



From Pricing to Reimbursement: Navigating the Turkish Pathway

Pricing & Reimbursement Conference, Athens Greece

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Arařtırımcı İlaç Firmaları Derneđi
Association of Research-Based Pharmaceutical Companies

Outline

Stakeholders



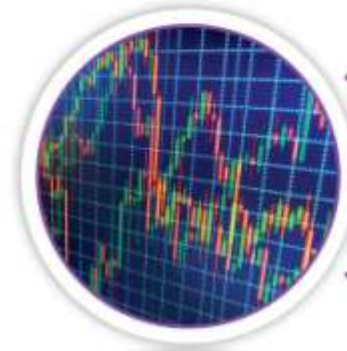
Reimbursement



Uncertainties & Issues



International
Reference Pricing



Shortcomings and
Alternatives



The Goal for any Country is to Have a Pricing and Reimbursement System That Ensures and Supports Access to Innovative Drugs for Patients.

➤ Sustainability of the system:

- Both from payer and supplier perspective.
- Clear, transparent and fair rules for all parties.
- Other mechanisms apart from drug pricing to be considered to ensure sustainability (e.g. rational drug use, co-pays etc...)

➤ Predictability:



Stakeholders



➤ Pricing

- Price Assessment Commission
-



➤ Reimbursement

- Clinical & Economical Evaluation commission
 - Reimbursement Commission
-

Hierarchy & Relationship Between Stakeholders



Market Access Process for Pharmaceuticals



Ministry of Health
Turkish Drug Agency (TITCK)

GMP



REGULATORY

PRICING

Ministry of Labor
Social Security Institution (SSI)

REIMBURSEMENT

National submission is possible only after GMP certificate

Ex-factory prices are determined via international reference pricing and subject to fixed FX rate

Prices of drugs on positive list are subject to mandatory gov discount

Pricing of Pharmaceuticals

➤ International Reference Pricing



- Reference price = **lowest price** within the reference basket
- On-patent drugs take **100% of reference price**; whereas **off-patent drugs take 60%**
- FX rate is defined based on **70% of former year's average**
- **Fixed FX rate** (2,1166 in 2016) is used to convert EUR reference prices into TRY ex-factory prices
- Reference prices are updated twice a year
- Exceptions for specific product groups are in place



Reimbursement of Pharmaceuticals



- **Predefined application deadlines**
 - 2 working periods for a year






- **Two tier evaluation**
 - Clinical & Economical Evaluation
 - Technical advise obtained if necessary
 - Reimbursement decision



- **Reimbursed price:
Discounting from official price**
 - Base discount
 - Reimbursement band
 - Exceptions

Price and Discount Evolution in TR



	Country of Import Country of Release	Reference price level (%)			Institutional discount %			
		2008	2009 - 2010	2011 - 2015	2008	2009	2010	2011 - 2016
Originals (wo Gx)		100%	100%	100%	11%	23%	32,5%	41%
Originals (w Gx)		100%	66%	60%	11%	11%	20,5%	28%
Gx		80%	66%	60%	11%	11%	20,5%	28%

Reimbursement band

As of 2011: above 10% of the cheapest drug in the same equivalent group

Current Situation of Drug Pricing



FX Effect By 20.5.2016

fx=2,1166 vs 3,3483

European Lowest List Price
Among 5 Referred
Countries in TL



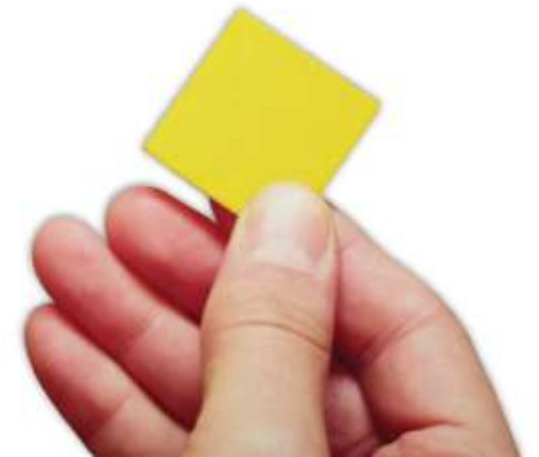
Difference Btw. Current and
Applied Fx ~59%

Institutional Discount
41%

Current Public Price

Shortcomings & Alternatives

- Unregistered /Registered, yet market unavailable products via Turkish Pharmacists' Association on a prescription basis
 - Foreign Drug List
- Alternative Reimbursement Models
 - Individual drug based agreements (MEA's)
 - need to be more structured and transparent by the implementation guidelines



Uncertainties & Further Challenges

- Application of pricing regulation as a budget control instrument
- Direct impact of bureaucratic changes (i.e. general election) on timelines and process



Price and Discount Evolution in TR



Source for Reference Price		Reference Price Level (%)			Institutional Discounts (%) by Years					
Country of Import	Country of Release	2008	2009 2010	2011 2016	2008	2009	2010	2015	2016	2016 Ex-man, Price
Originals (wo Gx)		100%	100%	100%	31%	23%	32,5%	41%	41%	≤ 11,03
								41%	32%	≤ 7,33 and ≤11,02
Originals (w Gx)		100%	66%	60%	11%	11%	20,5%	28%	28%	≤ 11,03
								28%	18%	≤ 7,33 and ≤11,02
Gx		80%	66%	60%	11%	11%	20,5%	28%	28%	≤ 11,03
								28%	18%	≤ 7,33 and ≤11,02
					4%	4%	4%	0%	0%	≤ 3,84 and 7,32
										≤ 3,84 and 7,32
										≤ 3,84 and 7,32
										≤ 3,83 TL

Reimbursement band

As of 2011: above 10% of the cheapest drug in the same equivalent group



THANK YOU

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