Authorisation&Classification

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The pharmaceutical system in Estonia in the in- and out-patient sector

New Medicine

EMA

Estonian State Agency of Medicines consulted by Marketing Authorisation Commitee

Task: Decision on marketing authorisation Criteria: Quality, safety, efficacy, Directive 2004/83/EEC

State Agency of Medicines

Task: Classification, decision on prescription, dispensing restrictions Criteria: Directive 2004/83/EEC and Estonian Medicines Act 2002

Register of Human Medicines

Register of Veterinary Medicines

Pricing

Ministry of Social Affairs

External and internal price referencing for reimbursable medicines, set maximum wholesale purchase price

Out-patient Pharmacy

Maximum regressive/margin mark-ups set by Government

In-patient Pharmacy

In-patient

Estonian Health

Insurance Fund (EHIF)

Negotiate treatment

scheme price

Contracts with health care

providers

Hospital Drug Committee

Formulary (no central

regulation)

Regulation of Government

"List of the health care

services of EHIF"

Price negotiations by each hospital

VAT 9% (pharmaceuticals and medicinal devices), others goods at pharmacy VAT 20%

Out-patient

Ministry of Social Affairs consulted by **Drug Committee**

Task: Decision on pricing and reimbursement Criteria: Directive 89/105/EEC and Estonian Health Insurance Act 2005 overall need for reimbursement, availability of alternative pharmaceuticals and treatment options, (comparative) efficacy, safety and cost-effectiveness, budget impact

Ministry of Social Affairs (MSA)

Price Agreements, reference prices

Regulation of MSA "List of pharmaceuticals reimbursed by EHIF"

50%

3,20 € + 50% of reference price

75%/90%

Diagnosebased: 1,28 € + 25%/10% of reference price

100%

Diagnosebased: out-ofpocket payment 1,28 € + 0% of reference price

Ministry of Social Affairs

TBC, ARV medicines and vaccines (free to patients) Public procurement Central warehouse Treatment centers

<u>Infertility treatment</u>

Security reserve

Statistics Insurance Fund (reimbursement and prescription statistics)

All are covered from State Budget

Special groups

75% turns to 90% for children ≤ 16y, disabled and retired people. Children ≤ 4 y -100%.

Additional reimbursement: if the patients annual expenses for the pharmaceuticals ≥ € 383,47

National Institute for Health Development

Opioid dependence treatment Public procurement State Budget

The prices of pharmaceuticals have binded into the reference price of hospital day or price of health care service and are reimbursed 100% by EHIF

Out-patient

Hospital Drug Commitee

Non-reimbursed

Reimbursement

For individual reimbursement of unregistered medicines, application is made directly to Health Insurance Fund

can decide over purchase of non-reimbursable medicines from hospital budget

In-patient