

AVAILABILITY OF MEDICINES: IMPACT ON PUBLIC HEALTH

Unique example of cancer

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European Society for Medical Oncology

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WHAT ARE IMPORTANT CANCER MEDICINES?

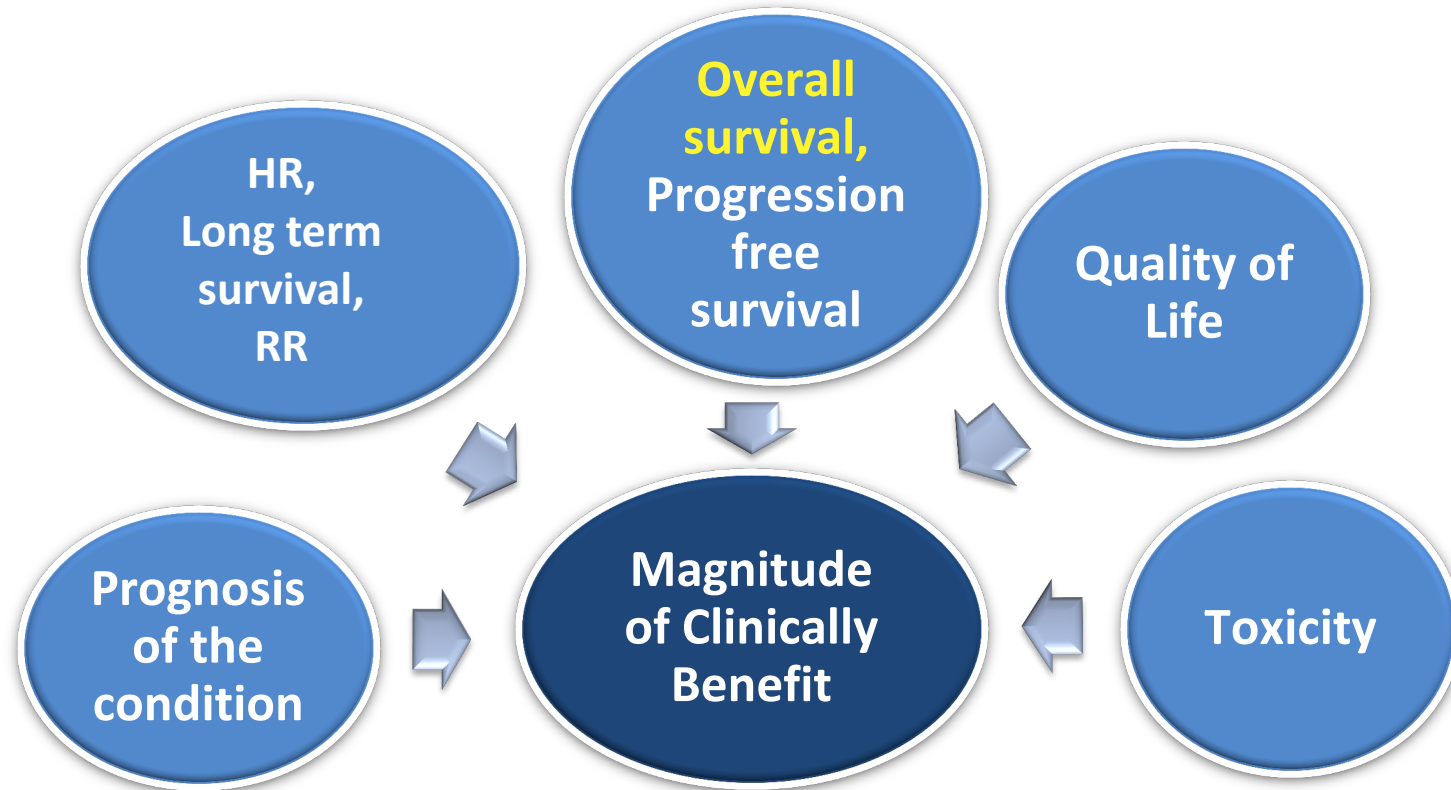


1. **Drugs that score high on the ESMO-Magnitude of Clinical Benefit Scale (MCBS)**
2. **Drugs on the Essential Medicine List of the World Health Organization (WHO)**

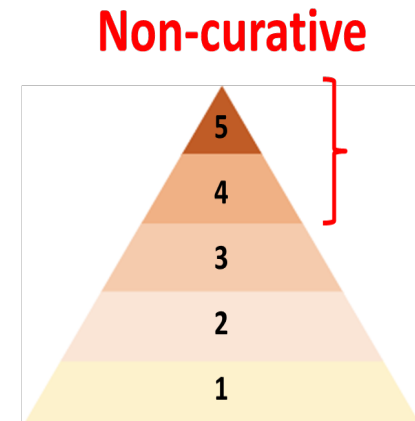
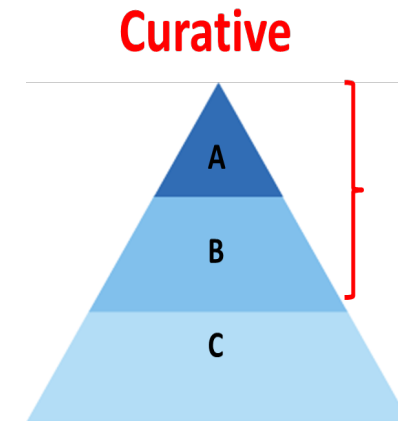
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ESMO-MCBS

Factors taken into account for ESMO-MCBS



Substantial improvements:
A & B in curative and 5 & 4 in non curative setting



WHO ESSENTIAL MEDICINES LIST FOR SOLID TUMORS 2017

Cytotoxics			Miscellaneous	Hormones
Bleomycin	Doxorubicin	Oxaliplatin	Calcium folinate	Anastrozole
Capecitabine	Etoposide	Paclitaxel	Filgrastim	Bicalutamide
Carboplatin	Fluorouracil	Procarbazine	Imatinib A	Dexamethasone
Cisplatin	Gemcitabine	Vinblastine	Trastuzumab A	Leuprorelin
Cyclophosphamide	Ifosfamide + mesna	Vincristine	Zoledronic acid	Tamoxifen
Dactinomycin	Irinotecan	Vinorelbine		
Docetaxel	Methotrexate			

ESMO SURVEY EUROPE EXAMPLE: RESULTS PROSTATE CANCER

Country:	Prostate Cancer : Formulary and Cost					
	Docetax.	Cabazitax.	Ketocon.	Abirat.	Enzalut.	Radium-223
Austria						
Belgium						
Cyprus						
Denmark						
Finland						
France						
Germany						
Greece						
Holland						
Iceland						
Ireland						
Israel						
Italy						
Luxembourg						
Norway						
Portugal						
Spain						
Sweden						
Switzerland						
Turkey						
United Kingdom						
Albania						
Armenia						
Belarus						
Bosnia and Herzegovina						
Bulgaria						
Croatia						
Czech Republic						
Estonia						
Georgia						
Hungary						
Kazakhstan						
Kosovo, Republic of						
Kyrgyzstan						
Latvia						
Lithuania						
Macedonia						
Malta						
Montenegro						
Poland						
Romania						
Russian Federation						
Serbia						
Slovenia						
Slovakia						
Turkmenistan						
Ukraine						
Uzbekistan						

	Free
	<25% cost
	25-50% cost
	Discount >50% and <100%
	Full cost
	Not available
	Missing data

Docetax=Docetaxel, Carbazitx=Carbazitaxel,
Ketocon=Ketoconazole, Abirat=Abiraterone,
Enzalut=Enzalutamide

ESMO SURVEY EUROPE: ESSENTIAL MEDICINE LIST AVAILABILITY 1

	Bleom.	Capecit.		Carboplatib			Cis Platinum				Cycloph.		Docetaxel			Doxorubicin			Etoposide	
Country:	GCT	CRC	MBC	Adj BC	Ovarian	Lung	Lung	Sarcoma	Ovarian	GCT	Adj BC	MBC	Adj BC	MBC	Prostate	Adj. BC	MBC	Sarcoma	GCT	Lung
Austria																				
Belgium																				
Cyprus																				
Denmark																				
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Russian Federation																				
Serbia																				
Slovenia																				
Slovakia																				
Turkmenistan																				
Ukraine																				
Uzbekistan																				

	Always
	Usually
	Half the time
	Occasionally
	Never
	Not available
	Missing data

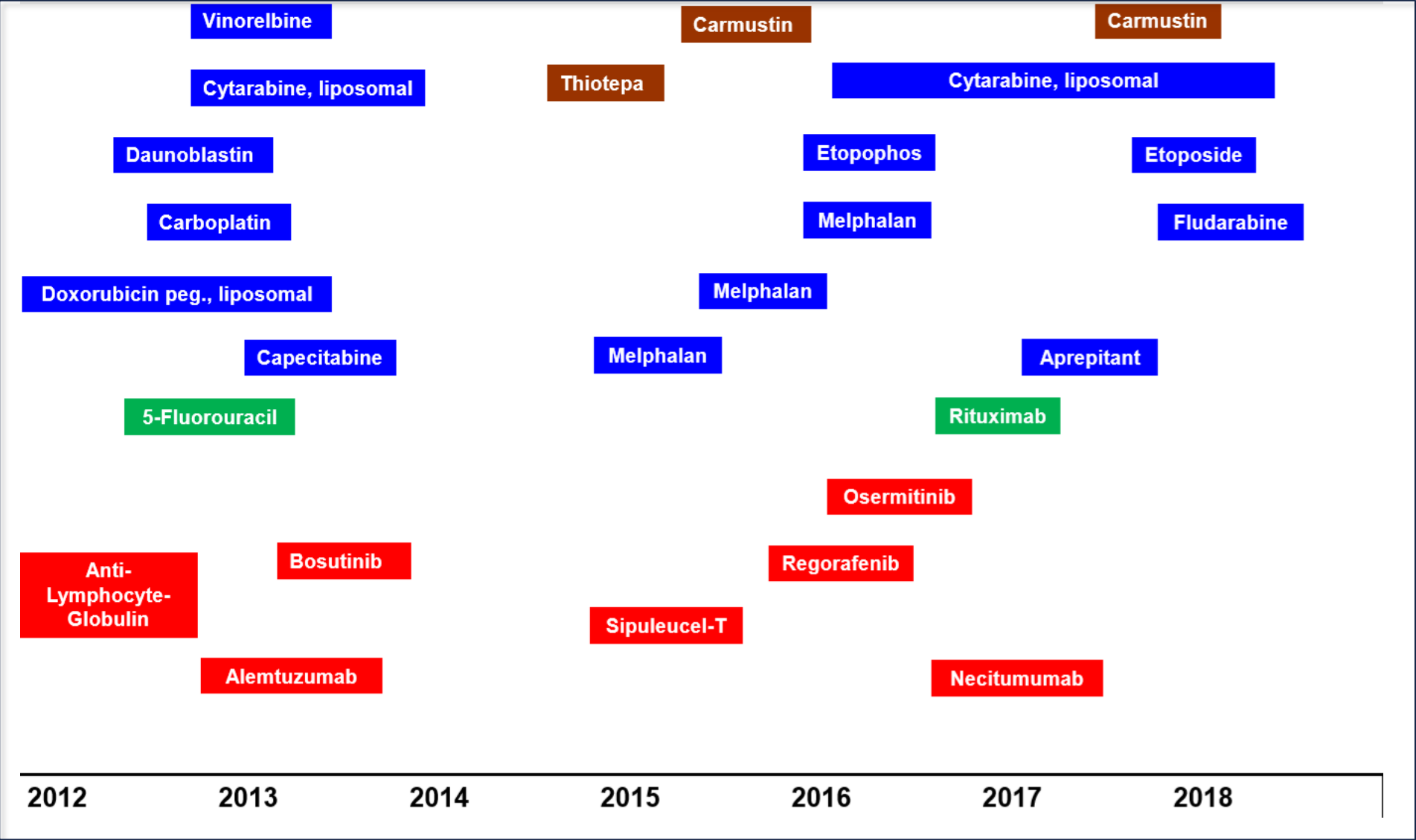
ESMO SURVEY EUROPE: ESSENTIAL MEDICINE LIST AVAILABILITY 2

	5-FU			Gemcit.		Ifos.		Imatin.	Irinot.	MTX	OxaliPI	Paclitaxel				Trastuz.		Vinblast.	Vinorelbine	
Country:	Adj. BC	MBC	CRC	Ovarian	Lung	GCT	Sarcoma	GIST	CRC	Adj BC	CRC	Ovarian	Adj BC	MBC	Lung	Adj.BC	MBC	GCT	Lung	MBC
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DRUG SHORTAGE IN GERMANY



- Production, quality
- Increased demand
- Pricing
- Market withdrawal



GERMANY: SOLUTION DRUG SHORTAGES

Jour Fixe (2016)

ABDA	Pharmacists
ADKA	Hospital pharmacists
AkdÄ	Physicians
AWMF	Medical Societies (DGHO)
BAH	Pharmaceutical industry
BfArM	National Institute for drug approval
BMG	Ministry of Health
BPI	Pharmaceutical industry
Landes ministerien	Regional institutions for drug surveillance
PEI	National Institute for biomedical products
VfA	Pharmaceutical industry

Jour Fixe

 Management of shortages	 No longterm solution
1. Early information 2. Facilitated import 3. Recommendation on alternatives	1. Quality of production 2. Dependency on Asia/US 3. Adequate pricing

EIU-ESMO REPORT ON CANCER MEDICINES SHORTAGES & MEETING AT THE EUROPEAN PARLIAMENT



Cancer medicines shortages in Europe

Policy recommendations to prevent and manage shortages

A report by The Economist Intelligence Unit
Supported by the European Society for Medical Oncology



INEXPENSIVE BUT ESSENTIAL

Calling for a better European Supply
of Essential Cancer Medicines

CO-CHAIRS

Alojz Peterle MEP
Lieve Wierinck MEP
Françoise Grossetête MEP

17 MAY | 16:00 - 18:00
EUROPEAN PARLIAMENT STRASBOURG
ROOM N3.5



EIU-ESMO RECOMMENDATIONS ON HOW TO TACKLE MEDICINES SHORTAGES



1. Introduce **legislation for early notification** requirements for medicines shortages
2. Establish **strategic plans** for medicines shortages
3. Develop **catalogues of shortages**
4. Develop **essential medicines lists** and assess the risk for shortages
5. Introduce **incentives** for production infrastructure improvements
6. Establish **procurement** models designed to prevent medicines shortages

EIU – ESMO RECOMMENDATIONS 1-3



1 Introduce legislation for early notification requirements for medicines shortages

- National legislation for early notification from manufacturers should be implemented in all European countries, as stipulated in Directive 2001/83/EC.
- The legislation should include a requirement for manufacturers to provide information about the reasons for discontinuation of supply.

2 Establish strategic plans for medicines shortages

- Countries should establish a task force to develop a national strategic plan for medicines shortages, underpinned by national legislation and funding.
- This initiative could be proposed at a European level, with countries having an option to implement it on a national level.

3 Develop catalogues of shortages

- All European countries should develop a national system for reporting medicines shortages based on a minimum set of data requirements.
- European regulatory authorities (Heads of Medicines Agency (HMA)/EMA) could 1) coordinate the development of a harmonised procedure for reporting of shortages, based on a shared definition, and 2) develop a platform/database to collate the reports from the national systems.
- All stakeholders, including patients and physicians, should have access to a user-friendly, web-based system to report shortages

EIU – ESMO RECOMMENDATIONS 4-6



4 Develop essential medicines lists and assess the risk for shortages

- Countries should develop **national essential medicines** lists based on the WHO Model List of Essential Medicines (EML).
- The EMA Risk Indicators for Shortages (manufacturing and quality) should be used to **identify high-risk products**.

5 Introduce incentives for production infrastructure improvements

- Health systems/payers in European countries should consider **financial incentives for production infrastructure improvements** to address economic causes of manufacturing issues.
- **Incentives for suppliers** to enter and remain in a national market could also be considered.

6 Establish procurement models designed to prevent medicines shortages

- **Good procurement practices** that address predictability and profitability for medicines manufacturers should be identified. These could include using tender criteria that include price as well as other factors, e.g. quality track record of manufacturers.
- **Tender cycle harmonisation** could be considered within and across countries.
- National procurement for medicines experiencing shortages could be considered.



MOST IMPORTANTLY...

...have a common EU definition on shortages.

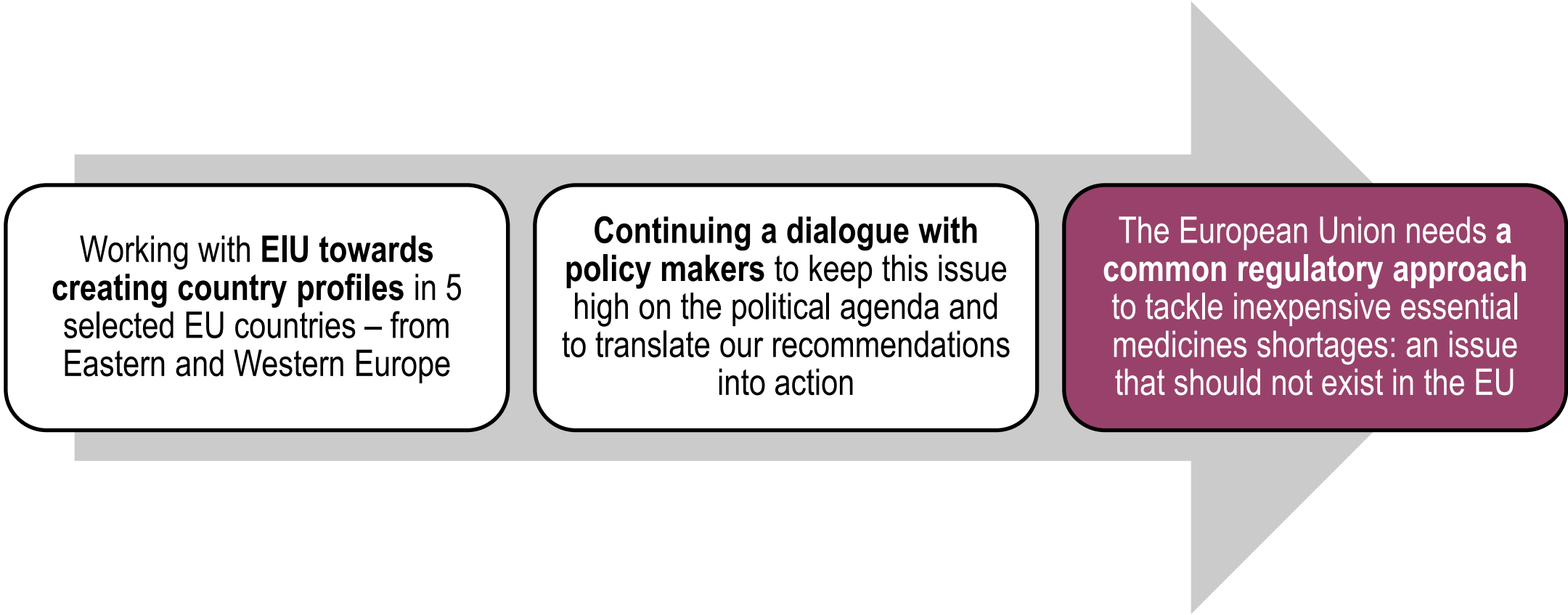
Referring to Article 23a of Directive 2001/

EU directives require Member States to achieve specific goals, and to this end appropriate rules need to be introduced in national laws. A 2015 survey conducted by the EMA found that mandatory notification for shortages is required by law in most EU Member States (21 of 28 countries) however seven countries had not introduced this requirement into national legislation.¹¹ However the lack of a common definition (or a definition at all in 18 of 28 countries) and the consequent different conditions of reporting of shortages, make comparisons across countries very difficult.¹¹



CONCLUSION

ESMO is continuing its efforts to find an EU-wide solution to mitigate these shortages



Working with **EIU** towards **creating country profiles** in 5 selected EU countries – from Eastern and Western Europe

Continuing a dialogue with policy makers to keep this issue high on the political agenda and to translate our recommendations into action

The European Union needs a **common regulatory approach** to tackle inexpensive essential medicines shortages: an issue that should not exist in the EU

THANK YOU

www.esmo.org

