

CANCER MEDICINES WORKING GROUP

ACTIONS TOWARDS UNIVERSAL ACCESS TO ANTI-CANCER DRUGS

Josep Tabernero

Chair, Cancer Medicines Working Group

President-Elect, ESMO



DISCLOSURE SLIDE

Consultant/Advisory role:

Amgen, Bayer, Boehringer Ingelheim,
Celgene, Chugai, Imclone, Lilly, MSD,
Merck Serono, Novartis, Roche,
Sanofi, Symphogen and Taiho

WHAT IS THE CMWG?

ESMO created the Cancer Medicines Working Group (CMWG) in 2015, to address topics related to inexpensive and expensive cancer medicines

- **Chair:** Josep Tabernero, President-Elect, ESMO,
Head, Medical Oncology Department, Vall d'Hebron University
Hospital, Barcelona, Spain
- **ESMO Staff:** Malvika Vyas, Head of Public Policy
- **Structure:** Two expert groups:
 - 1) Inexpensive, essential cancer medicines;
 - 2) Expensive, innovative cancer medicines and biosimilars
- **Objective:**
To work with leading experts to brainstorm and jointly come up with recommendations and solutions addressing issues in the field of cancer medicines

INEXPENSIVE, ESSENTIAL CANCER MEDICINES



Rationale

- ESMO-conducted surveys on the availability of anticancer medicines indicated a imminent need to address the issue of shortages of essential, cancer medicines.

WHO ESSENTIAL MEDICINES LIST 2015

Solid Tumors

- **UICC Task Force on EML:** UICC, Dana Farber Cancer Institute, ESMO, ASCO, SIOP, US NCI, NCCN International & others
- New drugs, tumor-specific indications

Cytotoxics	Cytotoxics	Cytotoxics	Hormones
bleomycin	docetaxel	irinotecan	anastrozole
calcium folinate	doxorubicin	methotrexate	bicalutamide
capecitabine	etoposide	oxaliplatin	dexamethasone
carboplatin	fluorouracil	paclitaxel	leuprorelin
cisplatin	filgrastim	rituximab	tamoxifen
cyclophosphamide	gemcitabine	trastuzumab	
dacarbazine	ifosfamide+mesna	vinblastine	
dactinomycin	imatinib	vincristine	
		vinorelbine	

http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf

WHO ESSENTIAL MEDICINES LIST 2015

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	Total Countries	Surveyed Countries	percent	Total Pop (bil)	Surveyed population	Percent
Sub Saharan Africa	51	9	18%	0.795	0.245	32%
North Africa	6	4	67%	0.161	0.155	96%
Mid East	16	9	56%	0.195	0.117	60%
Asia and Indian	29	13	49%	3.703	3.192	86%
Ocana	21	1	5%	0.033	0.02	61%
N America	5	2	40%	0.332	0.332	100%
Latin AM and Carrib	45	6	13%	0.562	0.423	75%
	173	44	25%	5.781	4.484	76%

High

Multi-use EML

**Upper
Middle**

**Low
Middle**

Low

COST AND AVAILABILITY

Country	Bleo	CarboP	CisP	Cyclo (IV)	Cyclo (tab)	DTIC	Dox.	Epir.	Etop (IV)	SFU	Ifos.	MTX (IV)	MTX (tab)	VBL	VCR
Argentina	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Australia	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Canada	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Chile	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Cyprus	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Israel	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Japan	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost
Korea, South	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost
Oman	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Qatar	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost
Saudi Arabia	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Singapore	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost
United Arab Emirates	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
USA	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost
Algeria	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Brazil	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
China	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost
Colombia	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Iran	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost
Kazakhstan	Free	Free	Free	Free	Not available	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Lebanon	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Malaysia	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Mexico	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Peru	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
South Africa	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Thailand	Free	Free	Free	Free	Free	Not available	Free	Not available	Free	Free	Free	Free	Free	Free	Free
Tunisia	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Turkey	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Bangladesh	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Egypt	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Ghana	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
India	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost	<25% cost
Kenya	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Morocco	Free	Discount >50% and <100%	Discount >50% and <100%	Discount >50% and <100%	Discount >50% and <100%	Discount >50% and <100%	Discount >50% and <100%	Discount >50% and <100%	Discount >50% and <100%	Discount >50% and <100%	Discount >50% and <100%	Discount >50% and <100%	Discount >50% and <100%	Discount >50% and <100%	Discount >50% and <100%
Pakistan	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Palestine	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Sudan	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Vietnam	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Zambia	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Afghanistan	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Burkina Faso	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Tanzania	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Uganda	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free
Zimbabwe	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free	Free

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

INEXPENSIVE, ESSENTIAL CANCER MEDICINES



Rationale

- ESMO-conducted surveys on the availability of anticancer medicines indicated a imminent need to address the issue of shortages of essential, cancer medicines.
- There are 3 main reasons to address this topic (in Europe and internationally):
 - Growing disparities within Europe, Asia, Africa and rest of the world
 - Depleting stocks of medicines crucial to the treatment of cancer patients (in EU and globally)
 - Lack of incentives to produce essential medicines
- Thus, based on the sentiment within ESMO, we decided to prioritize this crucial topic, which is being overlooked at the national (EU), European and global levels.

INEXPENSIVE, ESSENTIAL CANCER MEDICINES



Summary of the discussion points (1)

- Challenges faced by the physicians, patients and industry
- Describe all the potential barriers for access including, but not limited to:
 - Manufacturing/Production
 - Distribution
 - Reimbursement
- Understand different realities:
 - Frequent vs infrequent tumours
 - Small vs big size countries
- Create coalition with other medical societies

INEXPENSIVE, ESSENTIAL CANCER MEDICINES



Summary of the discussion points (2)

- Brainstorm and understand the reasons behind the shortages of inexpensive but essential cancer medicines
- Propose solutions to address those shortages
- Acknowledge the lack of data concerning multiple aspects of those shortages:
 - The extent of the shortages
 - The products more touched by those shortages
 - The reasons behind those shortages
- Acknowledge the lack of political awareness concerning those shortages

INEXPENSIVE, ESSENTIAL CANCER MEDICINES



Next steps

- Obtain more precise information on access to inexpensive medicines – notably on shortages – through an agreement with the Economist Intelligence Unit to do a report on this issue in 2017
- Increase awareness about this issue with high-profile partners, such as the EIU
- Garner support and present the recommendations to the politicians (2017)
- Work towards translating the recommendations into action at the national levels in collaboration with the ESMO National Representatives and local Oncology Societies (2017-2018)

EXPENSIVE, INNOVATIVE CANCER MEDICINES



Rationale

- As a Scientific Society, ESMO has:
 - Conducted surveys on the situation of antineoplastic medicines
 - Created tools that aim to address the topic of the value of cancer medicines (in curative and non-curative settings):
 - **Magnitude of Clinical Benefit Scale**
 - Strong relationships with Regulators (EMA) and HTA bodies (EUnetHTA)
- ESMO has also recognized that our **society is entering a new era where the sustainability of healthcare systems and management of costs of cancer medicines (both for the Reimbursing Bodies/National Health Services and the Developers) will become crucial**

EXPENSIVE, INNOVATIVE CANCER MEDICINES

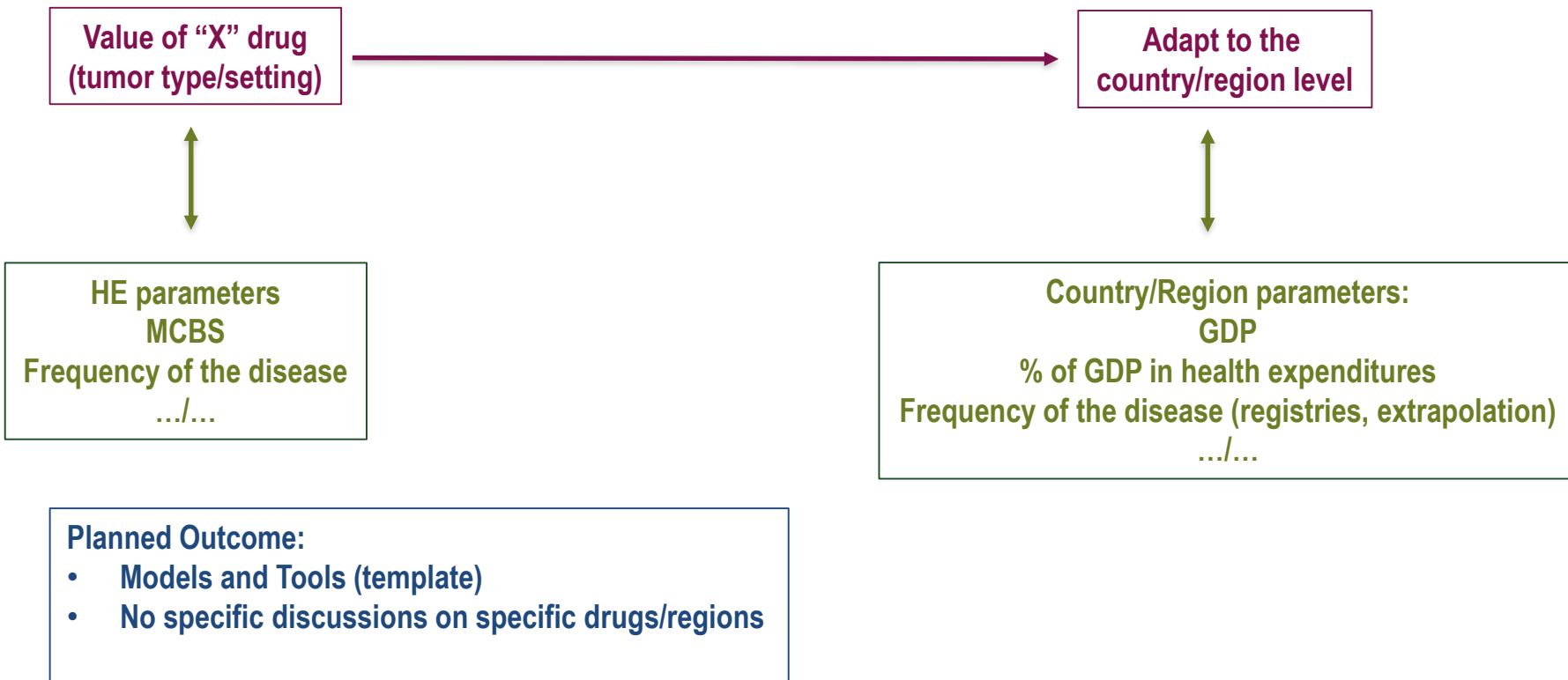


Actions

- ESMO has created an expert group aimed to:
 - Brainstorm and highlight areas that need to be addressed (management of cancer medicine costs, reimbursement of medicines, etc)
 - Devise a plan of action with the input of the experts
 - Work towards creating a balanced ESMO position on this topic
 - Work towards translating the recommendations into models that could facilitate the interaction between different stakeholders at the regional level (2017)

EXPENSIVE, INNOVATIVE CANCER MEDICINES

Outline of the model: Reimbursement based on local-referenced value





BIOSIMILARS

ESMO'S POSITION

- To ensure that patients are being prescribed the safest and most efficacious possible treatments, **all key actors** including the prescribers and patients will **need to understand the complexities of biosimilars** and take decisions that will be in the patient's interests
- Given the importance of the topic, **ESMO developed a manuscript** that aims to explore the issues surrounding biosimilars that are relevant to the field of oncology, especially the prescribers
- The Manuscript has been published in ESMO Open

OUTLINE OF MANUSCRIPT



- Definitions: bioequivalence, biosimilars, biobetters, non-comparable biologics
- Labelling process, including sensitive endpoints
- Extrapolation
- Interchangeability, switching and automatic substitution
- Clinical standards: safety and efficacy of biosimilars
- Responsibilities between prescribers and pharmacists
- Impact on the financial burden



Open Access

Review



Biosimilars: a position paper of the European Society for Medical Oncology, with particular reference to oncology prescribers

Josep Tabernero,¹ Malvika Vyas,² Rosa Giuliani,³ Dirk Arnold,⁴ Fatima Cardoso,⁵ Paolo G Casali,⁶ Andres Cervantes,⁷ Alexander MM Eggermont,⁸ Alexandru Eniu,⁹ Jacek Jassem,¹⁰ George Pentheroudakis,¹¹ Solange Peters,¹² Stefan Rauh,¹³ Christoph C Zielinski,¹⁴ Rolf A Stahel,¹⁵ Emile Voest,¹⁶ Jean-Yves Douillard,² Keith McGregor,² Fortunato Ciardiello¹⁷



NEXT STEPS



- ESMO will continue to be **present in discussions on this topic** at the EU and international levels, as necessary
- ESMO will continue to carry out **educational activities** on the topic of biosimilars

THANK YOU

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