CONFERENCE "SHORTAGES OF HUMAN MEDICINES IN THE EUROPEAN UNION"

Report form the conference organised by the Slovak Presidency of the Council of The EU

17-18 November 2016, Bratislava

François Houÿez
Director of Treatment Information & Access

Joint PCWP/HCPWP meeting, 15 March 2017, EMA

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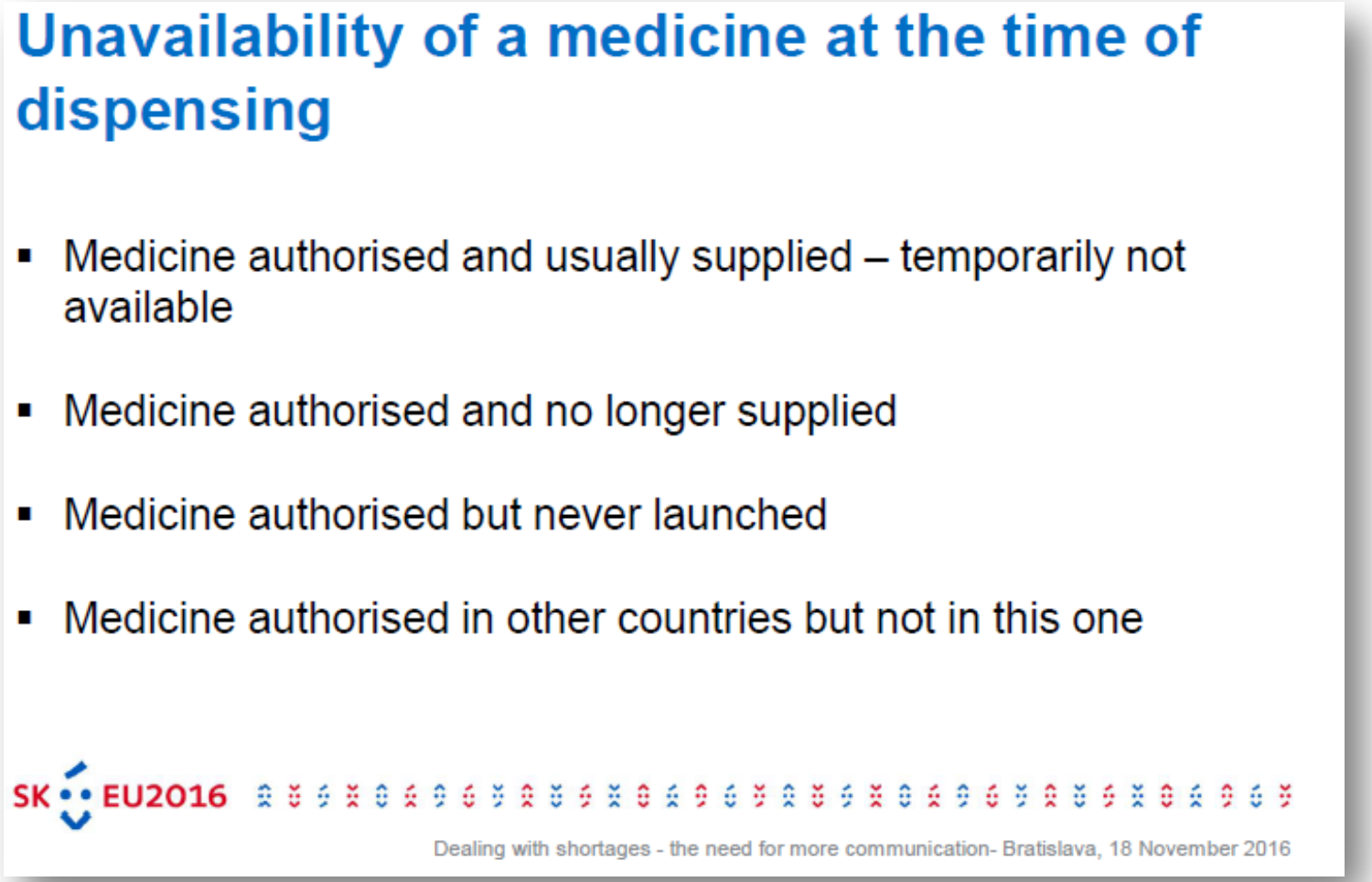
Presenters:

SK EU2016
Slovak Presidency of the Council of the European Union

Andrea Kalavská	State secretary, MofH, Slovak Republic
Matej Petrovič	Director General, Pharmacy and Medicines Policy SLK
Ján Klimas	Faculty of Pharmacy, Bratislava
Tomáš Turiak	Slovak Chamber of Pharmacists
François Houÿez	EURORDIS
Zdeněk Blahuta	SUKL, Czech Republic
Zuzana Baťová	SUKL, Slovak Republic
Brendan Cuddy	Head of Manufacturing/Quality Compliance, EMA
Marcel van Raaij	MofH, Dir. Medicines and Med Tech, Netherlands
Richard Bergström	Director General, EFPIA
Adrian van den Hoven	Director General, Medicines for Europe
Patricia Vella	Medicines Authority, Malta
Agnès Mathieu-Mendes	European Commission

Different solutions for different situations



Richard Bergström, Director General, EFPIA. From ISPOR 2016

Example of chronic supply difficulties for a product in SLK
(to treat epilepsy, neuropathic pain, fibromyalgia, generalised anxiety disorder)

Lyrica 56x150mg (Pfizer)

- Delivery in January was **4.420** packages
- Actual available quantity **33.453** packages (Pfizer declares)

Actual reserve at 4 wholesalers warehouses (covering 80% of maket)

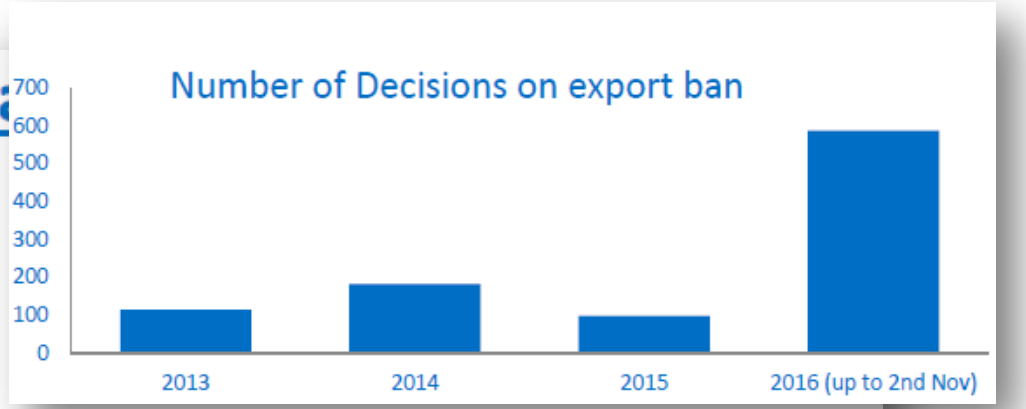
- Phoenix **288**
- Med-Art **330**
- Unimed **20**
- Unipharma **did not respond**

638 is less than **2%**

Tomáš Turiak, Slovak Chamber of Pharmacists

Re-export from Slovak Rep. 2015

STATISTICS of the pl



YEAR 2015

- 32,121 notifications (= app. 88 notifications per day including weekend and holidays)
- 34 wholesalers
- 1,289 medicinal products (according to the SIDC code)
- **77** pharmacological/therapeutic subgroups (ATC2)
- 4,896,709 packages
- 27 destination states

- 48 % Czech republic
- 17 % Germany
- 9,3 % United Kingdom
- 7,1 % Poland
- 5 % Denmark, Netherlands, Latvia

Comment: this is the state of the primary reexport – wholesalers, who buy the medicines (not the destination state)

Zuzana Baťová, SUKL, Slovak Republic

European Commission response to SLK measures

	
All exports of medicines to be notified to SUKL	Scope is not proportionate
Wholesaler notify intention to export 30 days in advance	Business is suspended for too long
Notification to include the batch numbers	Too restrictive
National authority can ban export if there is a shortage in the country	If there is a demonstrated risk for public health

→ SLK to adopt new measures

Top 15 re-exported medicines in Czech

Re-export x deliveries – TOP 15 MP by no. of packs in 2015

Seq.	Medicinal product	No. of re-exported packs	No. of packs supplied to pharmacies	Re-export % share
1	PROCTO-GLYVENOL, RCT SUP 10	143 473	51 831	73.46
2	ALVESCO 160 INHALER, INH SOL PSS 60X160RG	130 328	106 918	54.93
3	PROCTO-GLYVENOL, RCT CRM 1X30GM	127 179	75 502	62.75
4	BETASERC 24, POR TBL NOB 50X24MG	105 177	217 844	32.56
5	GLUCOPHAGE XR 500 MG TABLETY S PRODLOUŽENÝM UVOLŇOVÁNÍM, POR	103 300	202 982	33.73
6	RECTODELT 100 MG, RCT SUP 4X100MG	101 303	57 409	63.83
7	VERRUMAL, DRM SOL 13ML	76 109	39 987	65.56
8	SPIROPENT, POR TBL NOB 20X0.02MG	74 947	59 713	55.66
9	CONTROLOC 40 MG, POR TBL ENT 28X40MG I	74 085	48 441	60.46
10	PREDUCTAL MR, POR TBL RET 60X35MG	73 636	350 564	17.36
11	GERATAM 1200 MG, POR TBL FLM 60X1200MG	72 807	25 097	74.37
12	INHIBACE 2,5 MG, POR TBL FLM 28X2.5MG	70 510	27 699	71.80
13	DILATREND 25, POR TBL NOB 30X25MG	67 315	55 097	54.99
14	NIMESIL, POR GRA SUS 30X100MG	66 994	560 531	10.68
15	INHIBACE 5 MG, POR TBL FLM 28X5MG	64 053	15 832	80.18

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Reasons for unavailability of medicinal products in the Czech Republic, Bratislava, 18. 11. 2016

Zdeněk Blahuta, SUKL, Czech Republic

Actions proposed by MS

Possible solutions at EU level

- **Improve cooperation and information exchange:**
  - On shortages and manufacturers (HMA/ EMA)
  - Best-practice solutions at expert and policy level
  - Explore cross country distribution in case of shortages
  - Explore cross country stockpiling possibilities in case of small market volumes

- **Legal solutions**
  - Clarify responsibility manufacturer (ex. art. 81- 2001/83/EC)
    - E.g. risk management and supply continuity plans
    - Early notification obligation in case of supply disruption or cessation
    - Introduction of EU fines in case of imputable shortage
  - Clarify public health grounds for temporary parallel export restrictions for products with (emerging) shortages

Marcel van Raaij, MofH, Dir. Medicines and Med Tech, Netherlands

Legal tools (EU)

Agnès Mathieu-Mendes, European Commission

Legal tools (EU) (2)

Agnès Mathieu-Mendes, European Commission

Legal tools (EU) (3)

Agnès Mathieu-Mendes, European Commission

See Common Position on Shortages, patients consumers healthcare professionals

Next steps (EC)

Agnès Mathieu-Mendes, European Commission

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RARE DISEASES EUROPE

Thank you for your attention.

François Houÿez

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