

Implications of the findings from the ESMO study of regulatory barriers, cost and availability of anti-cancer agents for European oncologists and patients Preliminary Findings

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Disclosure slide

- Receipt of honoraria or consultation fees: Astra Zeneca, Roche, Novartis (none in relation to this presentation)

What information did we get?

■ Approval status (yes/no) across Europe

- Informative for new drugs

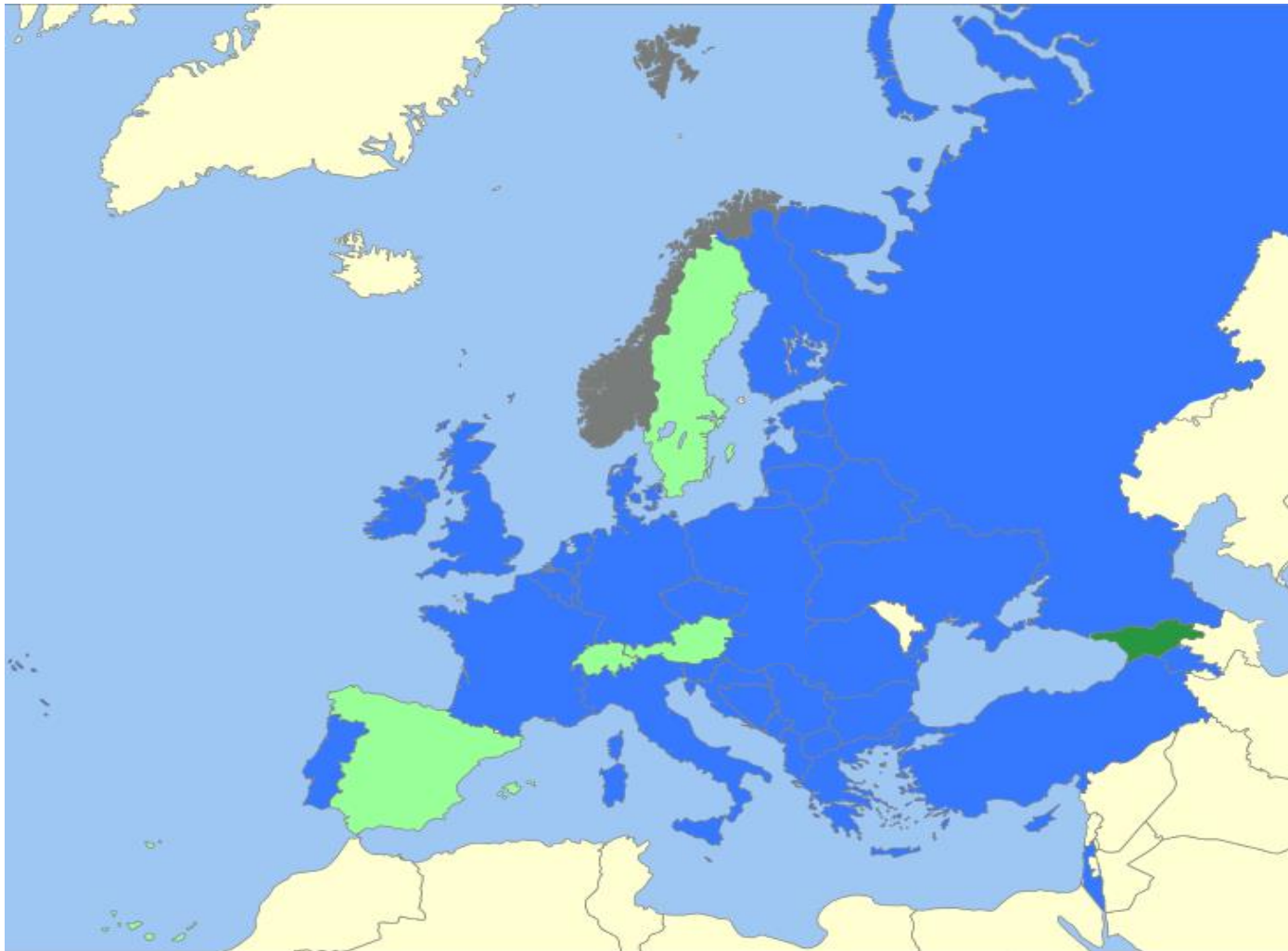
■ Reimbursement (yes/no)

- Highlight differences in cancer policies
- Residual (out of pocket) cost to patients
- Delays in access due to special authorization

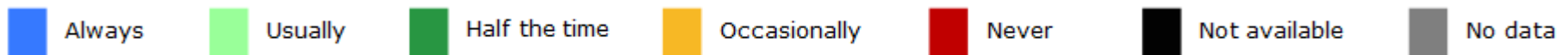
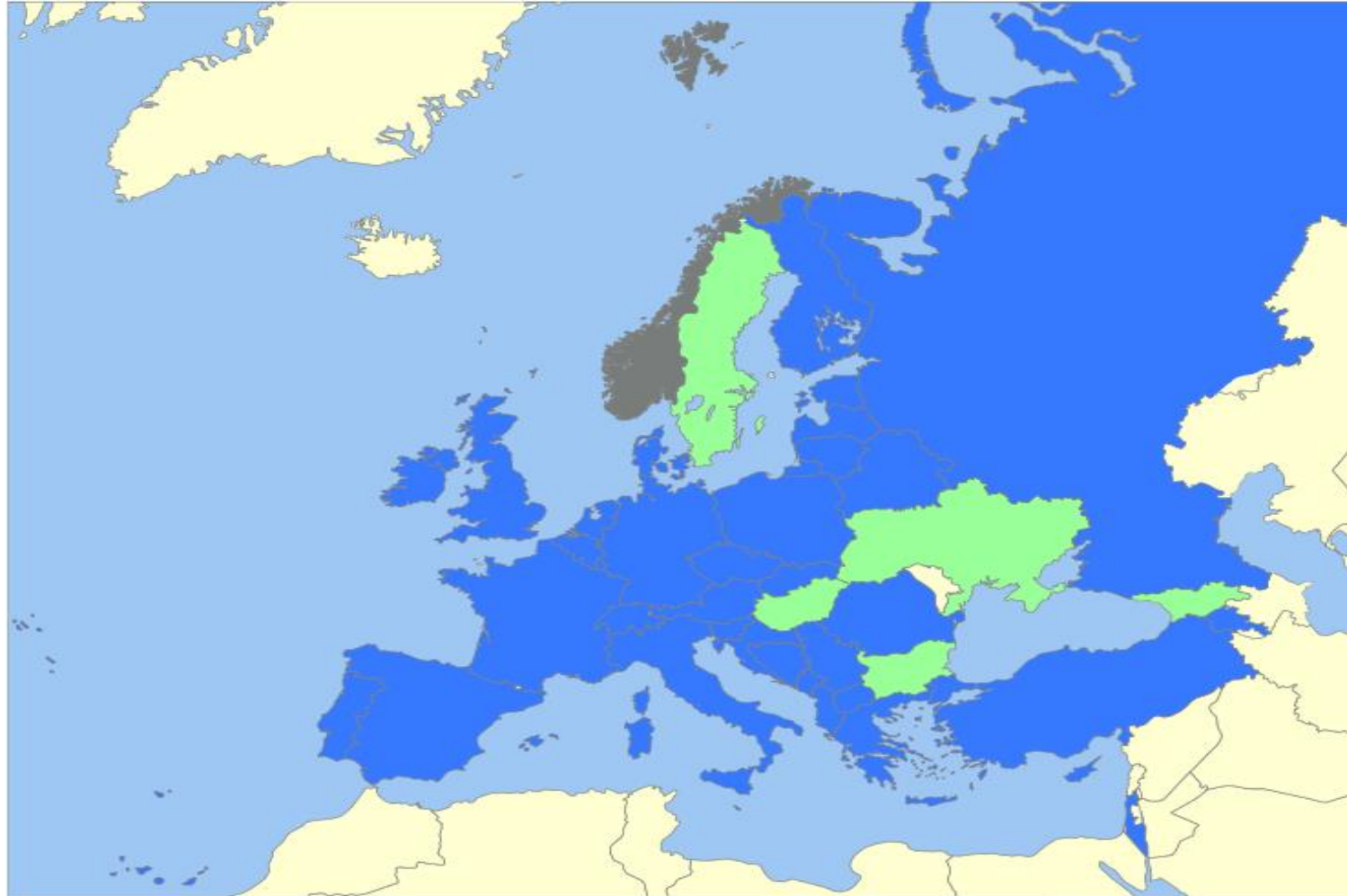
■ Actual availability

- Drug shortage for old drugs
- Unavailability in the pharmacy (parallel export) for expensive drugs

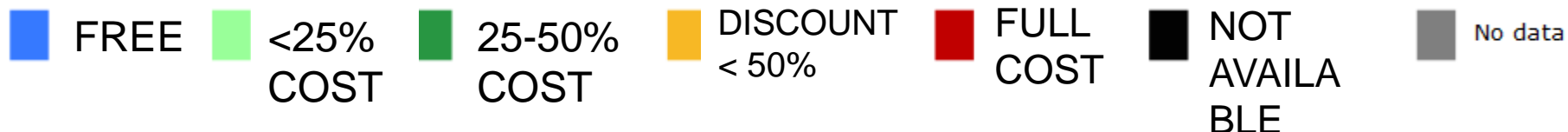
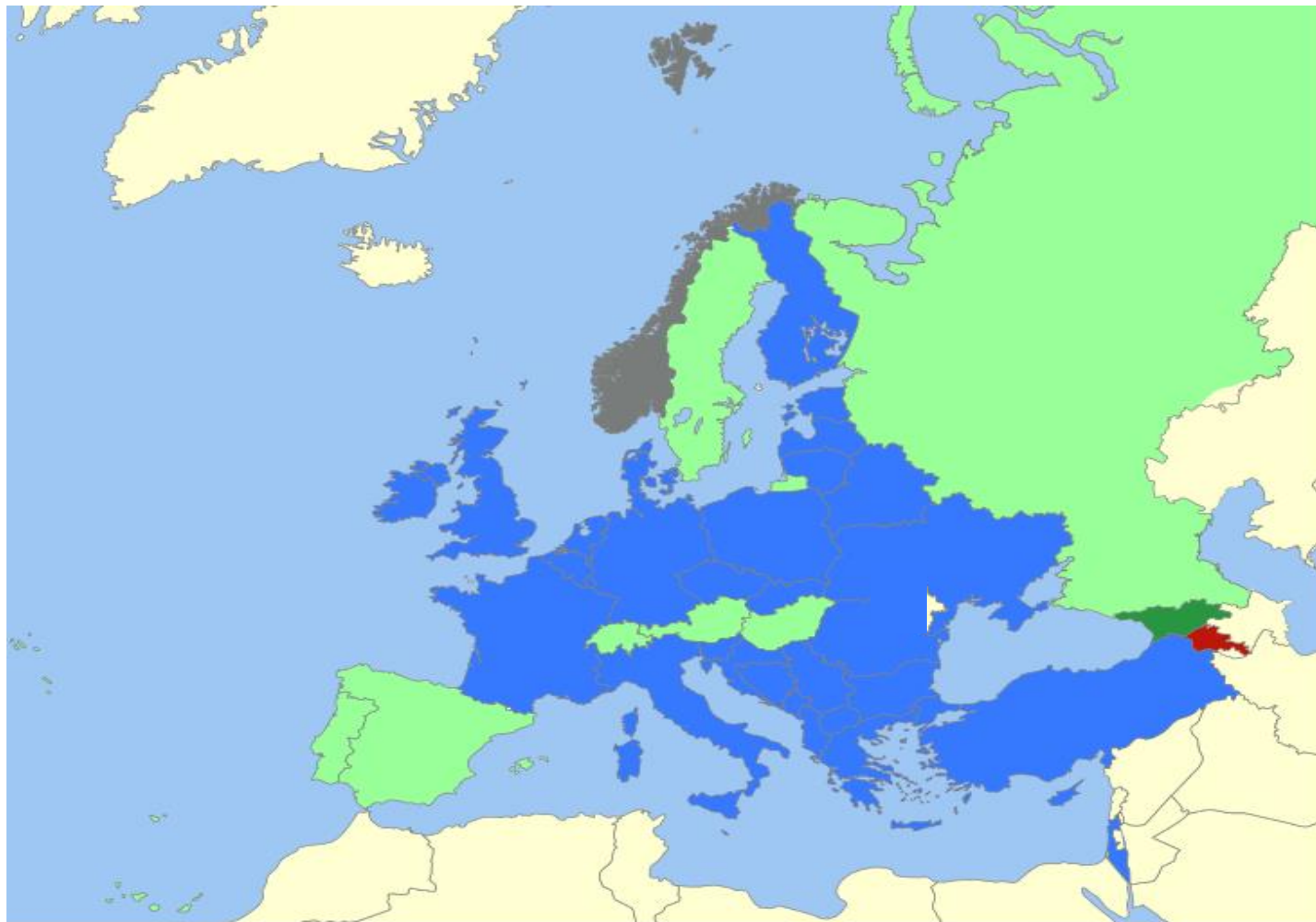
Adjuvant breast cancer: formulary and cost: TAMOXIFEN



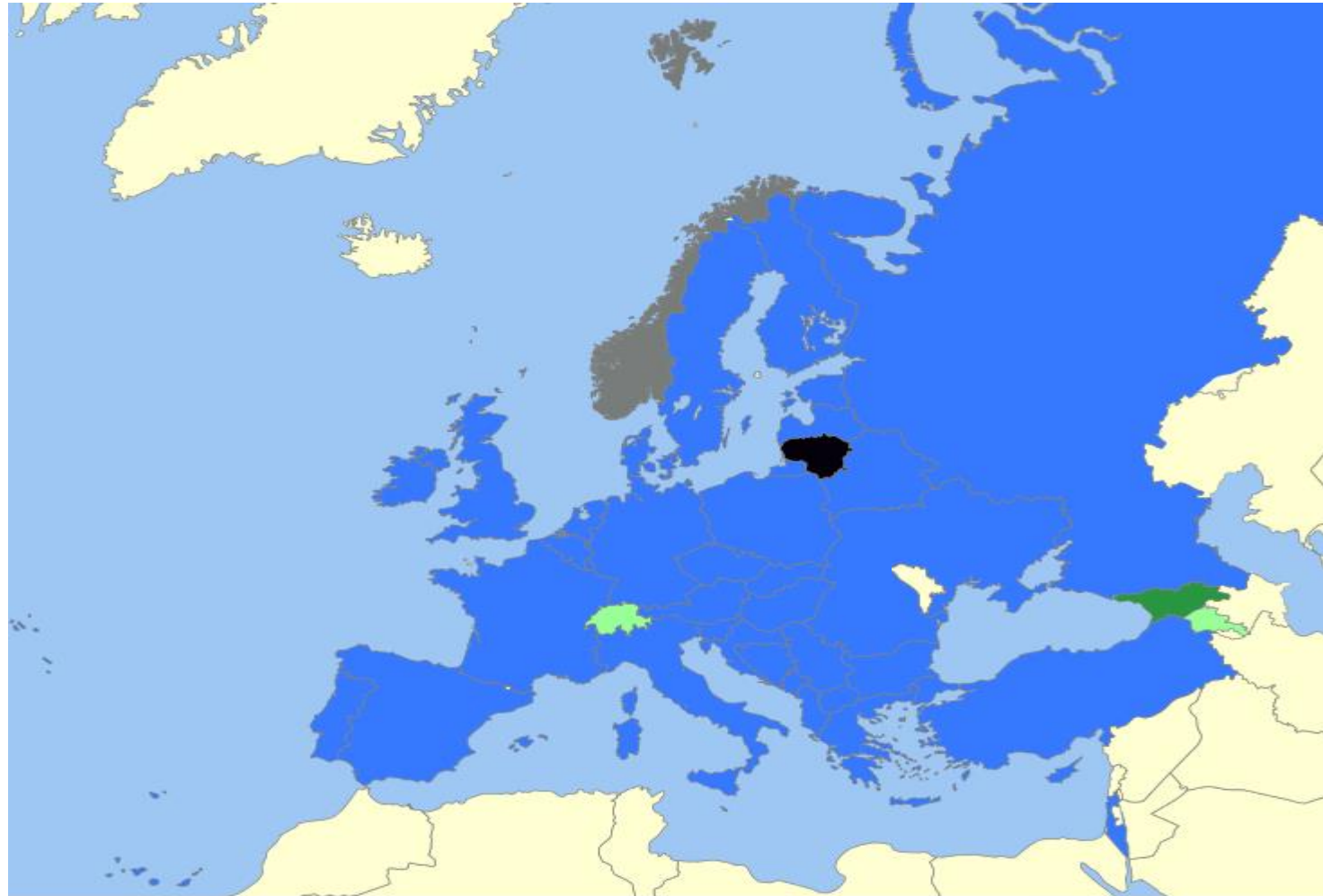
Adjuvant breast cancer: availability: **TAMOXIFEN**



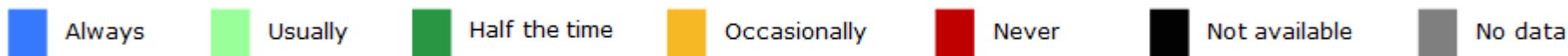
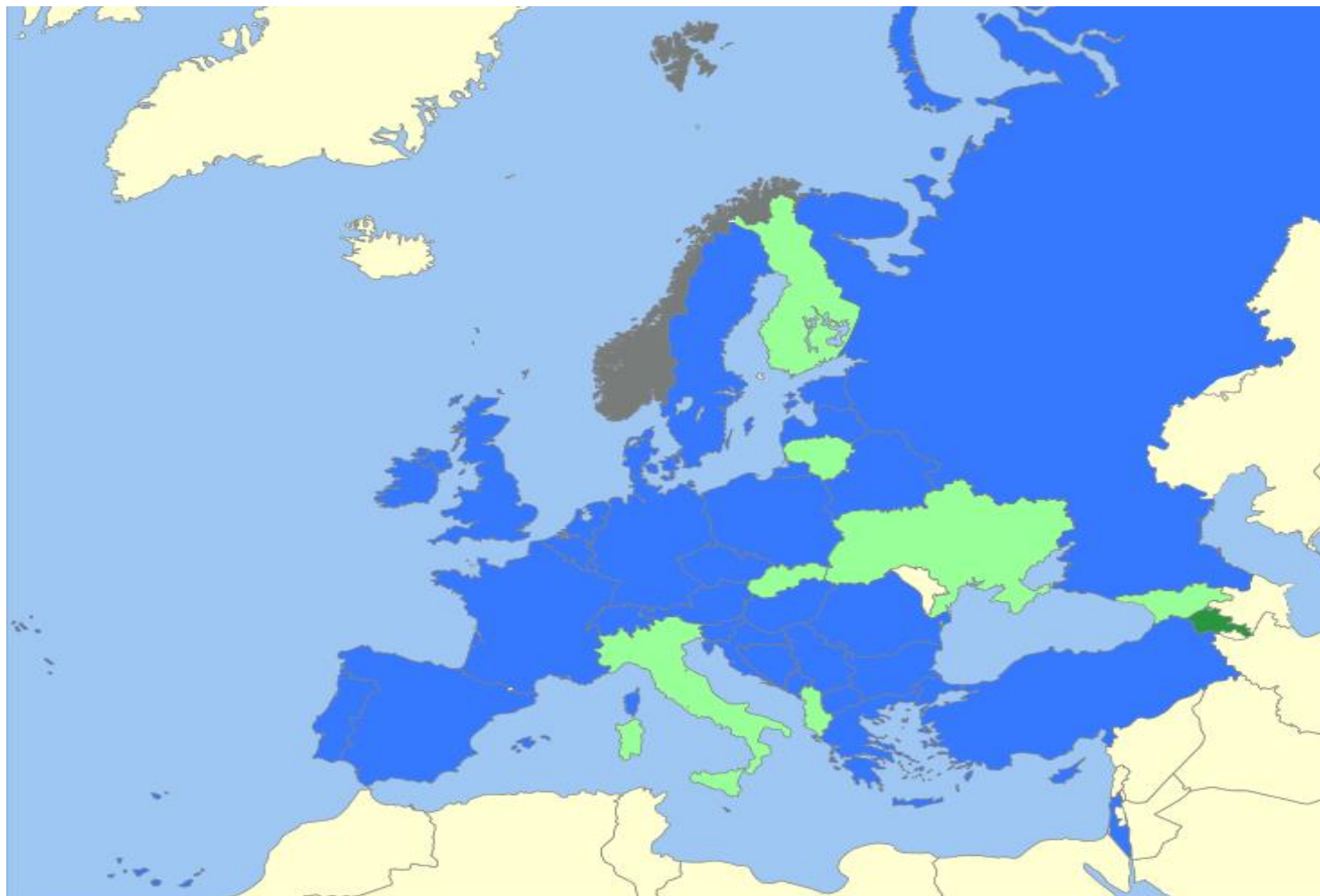
Adjuvant breast cancer: formulary and cost: ANASTROZOL



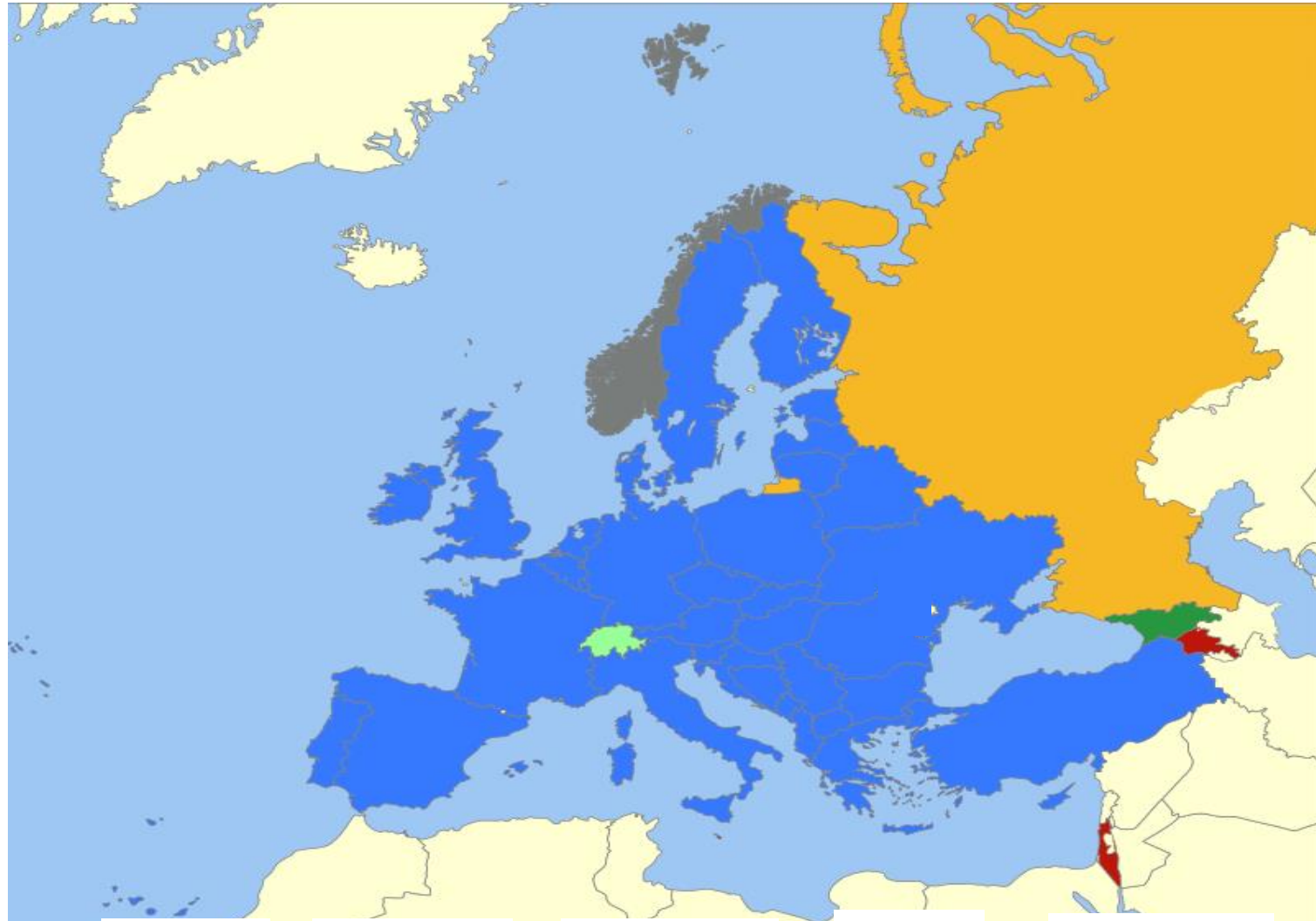
Adjuvant breast cancer: formulary and cost: DOXORUBICIN



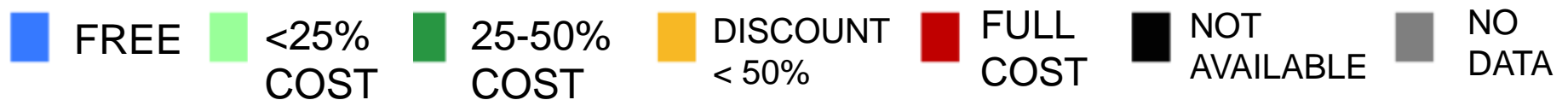
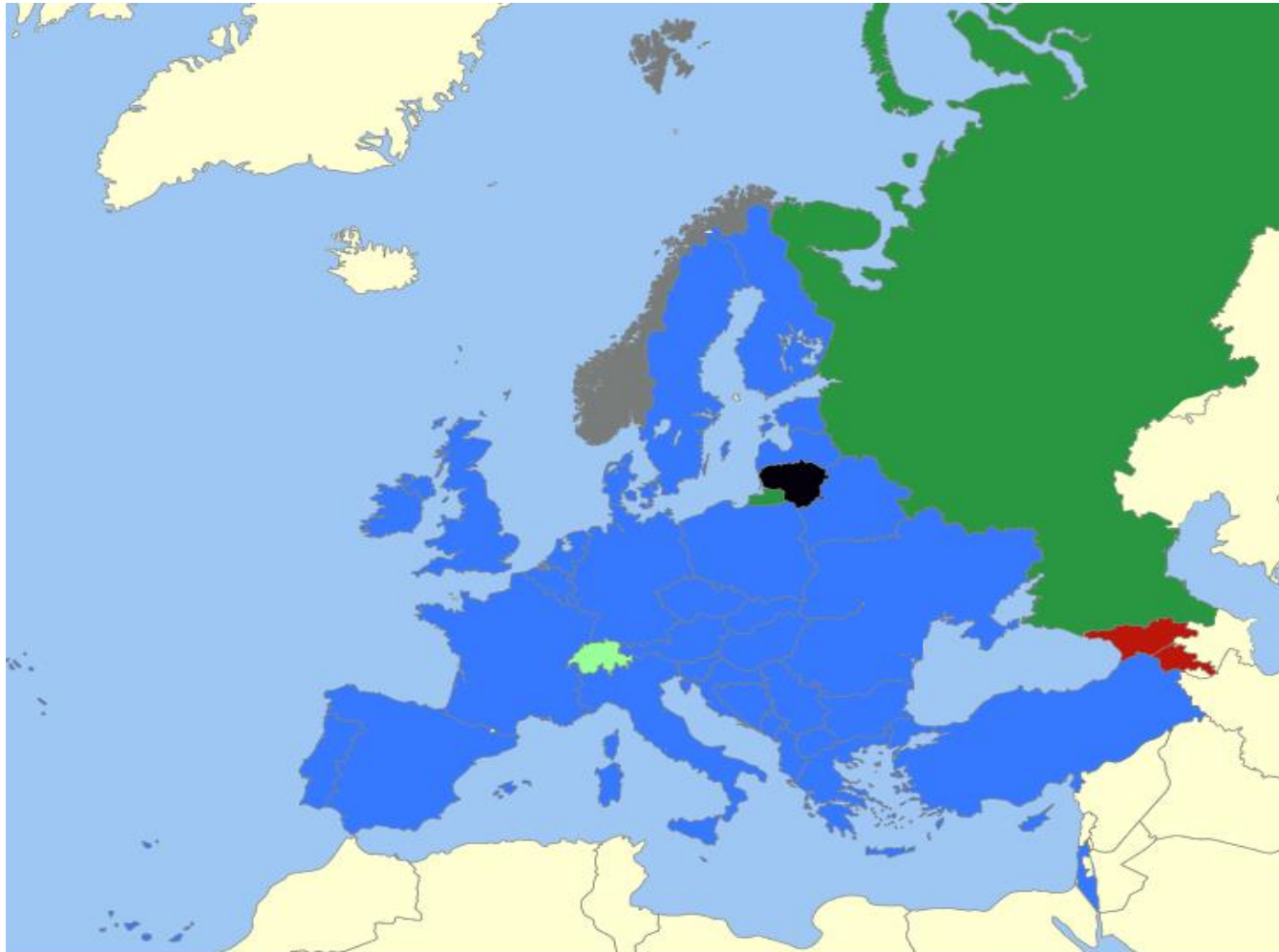
Adjuvant breast cancer: availability: **DOXORUBICIN**



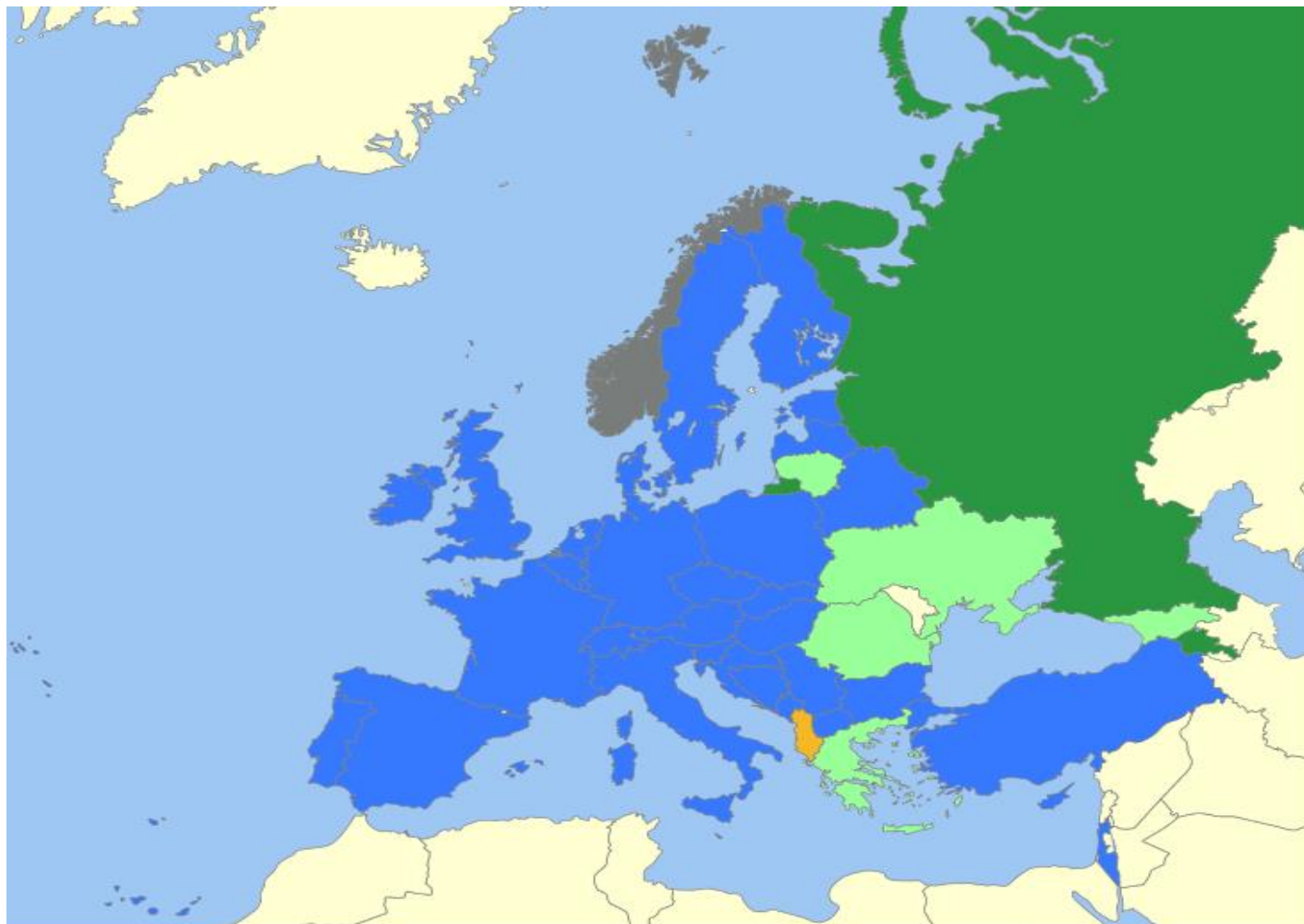
Adjuvant breast cancer: formulary and cost: DOCETAXEL



Adjuvant breast cancer: formulary and cost: TRASTUZUMAB



Adjuvant breast cancer: availability: TRASTUZUMAB



Always



Usually



Half the time



Occasionally



Never

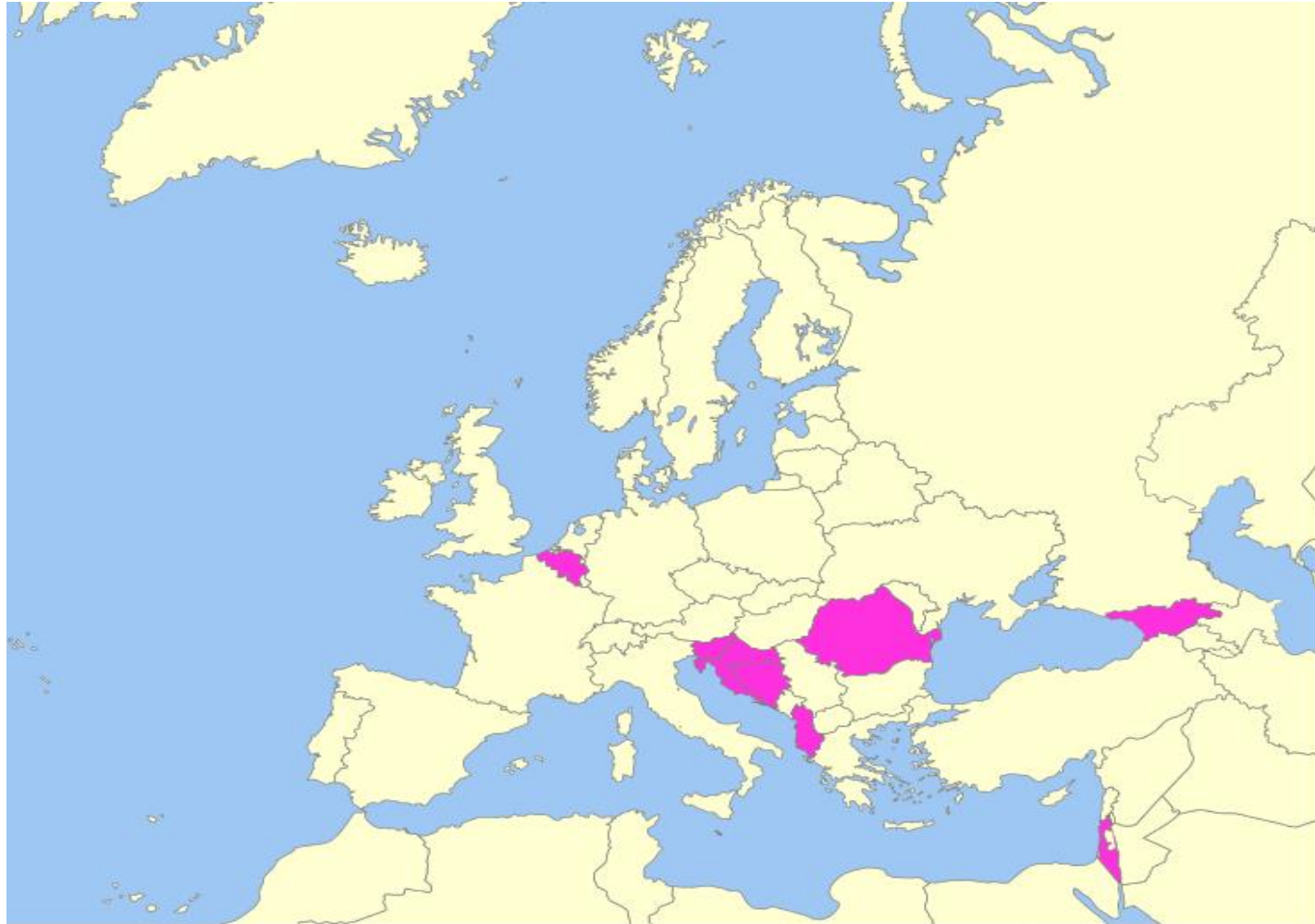


Not available



No data

Adjuvant breast cancer: preapproval required: TRASTUZUMAB



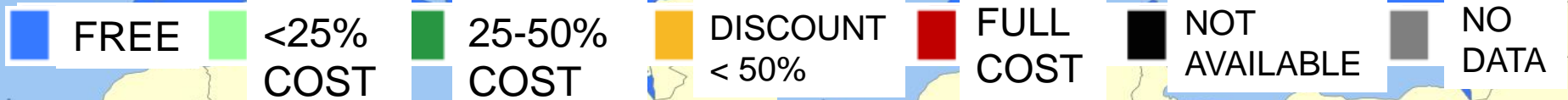
Metastatic breast cancer (formulary and cost):

TAM

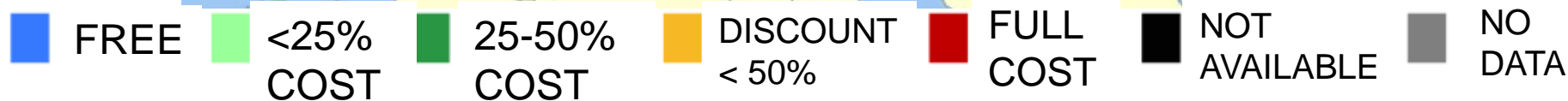
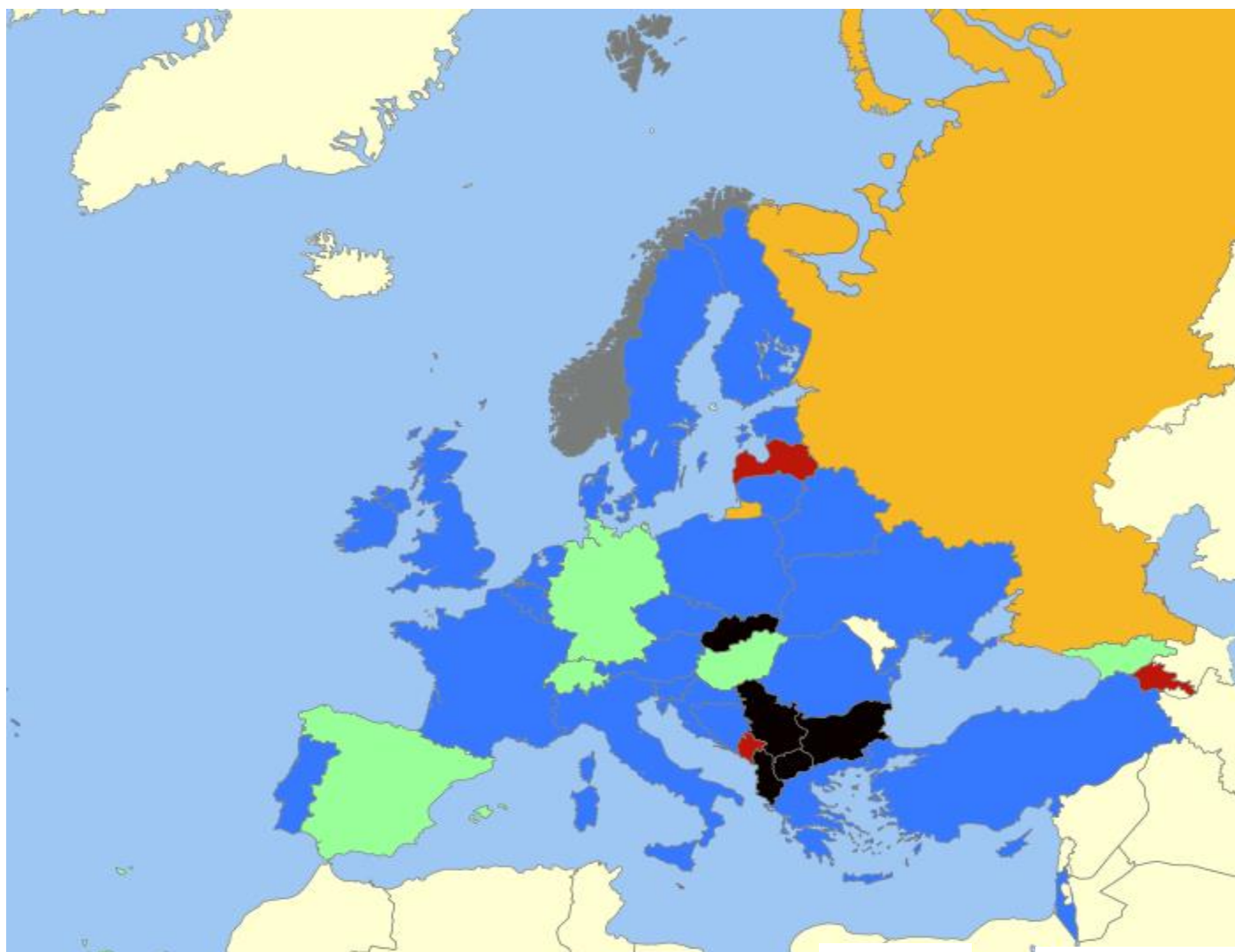
ANASTROZOLE

DOXORUBICIN

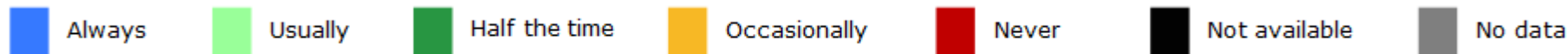
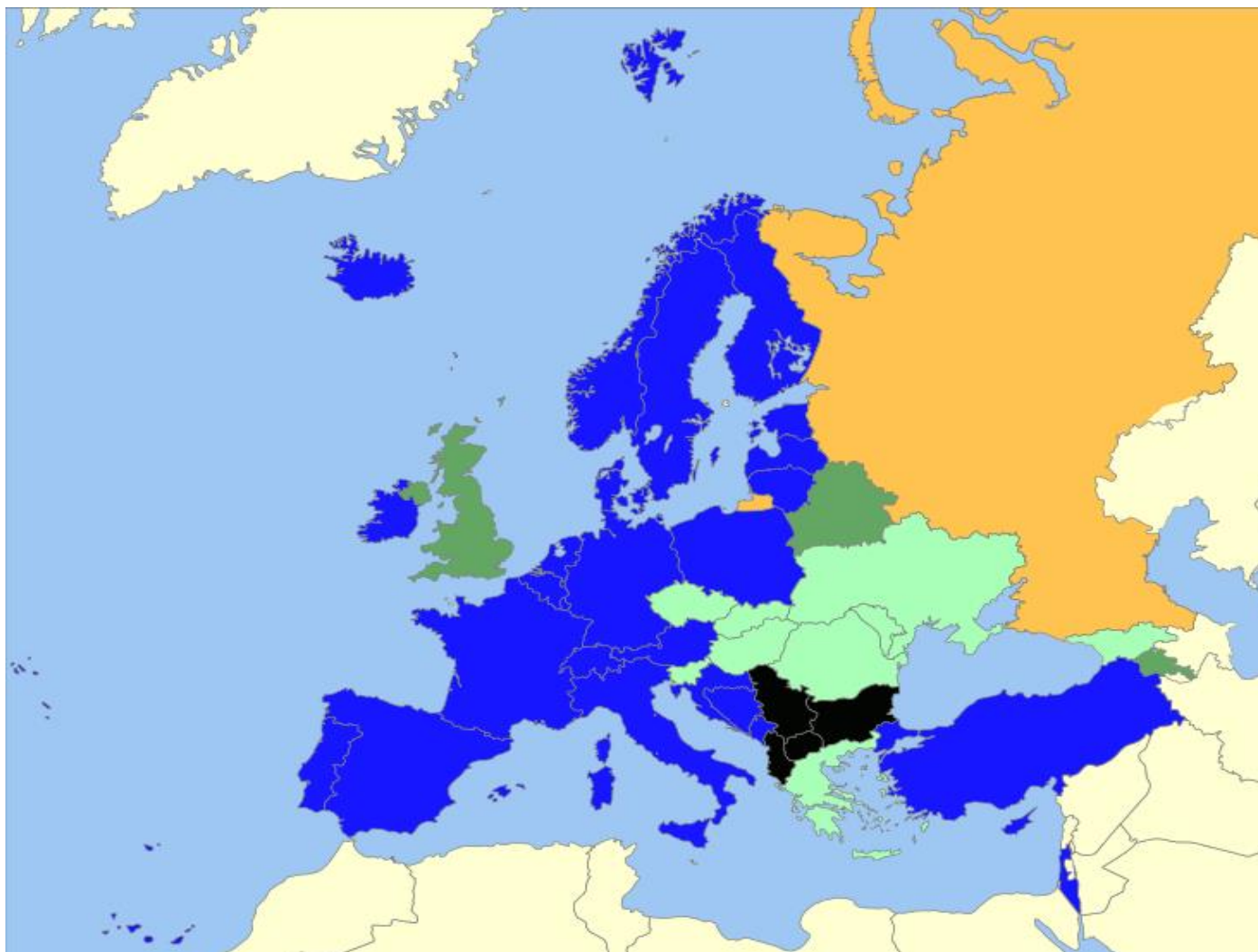
DOCETAXEL



Metastatic breast cancer (formulary and cost): Fulvestrant

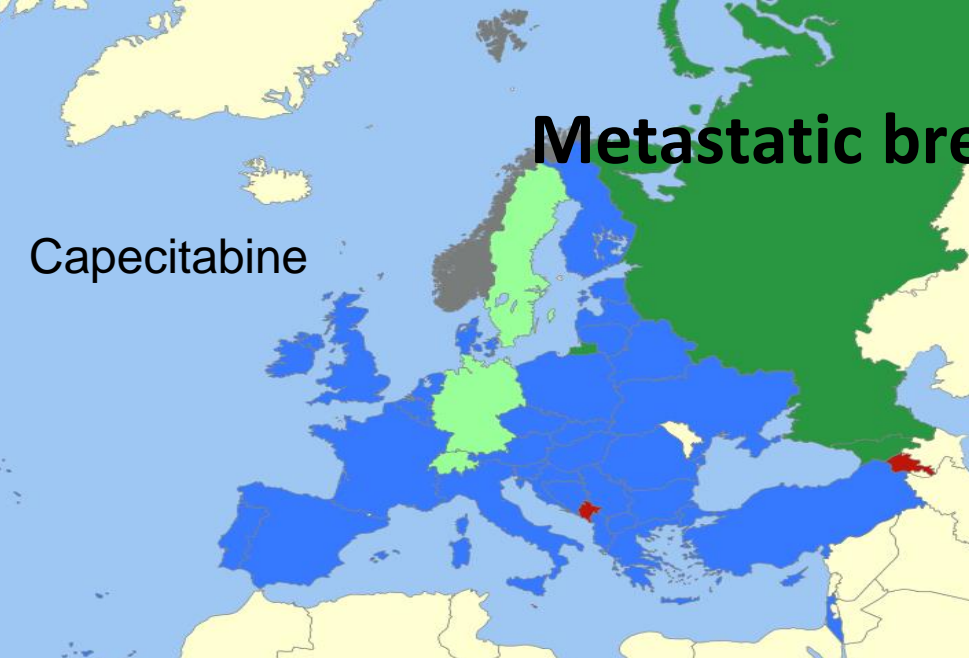


Metastatic breast cancer (availability): Fulvestrant

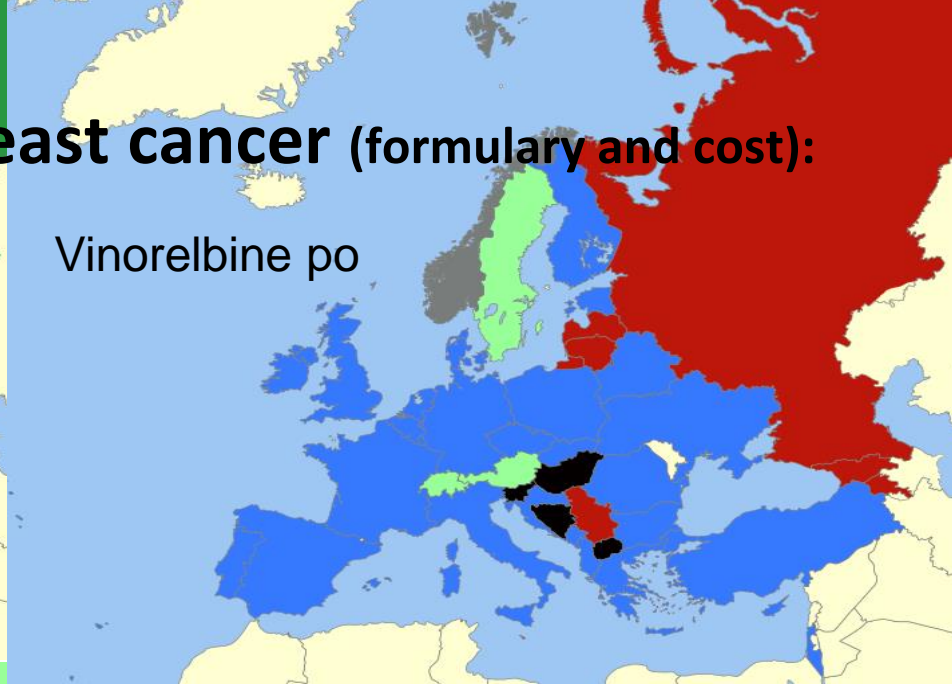


Metastatic breast cancer (formulary and cost):

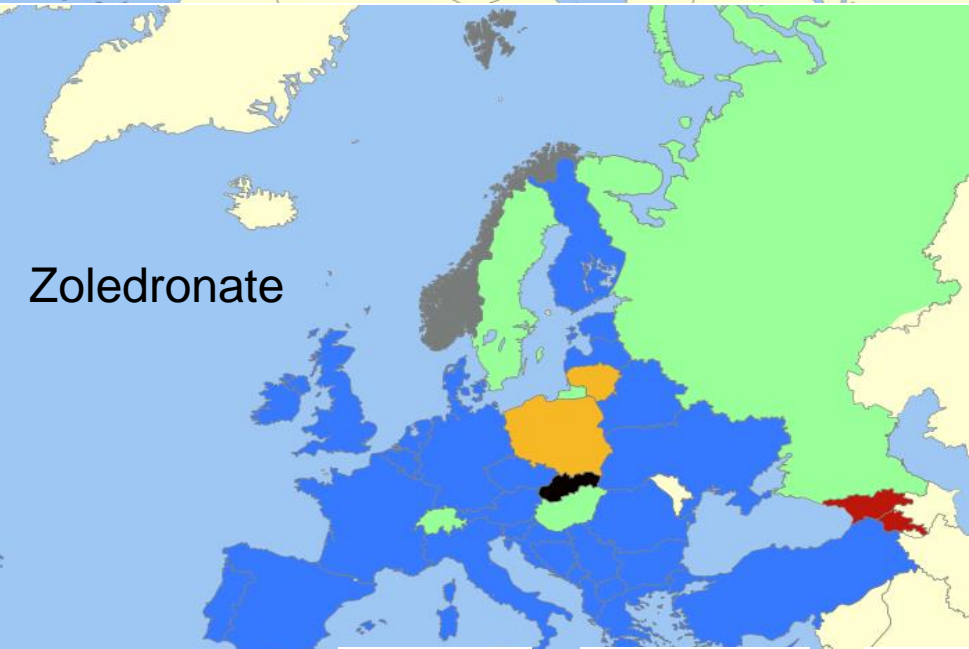
Capecitabine



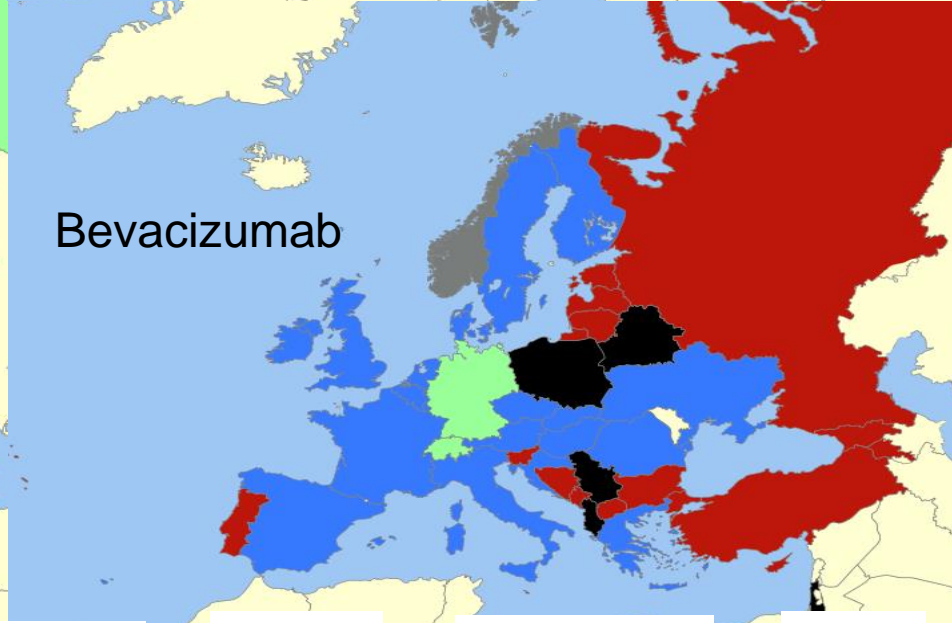
Vinorelbine po



Zoledronate

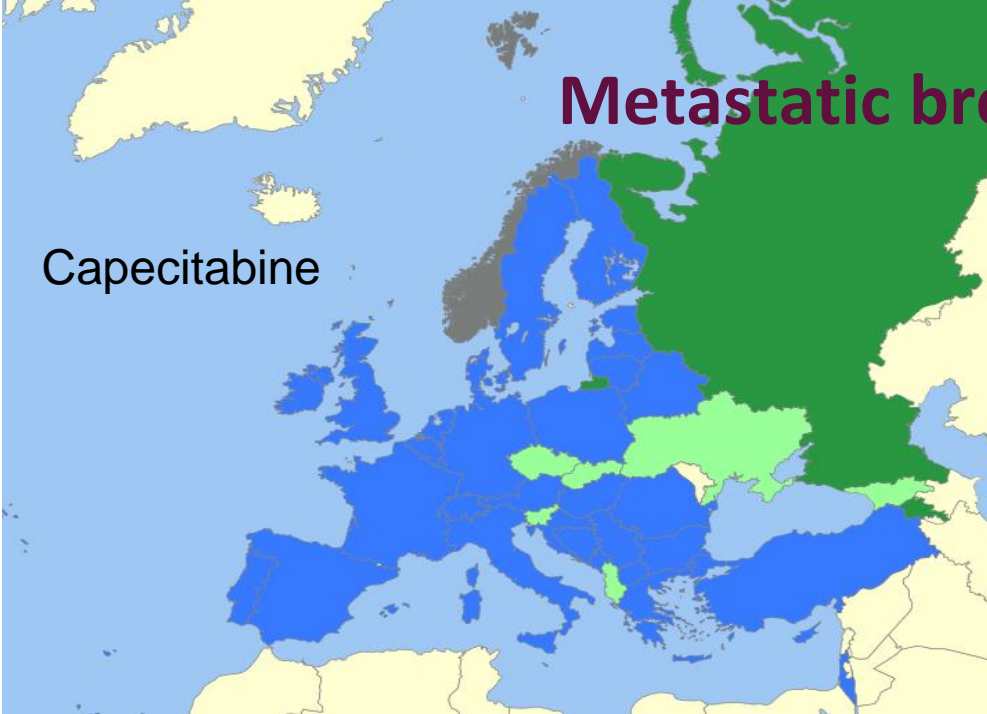


Bevacizumab

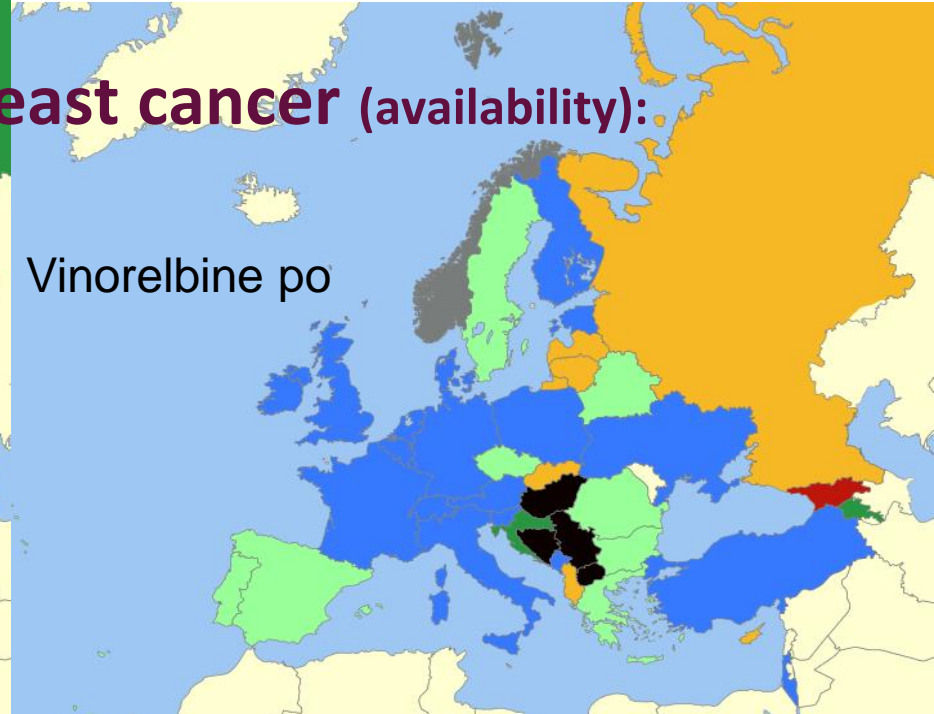


Metastatic breast cancer (availability):

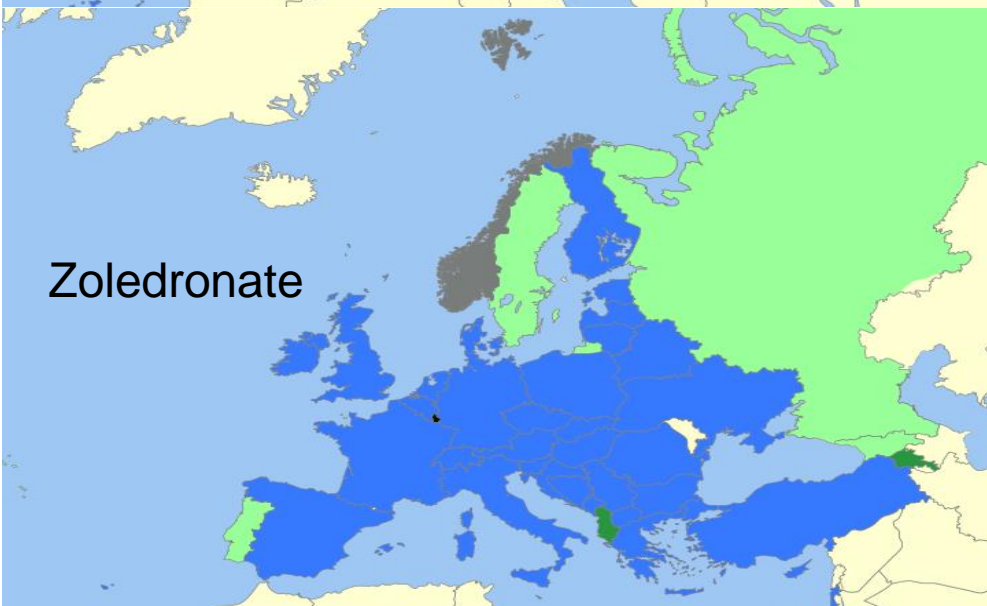
Capecitabine



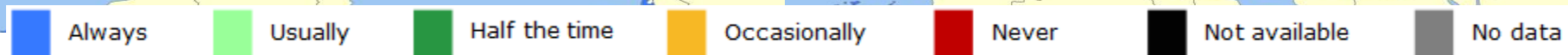
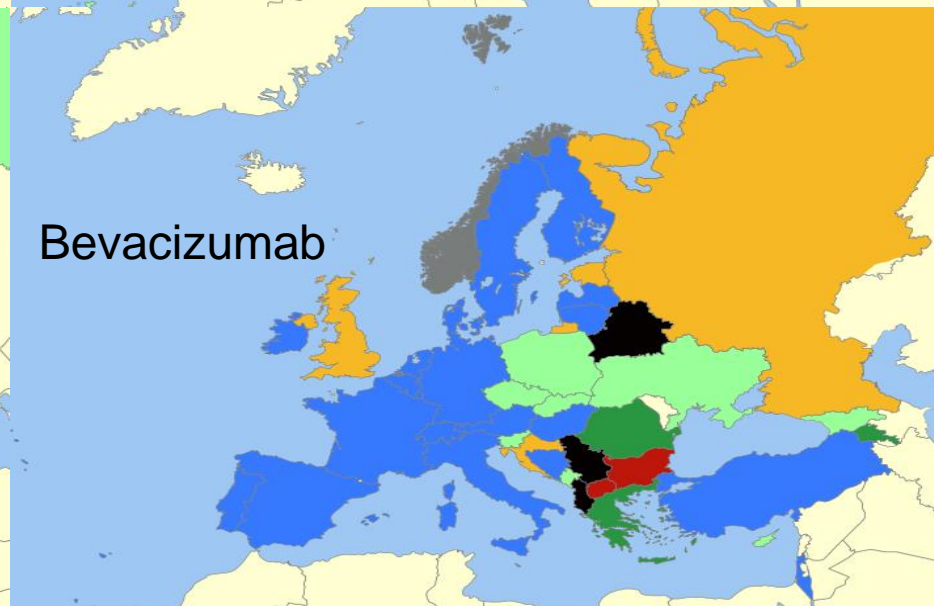
Vinorelbine po



Zoledronate



Bevacizumab



Metastatic breast cancer (formulary and cost): Anti-Her2 therapy

Trastuzumab

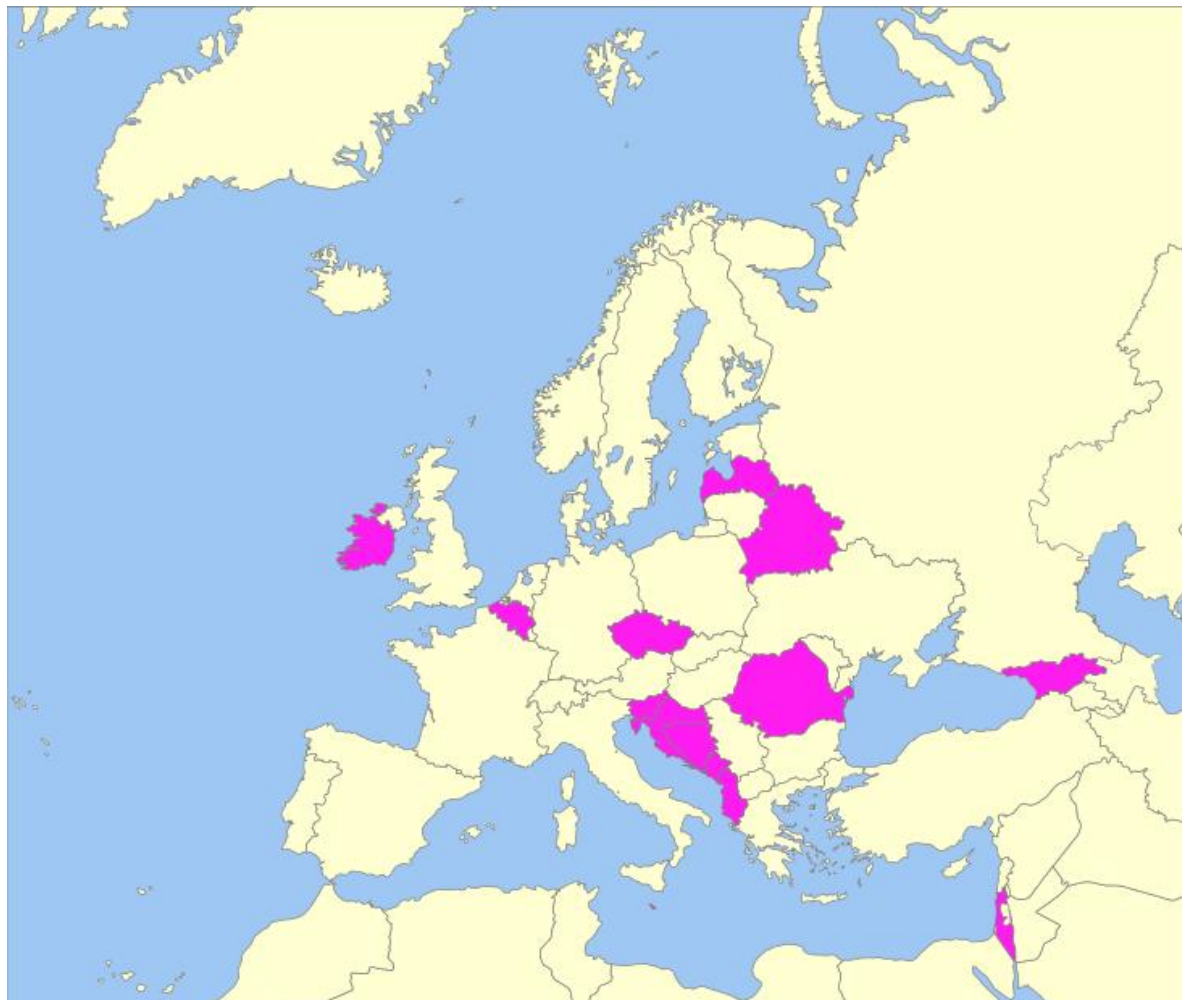
Lapatinib

Pertuzumab

T-DM1

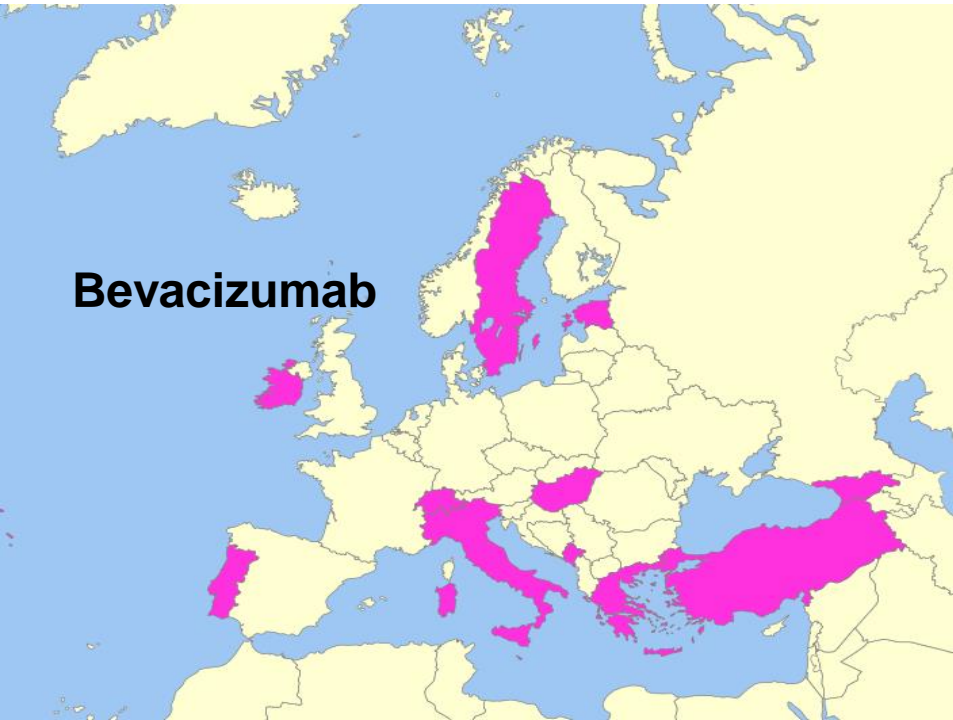


Metastatic breast cancer (Pre-approval required): Trastuzumab

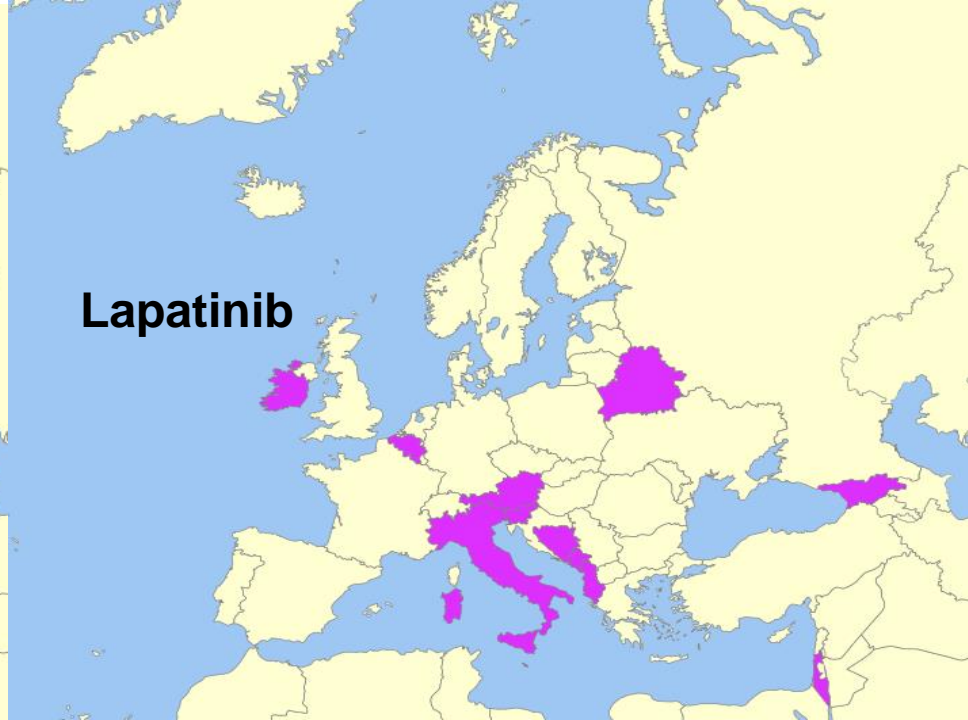


 Yes

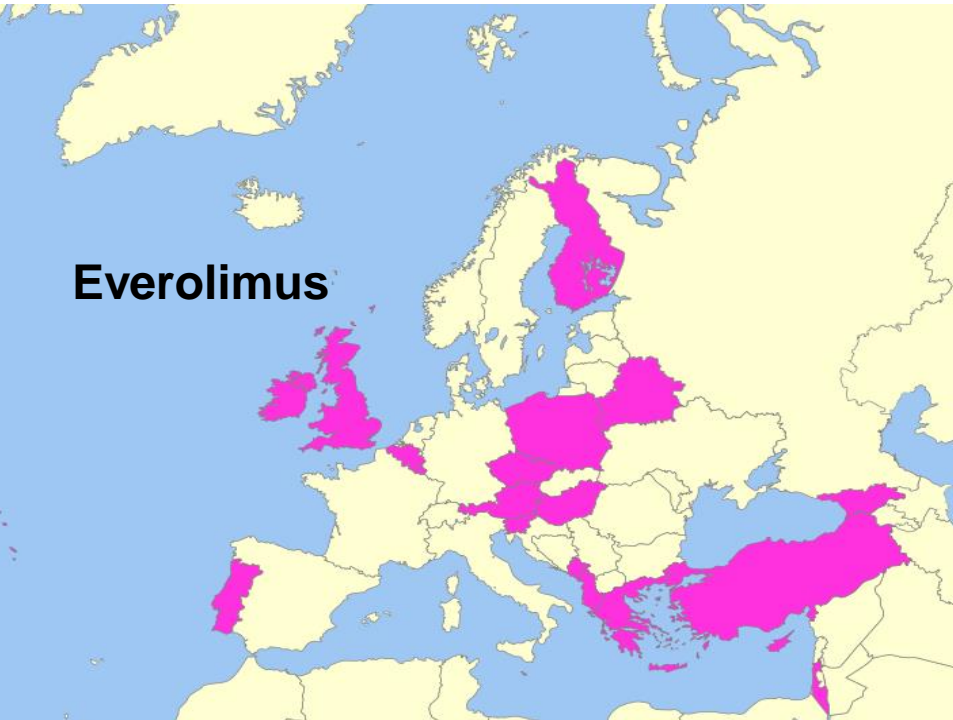
Bevacizumab



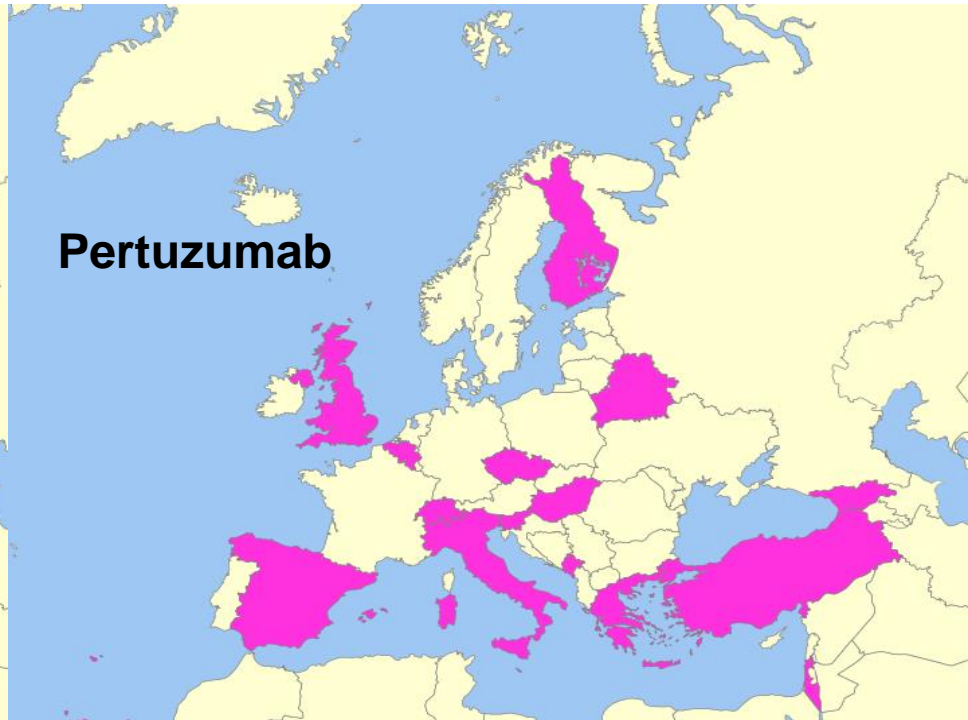
Lapatinib



Everolimus

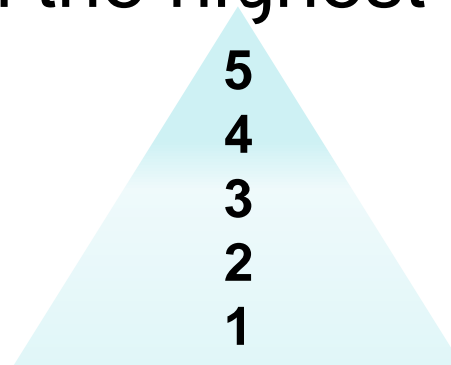


Pertuzumab



How will the ESMO Magnitude of Clinical Benefit Scale potentially be used?

- When a new anticancer drug is EMA approved, its benefit will be «scaled» by a dedicated ESMO committee
- Drugs which obtain the highest 4 and 5 score:





1. will be highlighted in the ESMO guidelines
2. represent the highest priority for rapid endorsement by national bodies across Europe

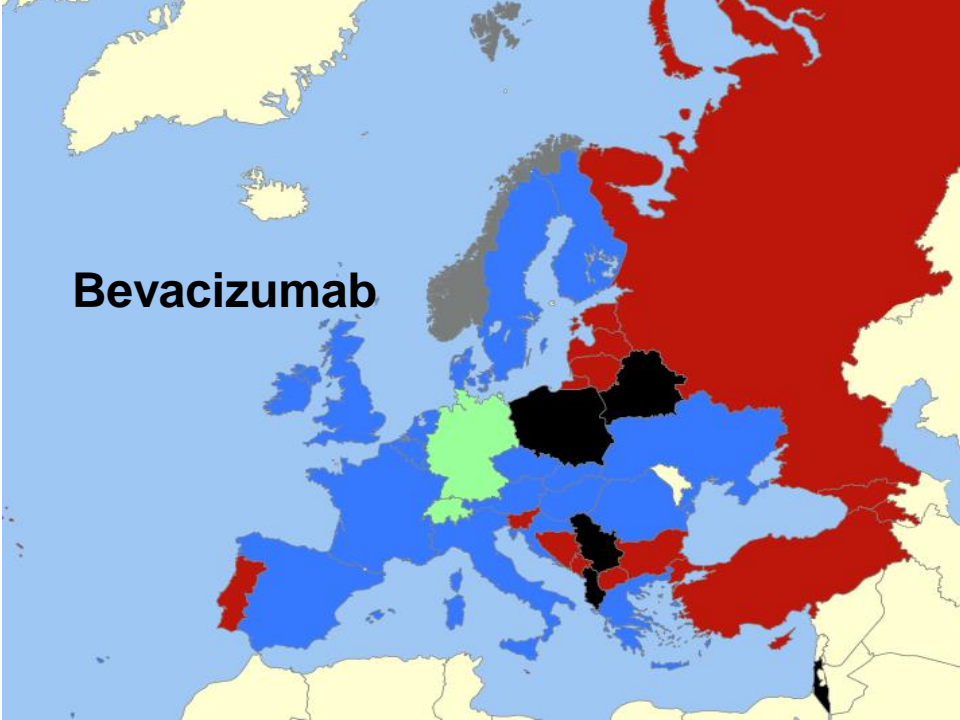
ESMO Magnitude of Clinical Benefit Scale examples applied to Breast Cancer Trials:

Non curative setting

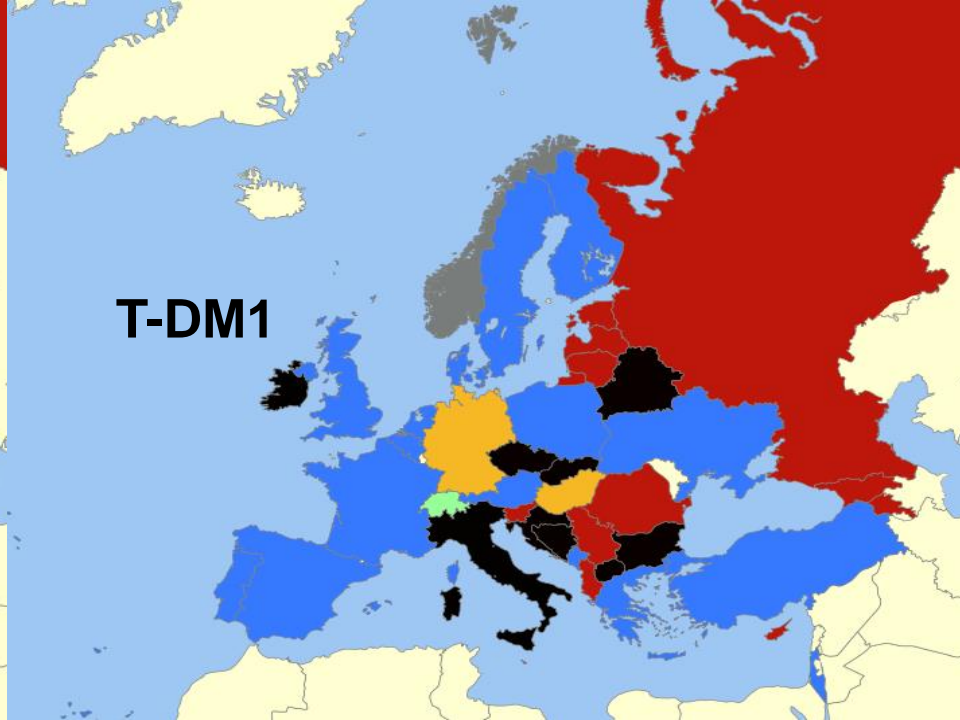


Drug	Clinical trial	Endpoint	Magnitude of benefit	Toxicity concerns	Final « grade »
TDM1 vs Lapatinib + capecitabine	EMILIA	PFS/OS no crossover	HR 0.68 (95%CI 0.55-0.85) gain 5.8 mo: 25.1 vs 30.9	-	4
Bevacizumab + paclitaxel vs paclitaxel	E2100	PFS no crossover	PFS HR 0.6 (95%CI 0.51–0.70) + 5.8 mo	Cerebro vascular ischemia 1.9% vs 0% (p 0.02) 	2
		↓ OS control arm: Median 25 mo	HR 0.88, +1.5 mo (p 0.16) 3 year survival <1%		
Exemestane + everolimus vs Exemestane	BOLERO-2	PFS no crossover	PFS HR 0.43 (95%CI 0.35-0.54) + 6.5 months	No QoL impact ↑ toxicity 	2: for PFS

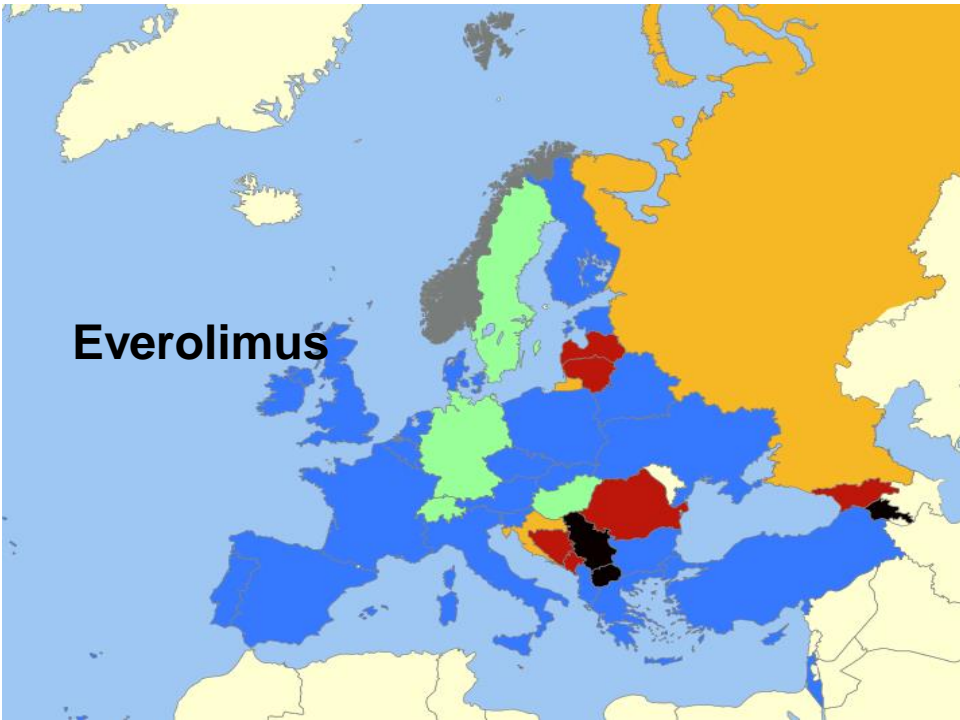
Bevacizumab



T-DM1



Everolimus



Implication of the findings: Adjuvant Breast Cancer

- Adjuvant hormonal therapy is reimbursed across Europe
- Aromatase inhibitors such as anastrozole are available, but in some countries are associated with out of pocket costs (25%)- an issue over 5 years
- Anthracyclines and taxanes are usually reimbursed in the adjuvant setting
- Even essential drugs, old and inexpensive as Tamoxifen and anthracyclines are not always available !
- Adjuvant trastuzumab is reimbursed, but there are issues of availability and pre-approval delays , mainly in Eastern Europe, Israel and Belgium

Implication of the findings: Metastatic Breast Cancer

- First line hormonal therapy (AI/TAM) is reimbursed across Europe
- First line chemotherapy (anthracyclines or taxanes) are usually reimbursed
- Further endocrine options (fulvestrant) are unavailable in several countries in Eastern Europe
- Newer chemotherapy agents (capecitabine, vinorelbine) are not universally available.
- Trastuzumab is reimbursed (...delays), but availability of further anti-Her2 therapies is severely limited in Eastern Europe
- **For the metastatic breast cancer patient, options are not always available beyond first/second line of therapy**

Conclusions and further steps

- Open peer review of data will take place over the next 2 months
- The ESMO Antineoplastic survey produced the first mapping of drug access in Europe
- Inequalities exist in availability and patient costs, especially for newer, more expensive drugs
- Drug shortages affect several essential, old and inexpensive drugs
- This information should allow for evaluation of approval / reimbursement priorities
- It provides WHO with availability data on the WHO Essential Medicines
- The ongoing ESMO project on Magnitude of Clinical benefit potentially offers a tool to analyze and establish priorities at national level
- The International Anti-Neoplastic Survey is planned for 2015