

### DVSV Code of Reimbursement (EKO) – Austrian Social Insurance

**Christian Hierländer** 

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### Overview - Austrian Social Insurance Dachverband der österreichischen Sozialversicherungen (DVSV)

**DVSV** = Strategic and coordinating entity of health insurance, pension funds and workers' compensation board

Department of pharmaceutical affairs (VPM) responsible for the "Code of Reimbursement" EKO - positive list including all pharmaceuticals regularly reimbursed in the outpatient sector

- Multidisciplinary department of pharmacists, pharmacologists, physicians, economists, data analysts and legal officers Assessment
- Assessment / Pricing / price negotiations
- Reimbursement decisions based on appraisal (by Drug Evaluation Committee)
- Shaping pharmaceutical Strategy, providing policy advice and expertise, monitoring and forecasting expenditures

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### **EKO – Code of Reimbursement (1)**

#### **Green Box**

Medicines qualifying for <u>"automatic" reimbursement</u>, broad use No prior approval needed

Some products with restrictions (e.g indication)

#### "Dark"/"Light"Yellow Box

Medicines with <u>substantial added therapeutic</u> <u>benefit</u> with <u>high costs</u> / budget impact Reimbursed at defined criteria after <u>prior approval</u> by chief medical officers

Medicines reimbursable at defined criteria BUT <u>expost control</u> (documentation) by chief medical officers <u>possible</u>

#### **Red Box**

When application is filed, Medicine is included <u>temporary category</u> <u>exceptional reimbursement after prior approval</u> by chief medical officers



#### Medicines outside EKO ("No Box")

- no EKO application
- negative reimbursement decision

reimbursable only in justified exceptional cases after prior approval by chief medical officers

# Principally not reimbursable medicines

- Hospital
- Cosmetics
- Homeopathic medicines
- etc.

### **EKO – Code of reimbursement (2)**





9.520 authorised medicines in Austria

- Medicines without benefits for patients should not be prescribed or reimbursed, regardless of the price
- Doctors should be able to prescribe even the most expensive medicines, if necessariy

Source: EKO Basisdatenbank (1.1.2024); different package sizes of one strength can count as reimbursed and not reimbursed

# **Proceedings for inclusion in EKO\***



Dachverband der österreichischen

Sozialversicherungen

\*based on: ASVG, Verfahrensordnung zur Herausgabe des Erstattungskodex, Geschäftsordnung der Heilmittel-Evaluierungs-Kommission, Transparency 4 directive (89/105/EWG)

# **Drug Evaluation Committee (HEK)**





- advisory body consisting of several federations
- supports the DVSV in the decision making concerning the inclusion of drugs into the EKO
- 22 members / 20 voting members
- majority decisions

### **Principles of Evaluation**



- Evaluation is based on **published clinical data**
- Pharmaceuticals are evaluated for their therapeutic value
  - in the licensed indication
  - in comparison to all available alternatives
- new pharmaceutical to be listed must provide <u>additional</u>
   <u>benefit</u>: therapeutic, economic or both

### Three stage evaluation





### Medical evaluation – Degree of therapeutic benefit for patients

- 1. No added therapeutic value (generic, biosimilar)
- 2. Further therapeutic option with similar benefit as products already on the list
- 3. Added therapeutic benefit for a subgroup of patients
- 4. Added therapeutic benefit for the majority of patients
- 5. Substantial added therapeutic benefit for a subgroup of patients
- Substantial added therapeutic benefit for the majority of patients

prolonged OS, increased QoL, reduced morbidity, fewer serious AEs

# **Benefit - Price Matrix**



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Therapeutic benefit	Number of patients	Price compared to comparator drug in EKO
Substantial added benefit	Majority (Z6)	higher => pharmacoeconomic study required to show positive "cost-benefit" ratio
	Subgroup (Z5)	
Minor added benefit	Majority (Z4)	max. + 10%
	Subgroup (Z3)	max. + 5%
Equal or similar benefit	(Z2)	min10%
Subsequent products with same active ingredients	(Z1) 1st 2nd 3rd further	Deductions for generics/biosimilars min50/38% min18/15% min15/10% min $\in 0,10$

Phramacoeconomic study is mandatory if no comparator is listed in the EKO



## Substantial added therapeutic benefit:

- Reimbursement can be accepted if the <u>"cost-benefit" ratio is</u> <u>meaningful and justified</u>. This needs to be demonstrated by the company with a <u>pharmaco-economic study</u> (=CEA, CUA, CBA, CMA...)
- No explicit ICER per QALY threshold
- Submitted by company
- ISPOR checklist (full appraisal) => credibility and relevance



## **Determination of the Price**





# **Consequences of negative decision**

#### • No inclusion into EKO but

every pharmaceutical has to be paid for by social health insurances if deemed necessary on a case-by-case basis and prior approval by the chief medical officer ("no box")

- Litigation / court
- New attempt



# Thank you for your interest