

Update on changes in SLOVENIA

Sharing of Information: Experience from Member States

Stanislav Primožič
Head, Sector for Pharmacoeconomics

PPRI 5th Coordination Meeting
Vienna, AUSTRIA, 28th June 2007

Changes in Pricing

April 2006: **Medicinal Products Act**

- Section on Pricing of Medicinal Products

Development of **Pricing Bylaws:**

- Sep 2006: Pricing Rule Amended (minor change)
- Jan 2007: New Pricing Rule Adopted (major change)
- Apr 2007: Changes Implemented

Concepts of the new Rule on Pricing

- Transparency and simplification of pricing procedures
- Principal division among MPs: access to public funds
 - with access: prices regulated
 - w/o access: free pricing with reporting of prices
- Cost-containment orientation
- Assure additional savings of public funds
- Increase the capacity of the public/private funds to adopt high-tech-high-cost new medicines
- Elements of reward for innovation – increasing competitiveness *among* generics

Structure

OGRS, No. 6-232/2007, p. 585

Date of Publication: 23.1.2007

Date of Entry into Force: 24.1.2007

Structure:

I. Body Text: 18 articles, 8 chapters

II. Anexes:

Annex 1 Notification Forms (obrazec A and B)

Annex 2 Factors for price structure calculations from external publications

Annex 3 Table for wholesale price calculation

Contents

- I. GENERAL PROVISIONS
- II. FIRST NOTIFICATION/FORMATION OF MP PRICE
- III. CRITERIA FOR PRICE FORMATION AND PRICE COMPARISONS
- IV. ADJUSTMENT AND CHANGES OF MP PRICES
- V. MINISTER'S CONSENT TO PRICES BEYOND EXTERNAL REFERENCING CRITERIA
- VI. WHOLESALE PRICE FORMATION
- VII. ARCHIVING; PUBLICATION AND COMMUNICATION OF PRICING DATA
- VIII. TRANSITORY AND FINAL PROVISIONS

Pricing Rule: Principal Characteristics

- Regulation of both ex-factory (administratively recognized) and wholesale prices
- Introduction of wholesale mark-ups (degressive)
- New external referencing MS (AT instead of IT)
- (MIN-MAX) price ranges in DE, FR, AT introduced for generics: means of the two extremes used for generics (85% of the grand mean)

Pricing Rule: Principal Characteristics

- Emphasizing lowest-priced external reference market for originator products (100% of the least expensive ext. ref. Price becomes SI price)
- Dynamics of price notification:
 - semiannual notification of external changes obligatory
 - lowering of price *ad libitum* for MAH
- Keeping the provisions for mutually interchangeable MPs unchanged (advance price announcements, followed by a adjustment of the announced price to the in-between declared maximal attributed value (NPV)).

Instruments I

- External referencing
 - originators: 100% of the $\text{MIN}(\text{DE}, \text{FR}, \text{AT})$
 - generics: 85% of the mean between the least and most expensive generics on the DE, FR, AT market
- Compendia:
 - Lauer-Taxe online (DE)
 - Vidal CD ROM (FR)
 - Erstattungskodex, Warenverzeichnis (AT)

Instruments II

- Minister's Consent to prices exceeding external referencing criteria
 - Intended for exceptions
 - Administrative procedure involving JAZMP and MoH
 - Pharmacotherapeutic and pharmacoeconomic evidence required in the application
 - Statement of MAH's measures influencing supply of the MP expected if consent not be given

Impact I

Changes in prices of medicines:

WS Price	No. MPs	Mean Chg	SD Chg
Decrease	757	80	16
Unchanged	264	100	-
Increase	618	120	30

Impact II

Savings in public funds allocated for medicines:
– reimbursement of MPs on the positive, intermediate lists and in the mutually interchangeable MPs with Max. Attributed Value

(expected in 2007)

- **32 MIO € (11%)** of the approx. 300 MIO € public and supplemental spending for pharmaceuticals

Reimbursement

- Recent additions to the positive/intermediate lists

L01XE04	sunitinib (Sutent)	R03AK07	beclomethasone/formoterol (Foster)
L01XE05	sorafenib (Nexavar)	G03AC03	levonorgestrol IUD (Mirena)
L01BB04	cladribinon (Litak)	N05AX08	risperidone (Risperdal Consta)
L01XE06	dasatinib (Sprycel)	A10AB06	glulisine (Apidra)
L01XE03	erlotinib (Tarceva)	J05AF10	entecavir (Baraclude)
A16AX06	miglustat (Zavesca)	C03DA04	eplerenone (Inspra)
N06BA04	methylphenidate (Concerta)	S01BA14	loteprednoletabonate (Lotemax)
V03AC03	deferasirox (Exjade)	L04AA14	anakinra (Kineret)
B01AC11	iloprost (Ventavis)	G04BD08	soliphenacin (Vesicare)
C02KX01	bosentan (Tracleer)		

Generic substitution – a flash

- System of mutually interchangeable MPs in place since Nov. 2003
 - Regulatory content (ATC5 – JAZMP)
 - Financial content (Max. Attrib. Value “NPV”- ZZZS)
- Updated semiannually
 - 6 months fixed prices
 - 2 consecutive announcements of prices every 6 months
- Currently:
 - 770 MPs interchangeable (out of approx. 3000 MP authoriz.)
 - 360 MPS with NPV
 - 53 chemical entities
 - 1/3 value of all reimbursed MPs

Interchangeable MPs with MAV*

- ATC5, n= 53 chemical entities/INNs, 360 presentations
- recent additions to the list at INN level:

M05BA04	alendronate	G04CB01	finasteride
N06AX11	mirtazapine	J02AC02	itraconazole
G04CA05	tamsulosin	A04AA02	granisetron
C09AA03	lisinopril	C09AA04/ C03BA11	perindopril/indapamide

* MAV: maximal attributed value = reference price

Thanks!

<http://www.jazmp.si>

PPRI 5th Coordination Meeting
Vienna, AUSTRIA, 28th June 2007

The logo for Jazmp, featuring a stylized graphic of horizontal lines to the left of the lowercase text 'jazmp'.

Agency for Medicinal Products and Medical Devices
of the Republic of Slovenia