



State Agency  
of Medicines  
Republic of Latvia

# Availability of medicines Experience from EU and Latvia

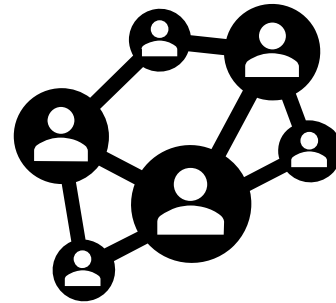
Svens Henkuzens  
Director of Latvian Medicines Agency

Riga, 10 May 2019



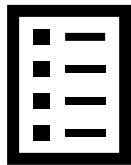
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# What the medicines network is doing?

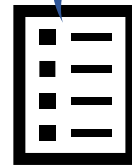


**Joint Task force on  
Availability of medicines**

Prevention  
Identification  
Management and  
communication of shortages  
Pricing



HMA Work plan



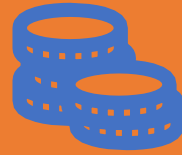
EMA Work plan



17 December 2015  
EMA/MB/151414/2015



# Main drivers for no authorization or marketing of medicinal products



**MAH Corporate strategy** –  
perceived costs vs benefits



**Regulatory system** – authorization  
process, pricing, reimbursement  
policy (reference pricing system)



Typically more severe in small  
markets, lower income countries

# Managing lack of authorization or marketing of medicinal product



LACK OF AUTHORIZATION



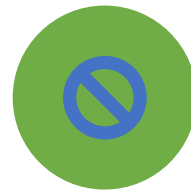
PROACTIVELY CONTACTING MAH-  
STIMULATE MRP



REDUCED TIMETABLES  
AND AUTHORIZATION  
FEES(?)



126A FROM DIRECTIVE  
2001/83/EC- "CYPRUS  
CLAUSE"



LACK OF MARKETING

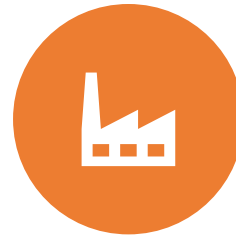


MULTI-LINGUAL,  
FOREIGN PACKS



REIMBURSEMENT  
DECISION

# Main causes for shortages



GMP NON  
COMPLIANCE



QUALITY DEFECTS



SUPPLY CHAIN  
CHALLENGES



PARALLEL EXPORT



SUDDEN INCREASE  
IN DEMAND E.G.:

# Managing shortages



Reporting system

Awareness – are stakeholders aware?

Completeness – who reports? Mandatory?  
Are reports checked? Updated?

Usability – Searchable, user friendly  
interface? Suggests alternatives?



Inform the prescriber on the shortage



Recommend alternative medicine (costs!)



Inform on when supply will be resorted



Recommend alternative supplier



EU medicines agencies single point of contact for  
coordination

# Managing shortage. Experience from Latvian Medicines Agency



In coordination with MAH and wholesalers  
encourage alternative supplies



Foreign packs



Parallel import



Medicines without marketing authorization





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Thank you!