

ESMO Study of formulary listing, out of pocket cost and actual availability of anti neoplastic agents in Europe

Preliminary Findings

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Background

Project background

- ESMO is committed to assuring timely and optimal treatment of cancer patients.
- The availability of opioids and anti-neoplastic medicines directly affects the daily practice of ESMO members and their ability to treat cancer patients according to the ESMO Clinical Practice Guidelines.
- Affordability of medications impacts on just distribution of care

Common issues with anti-neoplastic agents

■ Limitations in formulary

- No comprehensive mapping of formularies in Europe

■ Actual availability

- Recent drug shortages

■ Barriers to access to expensive drugs

- Resource allocation issues
- High out of pocket expense

Study development, design, methodology

Aims of the Study

■ To Evaluate in Europe

1. formulary availability of licensed anti-neoplastic medicines across Europe
2. Patient out of pocket cost for the medication
3. Pre approval requirements and delays
4. The actual availability of the medication for a patient with a valid prescription
5. Factor adversely impacting availability

Project leaders

■ Alexandru Eniu, Romania

- ESMO Emerging Countries Committee Chair

■ Nathan Cherny, Israel

- ESMO Palliative Care Working Group Past Chair

■ ESMO Committees involved in developing and completing the survey

- ESMO President and Executive Board
- ESMO Emerging Countries Committee
- ESMO Public Policy Committee
- ESMO Membership & National Representatives Committee
- ESMO Community Oncology Working Group
- ESMO Palliative Care Working Group
- ESMO Committee Chairs

Coordinating and Collaborating Partners

■ Coordinating Organization

■ ESMO

■ Collaborating Project Partners

1. World Health Organization (WHO)
2. Union for International Cancer Control (UICC)
3. Institute of Cancer Policy, Kings College, London
4. European Society of Oncology Pharmacy (ESOP)



Survey development

- Modelled on previous opioid studies
- Highlights common oncologic conditions
- 2 parts
 1. General questions about health care system
 2. Formulary assessment for 13 diseases

Diseases surveyed

- Breast Cancer
- Lung Cancer
- Colorectal Cancer
- Prostate Cancer
- Ovarian Cancer
- Sarcoma
- Pancreatic cancer
- Germ cell Tumors
- Renal cell Cancer
- GIST
- Urothelial Cancers
- Gastric and esophageal cancer
- Melanoma

General Questions regarding health care system

General Questions

Does the country have a National Essential Medicines List that includes anti cancer drugs?	Yes	No
Does the country have a national oncology association?	Yes	No
Are cancer medications covered by national insurance?	Yes	No
Is generic substitution allowed in your country?	Yes	No
Is oncology pharmacy service provided in your country?	Yes	No

Which of the following would best describe the national health care system in your country

1. a nationalized government run health care service for all citizens without an option for supplementary insurance
2. a nationalized government run health care service for all citizens with an option for supplementary insurance
3. a nationalized government run health care service for ALL uninsured citizens
4. a nationalized government run health care service ONLY for impoverished and or elderly uninsured citizens
5. a network of government funded but privately administered health management organizations WITHOUT an option for supplementary insurance
6. a network of government funded but privately administered health management organizations WITH an option for supplementary insurance

Example of form :Metastatic Breast Cancer

BREAST CANCER (METASTATIC)

	Is it permitted to prescribe the medication for this indication?		Is the medicine reimbursed for this indication?		Does reimbursement require pre-authorisation?		Does the pre-authorisation process delay treatment by more than 4 weeks?		Cost of medication to patients (What proportion of the full retail price does the AVERAGE PATIENT have to pay?)					Actual availability when needed for most patients in your country (Can patients actually get the medication when it is prescribed?)					If the medication is not always available, what are the reasons for this (one or more)?				
	Yes	No	Yes	No	Yes	No	Yes	No	Free	<25% cost	25-50% cost	Discount <50%	Full cost	Always	Usually	Half the time	Occasionally	Never	No / unreliable supplier	No commercial motive *	Parallel export **	Manufacturing problems	Budget capitation ***
Albumin-bound paclitaxel	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anastrozole	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bevacizumab	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Capecitabine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carboplatinum	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cisplatinum	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cyclophosphamide IV	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cyclophosphamide (tablets)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Denosumab	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Docetaxel	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Doxorubicin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Epirubicin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Eribulin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Identification of data reporters

- National representatives
- Known credible professionals nominated by coordinating and collaborating partners
- Minimum of 2 reporters for each country nominated
- Total 185 from 49 countries

Data Collection and Management

- Electronic dissemination of surveys and automated data entry
- Crosschecking data entry and clarification of discrepancies between reporters
- Conflicting data (Individual reporters, multiple reporters)
 - Priority given to highly credentialed reporters
 - Representative data presented
- Open peer review of preliminary representative data (planned)

Color coded tabulated data presentation

- Color coded tabulated data presentation
- Methodology developed on ESMO Opioid studies
- Established and widely endorsed clarity
- Readily allow cross country comparisons
- Facilitates presentation of changes over time

Expected results and outcomes: General

■ Identification of inequalities in availability and patient costs

■ Potential Users

1. European Medicines Agency (EMA)
2. European Union (EU)
3. WHO
4. Ministries of Health in improving national cancer control plans.
5. National cancer organizations
6. Patient advocacy organizations

■ Future Uses

- Cross correlation with essential drug lists
- Evaluation of formulary priorities

Results

Results

- 102/185 responses from 46/49 countries
- Respondents
 - 25 oncology pharmacists (22 countries)
 - 77 oncologists
 - 74 Academic cancer centers or hospitals

Diseases with high levels of variability in cost and availability

Renal cell

Melanoma

Renal Cell: Formulary and cost

	RENAL CELL: Formulary and Cost											
Country:	Pazopanib	Sorafenib	Sunitinib	Axitinib	Everolimus	Temsirolimus	Bevacizumab	High dose IL-2	IFN	Pamidronate	Zolederonate	Denosomab
Austria												
Belgium												
Cyprus												
Denmark												
Finland												
France												
Germany												
Greece												
Holland												
Ireland												
Israel												
Italy												
Luxembourg												
Norway												
Portugal												
Spain												
Sweden												
Switzerland												
Turkey												
United Kingdom												

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

	RENAL CELL: Formulary and Cost											
Country:	Pazopanib	Sorafenib	Sunitinib	Axitinib	Everolimus	Temsirolimus	Bevacizumab	High dose IL-2	IFN	Pamidronate	Zolederonate	Denosomab
Albania												
Armenia												
Belarus												
Bosnia and Herzegovina												
Bulgaria												
Croatia												
Czech Republic												
Estonia												
Georgia												
Hungary												
Kosovo, Republic of												
Kyrgyzstan												
Latvia												
Lithuania												
Macedonia												
Malta												
Montenegro												
Poland												
Romania												
Russian Federation												
Serbia												
Slovenia												
Slovakia												
Ukraine												
Uzbekistan												

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

Renal Cell : Actual Availability

	RENAL CELL: Actual Availability											
Country:	Pazopanib	Sorafenib	Sunitinib	Axitinib	Everolimus	Temsirolimus	Bevacizumab	High dose IL-2	IFN	Pamidronate	Zolederonate	Denosomab
Austria												
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Israel												
Italy												
Luxembourg												
Norway												
Portugal												
Spain												
Sweden												
Switzerland												
Turkey												
United Kingdom												

	Always
	Usually
	Half the time
	Occasionally
	Never
	Not available

	RENAL CELL: Actual Availability											
Country:	Pazopanib	Sorafenib	Sunitinib	Axitinib	Everolimus	Temsirolimus	Bevacizumab	High dose IL-2	IFN	Pamidronate	Zolederonate	Denosomab
Albania												
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Hungary												
Kosovo, Republic of												
Kyrgyzstan												
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Malta												
Montenegro												
Poland												
Romania												
Russian Federation												
Serbia												
Slovenia												
Slovakia												
Ukraine												
Uzbekistan												

	Always
	Usually
	Half the time
	Occasionally
	Never
	Not available

Renal Cell : Preapproval requirements and delays >4 weeks

[illegible]



High dose IL-

[illegible]

Melanoma: Formulary and cost

Country:	Interferon	Dacarbazine	Fotemustine	High-Dose IL-2	TNF (intraarterial)	Temozolomide	Ipilimumab	Vemurafenib	Trametinib	Dabrafenib
Austria										
Belgium										
Cyprus										
Denmark										
Finland										
France										
Germany										
Greece										
Holland										
Ireland										
Israel										
Italy										
Luxembourg										
Norway										
Portugal										
Spain										
Sweden										
Switzerland										
Turkey										
United Kingdom										

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

	MELANOMA: Formulary and cost									
Country:	Interferon	Dacarbazine	Fotemustine	High-Dose IL-2	TNF (intraarterial)	Temozolomide	Ipilimumab	Vemurafenib	Trametinib	Dabrafenib
Albania										
Armenia										
Belarus										
Bosnia and Herzegovina										
Bulgaria										
Croatia										
Czech Republic										
Estonia										
Georgia										
Hungary										
Kosovo, Republic of										
Kyrgyzstan										
Latvia										
Lithuania										
Macedonia										
Malta										
Montenegro										
Poland										
Romania										
Russian Federation										
Serbia										
Slovenia										
Slovakia										
Ukraine										
Uzbekistan										

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

Melanoma : Actual Availability

	MELANOMA: actual availability									
Country:	Interferon	Dacarbazine	Fotemustine	High-Dose IL-2	TNF (intraarterial)	Temozolomide	Ipilimumab	Vemurafenib	Trametinib	Dabrafenib
Austria										
Belgium										
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Holland										
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Norway										
Portugal										
Spain										
Sweden										
Switzerland										
Turkey										
United Kingdom										

	Always
	Usually
	Half the time
	Occasionally
	Never
	Not available

	MELANOMA: actual availability									
Country:	Interferon	Dacarbazine	Fotemustine	High-Dose IL-2	TNF (intraarterial)	Temozolomide	Ipilimumab	Vemurafenib	Trametinib	Dabrafenib
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Czech Republic										
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Malta										
Montenegro										
Poland										
Romania										
Russian Federation										
Serbia										
Slovenia										
Slovakia										
Ukraine										
Uzbekistan										

	Always
	Usually
	Half the time
	Occasionally
	Never
	Not available

Melanoma : Preapproval requirements and delays >4 weeks

Diseases with segmental of variability in cost and availability

Sarcoma

Lung Cancer

Breast Cancer

Colorectal Cancer

Ovarian Cancer

Lung Cancer: Formulary and cost

	LUNG CANCER :Chermotherapy Formulary and Cost											
Country:	Carboplatin um	Cisplatinum	Docetaxel	Doxorubicin	Etoposide IV	Etoposide (tablets)	Gemcitabine	Paclitaxel	Pemetrexed	Topotecan	Vinorelbine (IV)	Vinorelbine (Tablets)
Austria												
Belgium												
Cyprus												
Denmark												
Finland												
France												
Germany												
Greece												
Holland												
Ireland												
Israel												
Italy												
Luxembourg												
Norway												
Portugal												
Spain												
Sweden												
Switzerland												
Turkey												
United Kingdom												

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

	LUNG CANCER : Chemotherapy Formulary and Cost											
Country:	Carboplatin um	Cisplatinum	Docetaxel	Doxorubicin	Etoposide IV	Etoposide (tablets)	Gemcitabine	Paclitaxel	Pemetrexed	Topotecan	Vinorelbine (IV)	Vinorelbine (Tablets)
Albania												
Armenia												
Belarus												
Bosnia and Herzegovina												
Bulgaria												
Croatia												
Czech Republic												
Estonia												
Georgia												
Hungary												
Kosovo, Republic of												
Kyrgyzstan												
Latvia												
Lithuania												
Macedonia												
Malta												
Montenegro												
PolandR												
Romania												
Russian Federation												
SerbiaR												
Slovenia												
Slovakia												
Ukraine												
Uzbekistan												

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

	LUNG CANCER : Biological and Bone Formulary and Cost					
Country:	Erlotinib	Gefitinib	Crizotanib	Pamidronat e	Zolederonat e	Denosumab
Austria						
Belgium						
Cyprus						
Denmark						
Finland						
France						
Germany						
Greece						
Holland						
Ireland						
Israel						
Italy						
Luxembourg						
Norway						
Portugal						
Spain						
Sweden						
Switzerland						
Turkey						
United Kingdom						

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

LUNG CANCER: Biological and Bone Formulary and Cost

Country:	Erlotinib	Gefitinib	Crizotinib	Pamidronate	Zoledronate	Denosumab
Albania						
Armenia						
Belarus						
Bosnia and Herzegovina						
Bulgaria						
Croatia						
Czech Republic						
Estonia						
Georgia						
Hungary						
Kosovo, Republic of						
Kyrgyzstan						
Latvia						
Lithuania						
Macedonia						
Malta						
Montenegro						
PolandR						
Romania						
Russian Federation						
SerbiaR						
Slovenia						
Slovakia						
Ukraine						
Uzbekistan						

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

Lung: Actual Availability

	LUNG CANCER:Chemotherapy actual availability											
Country:	Carboplatin um	Cisplatinum	Docetaxel	Doxorubicin	Etoposide IV	Etoposide (tablets)	Gemcitabine	Paclitaxel	Pemetrexed	Topotecan	Vinorelbine (IV)	Vinorelbine (Tablets)
Austria												
Belgium												
Cyprus												
Denmark												
Finland												
France												
Germany												
Greece												
Holland												
Ireland												
Israel												
Italy												
Luxembourg												
Norway												
Portugal												
Spain												
Sweden												
Switzerland												
Turkey												
United Kingdom												

	Always
	Usually
	Half the time
	Occasionally
	Never
	Not available

	LUNG CANCER:Chemotherapy actual availability											
Country:	Carboplatin um	Cisplatinum	Docetaxel	Doxorubicin	Etoposide IV	Etoposide (tablets)	Gemcitabine	Paclitaxel	Femetrexed	Topotecan	Vinorelbine (IV)	Vinorelbine (Tablets)
Albania												
Armenia												
Belarus												
Bosnia and Herzegovina												
Bulgaria												
Croatia												
Czech Republic												
Estonia												
Georgia												
Hungary												
Kosovo, Republic of												
Kyrgyzstan												
Latvia												
Lithuania												
Macedonia												
Malta												
Montenegro												
PolandR												
Romania												
Russian Federation												
SerbiaR												
Slovenia												
Slovakia												
Ukraine												
Uzbekistan												

	Always
	Usually
	Half the time
	Occasionally
	Never
	Not available

LUNG CANCER: Biological and Bone Actual

Country:	Erlotinib	Gefitinib	Crizotinib	Pamidronate	Zoledronate	Denosumab
Austria						
Belgium						
Cyprus						
Denmark						
Finland						
France						
Germany						
Greece						
Holland						
Ireland						
Israel						
Italy						
Luxembourg						
Norway						
Portugal						
Spain						
Sweden						
Switzerland						
Turkey						
United Kingdom						

	Always
	Usually
	Half the time
	Occasionally
	Never
	Not available

LUNG CANCER: Biological and Bone Actual

Country:	Erlotinib	Gefitinib	Crizotinib	Pamidronate	Zoledronate	Denosumab
Albania						
Armenia						
Belarus						
Bosnia and Herzegovina						
Bulgaria						
Croatia						
Czech Republic						
Estonia						
Georgia						
Hungary						
Kosovo, Republic of						
Kyrgyzstan						
Latvia						
Lithuania						
Macedonia						
Malta						
Montenegro						
PolandR						
Romania						
Russian Federation						
SerbiaR						
Slovenia						
Slovakia						
Ukraine						
Uzbekistan						

	Always
	Usually
	Half the time
	Occasionally
	Never
	Not available

Colorectal: Formulary and cost

COLORECTAL CANCER : Formulary and cost

Country:	Capecitabine	Fluorouracil	Irinotecan	Mitiomycin C	Oxaliplatin	Bevacizumab	Cetuximab	Panitumumab	Regorafenib	Ralititrexed	Aflibercept
Austria											
Belgium											
Cyprus											
Denmark											
Finland											
France											
Germany											
Greece											
Holland											
Ireland											
Israel											
Italy											
Luxembourg											
Norway											
Portugal											
Spain											
Sweden											
Switzerland											
Turkey											
United Kingdom											

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

	COLORECTAL CANCER : Formulary and cost										
Country:	Capecitabine	Fluorouracil	Irinotecan	Mitomycin C	Oxaliplatin	Bevacizumab	Cetuximab	Panitumumab	Regorafenib	Raltitrexed	Aflibercept
Albania											
Armenia											
Belarus											
Bosnia and Herzegovina											
Bulgaria											
Croatia											
Czech Republic											
Estonia											
Georgia											
Hungary											
Kosovo, Republic of											
Kyrgyzstan											
Latvia											
Lithuania											
Macedonia											
Malta											
Montenegro											
PolandR											
Romania											
Russian Federation											
SerbiaR											
Slovenia											
Slovakia											
Ukraine											
Uzbekistan											

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

Colorectal : Actual Availability

COLORECTAL: Formulary and Cost

Country:	Capecitabine	Fluorouracil	Irinotecan	Mitiomycin C	Oxaliplatin	Bevacizumab	Cetuximab	Panitumumab	Regorafenib	Ralititrexed	Aflibercept
Austria											
Belgium											
Cyprus											
Denmark											
Finland											
France											
Germany											
Greece											
Holland											
Ireland											
Israel											
Italy											
Luxembourg											
Norway											
Portugal											
Spain											
Sweden											
Switzerland											
Turkey											
United Kingdom											

	Always
	Usually
	Half the time
	Occasionally
	Never
	Not available

	COLORECTAL: Formulary and Cost										
Country:	Capecitabine	Fluorouracil	Irinotecan	Mitomycin C	Oxaliplatin	Bevacizumab	Cetuximab	Panitumumab	Regorafenib	Ralititrexed	Aflibercept
Albania	Usually	Usually	Usually	Never	Usually	Occasionally	Never	Not available	Not available	Not available	Not available
Armenia	Usually	Never	Usually	Never	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Belarus	Always	Always	Always	Not available	Always	Always	Usually	Not available	Not available	Not available	Not available
Bosnia and Herzegovina	Always	Always	Always	Not available	Always	Always	Occasionally	Always	Not available	Not available	Always
Bulgaria	Always	Occasionally	Always	Always	Always	Always	Occasionally	Occasionally	Not available	Not available	Not available
Croatia	Always	Always	Always	Occasionally	Always	Always	Always	Not available	Not available	Not available	Not available
Czech Republic	Always	Always	Always	Always	Always	Always	Always	Always	Usually	Usually	Usually
Estonia	Always	Always	Always	Always	Always	Always	Always	Always	Never	Never	Never
Georgia	Usually	Usually	Usually	Usually	Usually	Usually	Occasionally	Never	Never	Never	Never
Hungary	Always	Usually	Usually	Usually	Usually	Always	Always	Never	Always	Not available	Usually
Kosovo, Republic of	Usually	Usually	Usually	Usually	Usually	Usually	Not available	Not available	Not available	Not available	Not available
Kyrgyzstan	Occasionally	Usually	Usually	Usually	Usually	Occasionally	Occasionally	Occasionally	Never	Occasionally	Never
Latvia	Always	Usually	Always	Always	Always	Always	Always	Always	Usually	Usually	Always
Lithuania	Always	Always	Always	Always	Always	Usually	Usually	Occasionally	Never	Never	Occasionally
Macedonia	Always	Always	Always	Not available	Never	Never	Not available	Not available	Not available	Not available	Not available
Malta	Always	Always	Always	Always	Always	Always	Always	Usually	Usually	Usually	Usually
Montenegro	Always	Always	Always	Usually	Always	Always	Always	Usually	Usually	Usually	Usually
PolandR	Always	Always	Always	Always	Always	Always	Always	Always	Never	Never	Never
Romania	Always	Always	Always	Occasionally	Always	Always	Always	Never	Never	Never	Never
Russian Federation	Usually	Always	Usually	Always	Usually	Occasionally	Occasionally	Occasionally	Never	Never	Occasionally
SerbiaR	Usually	Usually	Usually	Usually	Usually	Always	Always	Not available	Not available	Not available	Not available
Slovenia	Always	Always	Always	Always	Always	Always	Usually	Occasionally	Occasionally	Not available	Usually
Slovakia	Always	Usually	Usually	Usually	Always	Always	Usually	Always	Usually	Not available	Not available
Ukraine	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Uzbekistan	Occasionally	Not available	Always	Not available	Always	Occasionally	Not available	Not available	Not available	Not available	Not available

Always	Always
Usually	Usually
Half the time	Half the time
Occasionally	Occasionally
Never	Never
Not available	Not available

Colorectal : Preapproval requirements and delays >4 weeks

[illegible]

[illegible]

Diseases with less variability

Adjuvant Breast Cancer

Gastric

Germ Cell

Urothelial

Germ Cell: Formulary and cost

GERM CELL: Formulary and Cost

Country:	Bleomycin	Etoposide	Cisplatin	Carboplatin	Docetaxel	Paclitaxel	Gemcitabine	Ifosfamide	Vinblastine	Vincristine
Austria										
Belgium										
Cyprus										
Denmark										
Finland										
France										
Germany										
Greece										
Holland										
Ireland										
Israel										
Italy										
Luxembourg										
Norway										
Portugal										
Spain										
Sweden										
Switzerland										
Turkey										
United Kingdom										

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

GERM CELL: Formulary and Cost

Country:	Bleomycin	Etoposide	Cisplatin	Carboplatin	Docetaxel	Paclitaxel	Gemcitabine	Ifosfamide	Vinblastine	Vincristine
Albania										
Armenia										
Belarus										
Bosnia and Herzegovina										
Bulgaria										
Croatia										
Czech Republic										
Estonia										
Georgia										
Hungary										
Kosovo, Republic of										
Kyrgyzstan										
Latvia										
Lithuania										
Macedonia										
Malta										
Montenegro										
Poland										
Romania										
Russian Federation										
Serbia										
Slovenia										
Slovakia										
Ukraine										
Uzbekistan										

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

Germ Cell : Actual Availability

	GERM CELL: Actual Availability									
Country:	Bleomycin	Etoposide	Cisplatin	Carboplatin	Docetaxel	Paclitaxel	Gemcitabine	Ifosfamide	Vinblastine	Vincristine
Austria										
Belgium										
Cyprus										
Denmark										
Finland										
France										
Germany										
Greece										
Holland										
Ireland										
Israel										
Italy										
Luxembourg										
Norway										
Portugal										
Spain										
Sweden										
Switzerland										
Turkey										
United Kingdom										

	Always
	Usually
	Half the time
	Occasionally
	Never
	Not available

	GERM CELL: Actual Availability									
Country:	Bleomycin	Etoposide	Cisplatin	Carboplatin	Docetaxel	Paclitaxel	Gemcitabine	Ifosfamide	Vinblastine	Vincristine
Albania	Usually	Usually	Usually	Occasionally	Never	Occasionally	Never	Usually	Usually	Never
Armenia	Occasionally	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Belarus	Usually	Usually	Usually	Usually	Never	Usually	Usually	Usually	Usually	Never
Bosnia and Herzegovina	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Bulgaria	Usually	Usually	Usually	Usually	Never	Usually	Usually	Usually	Usually	Usually
Croatia	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Czech Republic	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Estonia	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Georgia	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Hungary	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Kosovo, Republic of	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Kyrgyzstan	Occasionally	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Latvia	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Lithuania	Usually	Usually	Usually	Usually	Never	Occasionally	Occasionally	Usually	Usually	Usually
Macedonia	Usually	Usually	Usually	Usually	Usually	Never	Never	Usually	Usually	Usually
Malta	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Montenegro	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Poland	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Romania	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Russian Federation	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Serbia	Usually	Usually	Usually	Usually	Never	Never	Never	Usually	Usually	Usually
Slovenia	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Occasionally	Usually	Usually
Slovakia	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Ukraine	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Uzbekistan	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually	Usually

Usually	Always
Usually	Usually
Usually	Half the time
Occasionally	Occasionally
Never	Never
Never	Not available

Urothelial : Formulary and cost

UROTHELIAL: Formulary and Cost

Country:	Carboplatinum	Cisplatinum	Docetaxel	Doxorubicin	Methotrexate	Paclitaxel	Vinblastine
Austria							
Belgium							
Cyprus							
Denmark							
Finland							
France							
Germany							
Greece							
Holland							
Ireland							
Israel							
Italy							
Luxembourg							
Norway							
Portugal							
Spain							
Sweden							
Switzerland							
Turkey							
United Kingdom							

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

UROTHELIAL: Formulary and Cost

Country:	Carboplatinum	Cisplatinum	Docetaxel	Doxorubicin	Methotrexate	Paclitaxel	Vinblastine
Albania							
Armenia							
Belarus							
Bosnia and Herzegovina							
Bulgaria							
Croatia							
Czech Republic							
Estonia							
Georgia							
Hungary							
Kosovo, Republic of							
Kyrgyzstan							
Latvia							
Lithuania							
Macedonia							
Malta							
Montenegro							
Poland							
Romania							
Russian Federation							
Serbia							
Slovenia							
Slovakia							
Ukraine							
Uzbekistan							

	Free
	<25% cost
	25-50% cost
	Discount <50%
	Full cost
	Not available

Urothelial : Actual Availability

	UROTHELIAL: Actual availability						
Country:	Carboplatinum	Cisplatinum	Docetaxel	Doxorubicin	Methotrexate	Paclitaxel	Vinblastine
Austria							
Belgium							
Cyprus							
Denmark							
Finland							
France							
Germany							
Greece							
Holland							
Ireland							
Israel							
Italy							
Luxembourg							
Norway							
Portugal							
Spain							
Sweden							
Switzerland							
Turkey							
United Kingdom							

	Always
	Usually
	Half the time
	Occasionally
	Never
	Not available

UROTHELIAL: Actual availability

Country:	Carboplatinum	Cisplatinum	Docetaxel	Doxorubicin	Methotrexate	Paclitaxel	Vinblastine
Albania	Usually	Usually	Usually	Occasionally	Half the time	Occasionally	Half the time
Armenia	Occasionally	Usually	Half the time	Occasionally	Occasionally	Half the time	Half the time
Belarus	Always	Always	Never	Always	Always	Always	Always
Bosnia and Herzegovina	Always	Always	Always	Always	Always	Always	Always
Bulgaria	Usually	Usually	Half the time	Half the time	Usually	Always	Usually
Croatia	Always	Always	Always	Always	Always	Always	Always
Czech Republic	Never	Never	Never	Never	Never	Never	Never
Estonia	Always	Always	Always	Always	Always	Always	Always
Georgia	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Hungary	Usually	Always	Usually	Usually	Usually	Usually	Usually
Kosovo, Republic of	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Kyrgyzstan	Usually	Usually	Usually	Always	Always	Always	Always
Latvia	Always	Always	Always	Always	Always	Always	Always
Lithuania	Occasionally	Always	Never	Always	Always	Occasionally	Occasionally
Macedonia	Always	Always	Never	Always	Always	Never	Always
Malta	Always	Always	Always	Always	Always	Always	Always
Montenegro	Always	Always	Always	Always	Always	Always	Always
Poland	Always	Always	Always	Always	Always	Always	Always
Romania	Always	Always	Always	Always	Always	Always	Always
Russian Federation	Usually	Always	Occasionally	Half the time	Usually	Occasionally	Always
Serbia	Always	Always	Never	Never	Always	Never	Always
Slovenia	Always	Always	Always	Always	Always	Always	Always
Slovakia	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Ukraine	Usually	Usually	Usually	Usually	Usually	Usually	Usually
Uzbekistan	Always	Always	Always	Always	Always	Always	Always

Always	Always
Usually	Usually
Half the time	Half the time
Occasionally	Occasionally
Never	Never
Not available	Not available

Preliminary Conclusions

- There are substantial differences in formulary availability , out of pocket costs and actual availability for many medications
- These differences
 - Are more profound in Eastern European Countries
 - Are related to the cost of new agents
- The impact of these differences are most profound in diseases where non curative outcomes are dependent on availability of expensive anticancer agents such as
 - EGFR or ALK mutated non small cell lung cancer
 - Melanoma
 - Renal Cell Cancer
 - RAS/RAF wild type colorectal cancer

Preliminary Conclusions 2

- These discrepancies are less pronounced in curative settings
 - This is best illustrated for Trastuzumab in adjuvant breast cancer which though expensive is generally subsidized and available in most countries
 - The discrepancies are even less when curative treatment do not require expensive therapies such as in Germ Cell Tumors
- Requirement for pre approval of treatments for purposes of coverage or reimbursement
 - is more common in Israel and many Eastern European Countries
 - is common for expensive anti cancer therapies
 - does not usually delay treatment by more than 4 weeks
 - Delays of more than 4 weeks caused by the pre-approval process tended to occur in specific countries in Eastern Europe (Albania, Armenia, Georgia, Romania)

Special Acknowledgments

ESMO Committees

1. ESMO President and Executive Board
2. ESMO Emerging Countries Committee
3. ESMO Public Policy Committee
4. ESMO Membership & National Representatives Committee
5. ESMO Community Oncology Working Group
6. ESMO Palliative Care Working Group
7. ESMO Committee Chairs

102 individual reporters

ESMO Logistics

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Marina Cogo, Survey Coordinator

Coordinator:

1. European Society for Medical Oncology (ESMO)

Collaborating Partners:

1. World Health Organization (WHO)
2. Kings College London Institute of Cancer Policy
3. European Society of Oncology Pharmacy (ESOP)
4. Union for International Cancer Control (UICC)

ESMO Study of formulary listing, out of pocket cost and actual availability of anti neoplastic agents in Europe

Concluding Remarks

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Preliminary Conclusions

- There are substantial differences in formulary availability , out of pocket costs and actual availability for many medications
- These differences
 - Are more profound in Eastern European Countries
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- The impact of these differences are most profound in diseases where non curative outcomes are dependent on availability of expensive anticancer agents such as
 - EGFR or ALK mutated non small cell lung cancer
 - Melanoma
 - Renal Cell Cancer
 - RAS/RAF wild type colorectal cancer

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International New York Times | <http://nyti.ms/1qDD7C3>



INTERNATIONAL BUSINESS | NYT NOW

Maker of Costly Hepatitis C Drug Sovaldi Strikes Deal on Generics for Poor Countries

By GARDINER HARRIS SEPT. 15, 2014

NEW DELHI — The maker of one of the costliest drugs in the world announced on Monday that it had struck deals with seven generic drug makers in India to sell lower-cost versions of the medicine — a \$1,000-a-pill hepatitis C treatment — in poorer countries.

Gilead Sciences, which is based in California, also said it would begin selling its own version of the drug in India and other developing countries at a fraction of the price it charges in the United States.

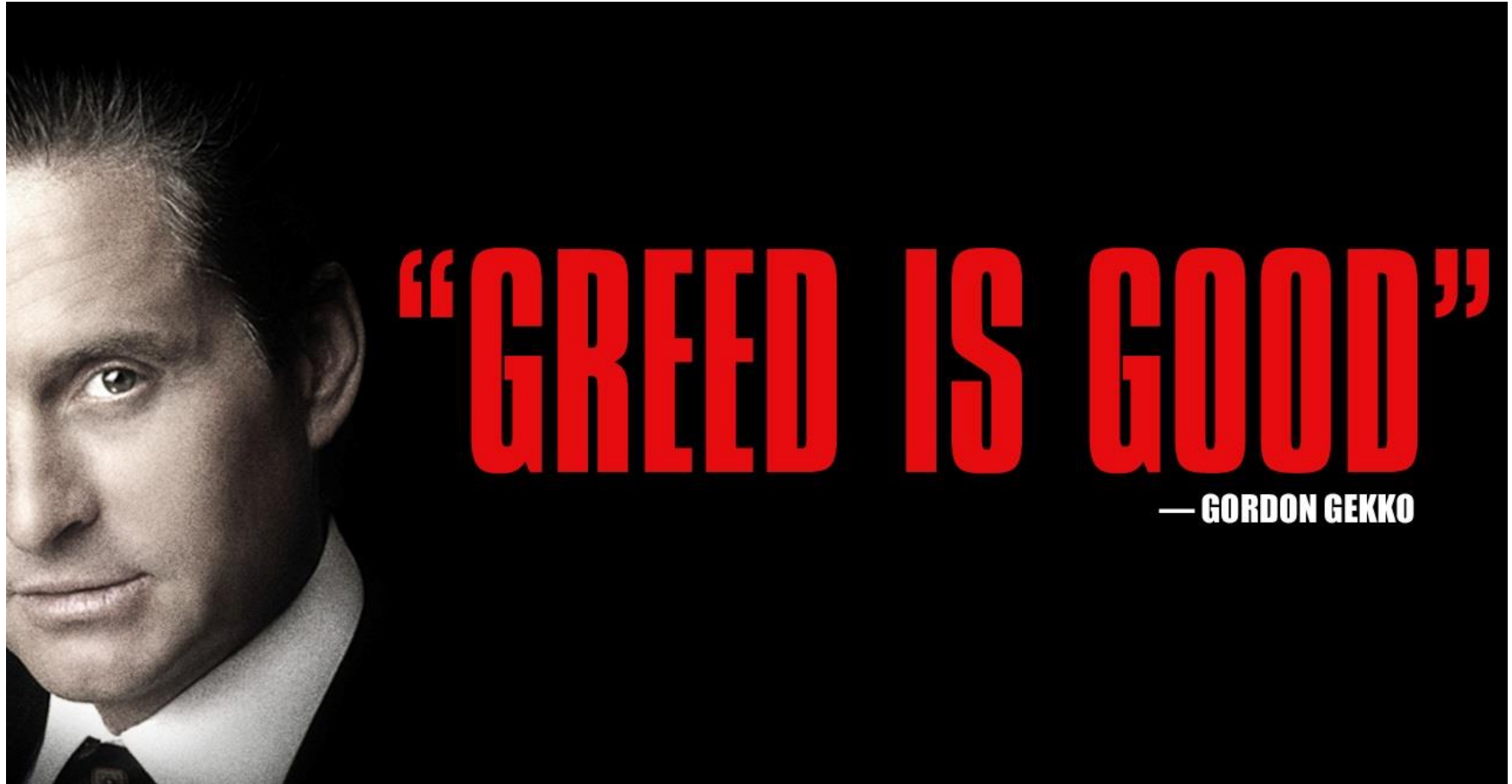
The company intends to provide greater access to the medicine, Sovaldi, for most of the nearly 180 million infected worldwide with hepatitis C who do not live in rich countries. Some 350,000 people die every year of hepatitis C infections, most of them in middle- and low-income nations.

Sovaldi, in only its initial year on the market after gaining approval in the United States in December, is on pace to exceed \$10 billion in sales in 2014, becoming one of the world's best-selling drugs. Its high price has led to intense criticism even in the United States, where officials say it could drain Medicaid budgets and insurers say it could cause increases in

Finding the right balance for the cancer medicine industry



Finding the right balance for the cancer medicine industry



Efficacy Does Not Necessarily Translate to Cost Effectiveness: A Case Study in the Challenges Associated With 21st-Century Cancer Drug Pricing

Bruce E. Hillner and Thomas J. Smith, *Department of Internal Medicine and the Massey Cancer Center, Virginia Commonwealth University, Richmond, VA*

(Table 1). Profiteering, the act of making a profit by methods considered unethical, such as raising prices after a natural disaster, is a pejorative term that we believe can be applied to this recent trend where a life-threatening disease is the natural disaster. Inequalities of

Professional public health advocacy

■ Responsibility

- Individual clinicians
- Professional organizations

■ Advocate for

- Affordability
 - Pharmaceutical industry: reduce prices
 - Governments: subsidies and reimbursements
- Equal access to care

■ Pharmaceutical industry

- Not bound by same ethical commitments as physicians
- Inherently seek to maximize profit and return
- Dynamic relationship: sometimes partner, sometimes adversary