximum price limits in 2008 - results

- Lowering prices of almost 3000 products
- Savings 113,5 million € from final decisions

Revision of reimbursement (still ongoing)- results

0. revision 2008-2009 (3 reference groups)

- 24,3 million € from finally decided revisions

1. revision 2009-2011 (303 reference groups + 572 active substances)

- 206,8 million € from finally decided revisions
- 141,9 million € from unfinished revisions

Overall estimated savings: 348,7 million €

Plans for the future – price regulation

- Widened reference basket (all EU countries except CZ, BG, EE, CY, LU, MT, DE, AT, RO)
- Maximum price set as:
 - an average of 3 lowest prices in reference basket
 - According to an agreement between MAH and the payer (new option)
 - Ex-factory price of similar (therapeutically interchangeable) product in the Czech republic or EU

Plans for the future – reimbursement regulation

- Streamlining of price tenders – price tenders for one molecule, 100% reimbursement for the winner, 75% reimbursement for all other pharmaceuticals (co-payment)
- Introducing the possibility of risk sharing schemes