

Cancer drugs shortages can be mitigated through an early detection system based on data transparency.

Cancer Drugs Shortages in Romania Magnitude, causes and solutions

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OBJECTIVES

Cancer drugs shortages have a significant impact on patient access to essential treatment. Our study shows the extent of cancer drugs shortages in Romania during 2015-2017 and analyses for the first time its causes. We propose a framework which can be used for early detection of cancer drugs at high risk of shortage.

METHODS

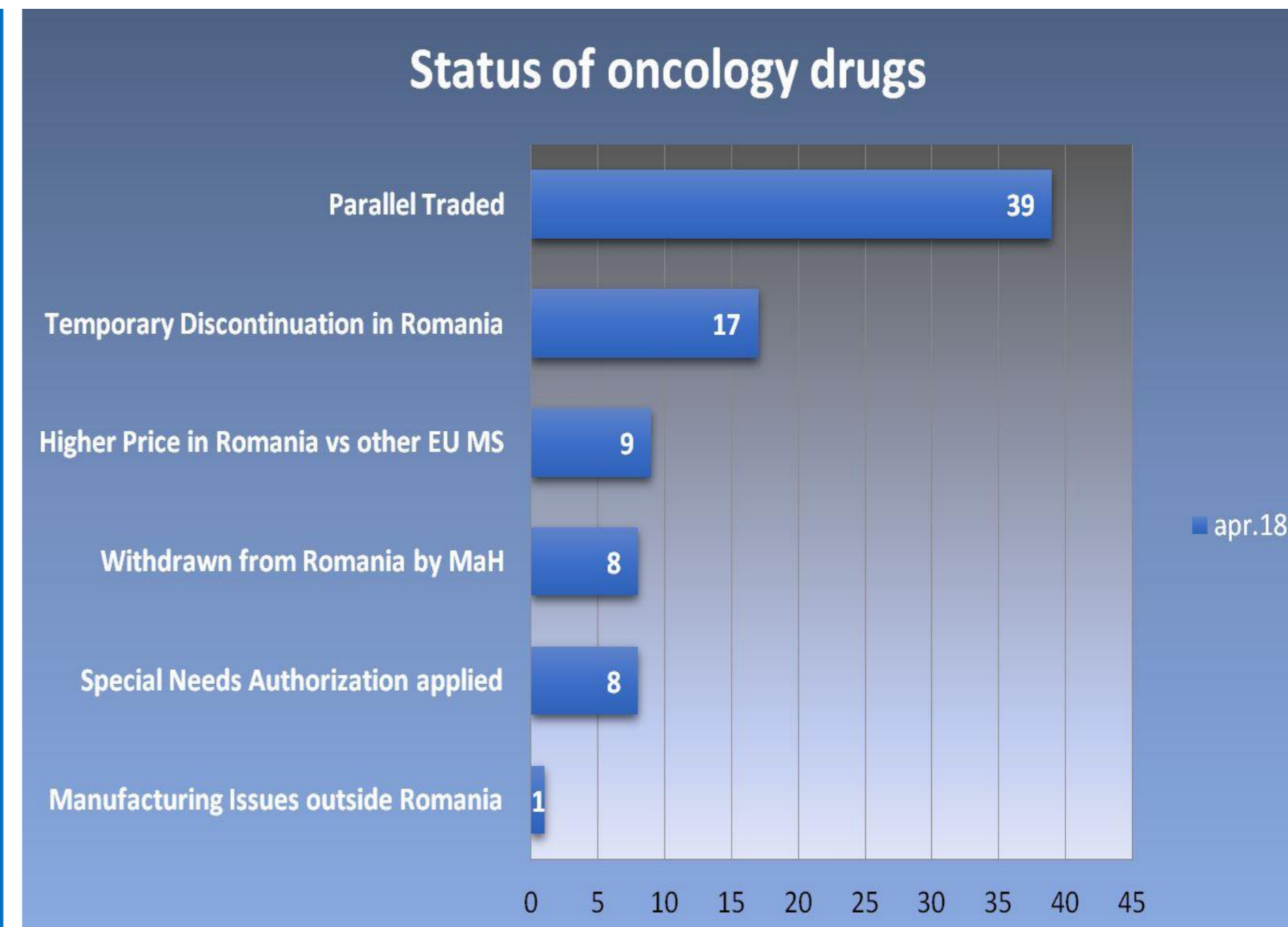
Available administrative data for 113 INNs, corresponding to 534 products, from the National Oncology Program were analyzed in terms of availability on the market, price status and parallel trade status. In addition, 2683 complains of shortages filled in by patients and HCP during 2015-2017 were analyzed. Analysis was performed separately for each pharmaceutical product and generic alternatives were included.

RESULTS

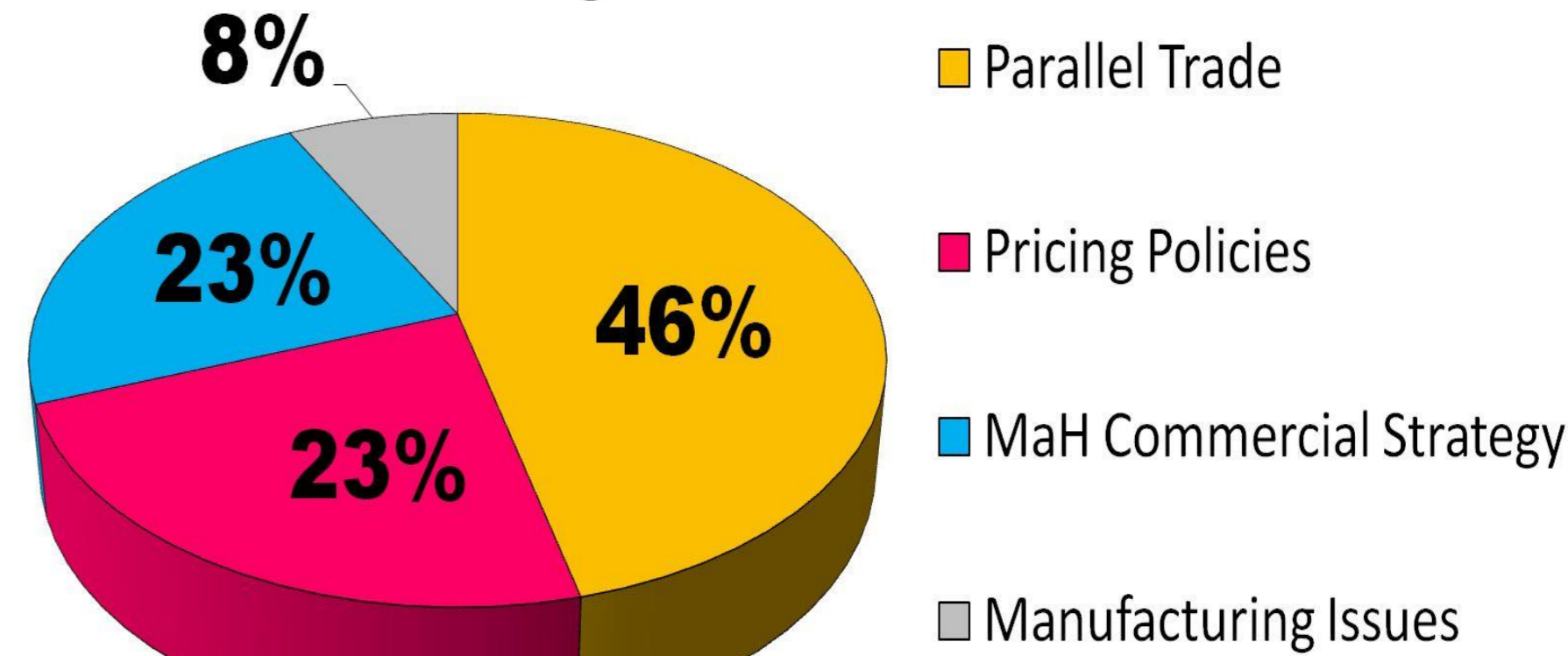
From the cancer medicines analyzed, 23 products were temporary unavailable on the Romanian market, 16 had their market authorization withdrawn by the MaH, 39 were at least once parallel traded, 16 products were more expensive than in the referenced EU countries thus not complying with the national regulations on external reference pricing, and 1 was registered with manufacturing difficulties. Results at INN level are visually represented below. By applying the decision tree developed, 13 cancer drugs were identified as having a high shortage risk. Shortage risk causes were identified, with the biggest preponderance being parallel trade, followed by pricing and regulatory policies, manufacturers' commercial interest and manufacturing difficulties.

CONCLUSION

Cancer drugs status should be continuously monitored to identify those with a high shortage risk and to enable early mitigation actions of the highly negative impact on patients. Policy tools and frameworks can be developed to implement proactive mechanisms if data on parallel trade, available stocks at regional level, discontinuation notifications from MaH and shortages notifications from patients/HCP are available in a transparent way.



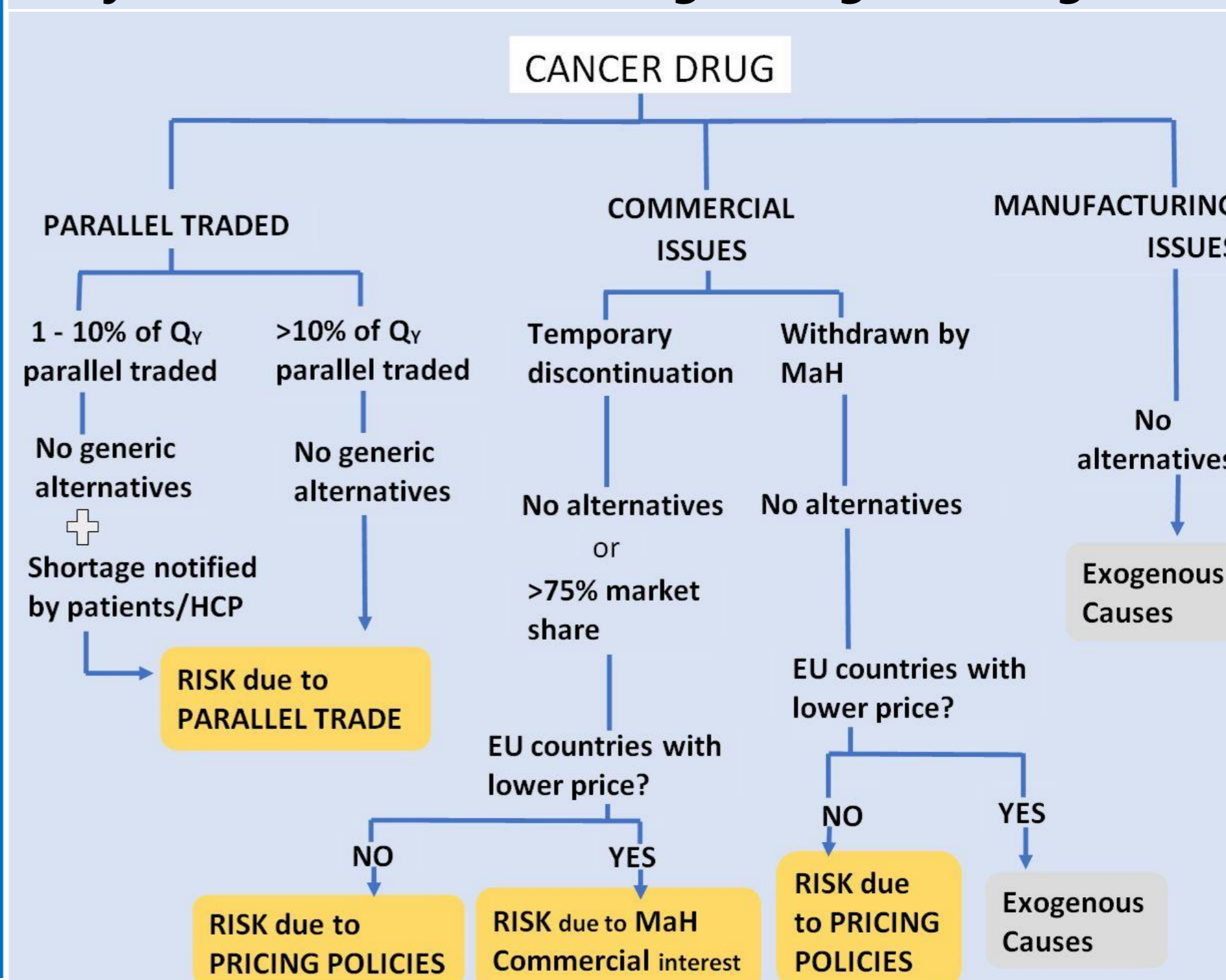
Causes of the risk of shortages for cancer drugs



Cancer drugs for which shortages were reported: prices & parallel traded

International Noproprietary Name (INN)	Brand Name	Quantity parallel traded in 2017 expressed as % of the quantity consumed in the previous year	Quantity parallel traded in 2016 expressed as % of the quantity consumed in the previous year	International Noproprietary Name (INN)	BRAND NAME	Price difference GERMANY vs ROMANIA	Price difference NETHERLANDS vs ROMANIA	Price difference DENMARK vs ROMANIA	Price difference SWEDEN vs ROMANIA
Leuporelin	Elgard	73.30%	18.30%	LANREOTIDUM	SOMATULINE AUTOGEL 120MG	2,9 x price RO			
Bortezomid	Velcade	39.30%	9.83%	LEUPRORELINUM	ELIGARD 22.5 MG	4,6 x price RO	3,2 x price RO	3 x price RO	
Vincristin	Navelbine	14.50%	3.62%		ELIGARD 45 MG	4,4 x price RO	3 x price RO	3 x price RO	
Dactinib	Sprycel	13.31%	3.33%	BORTEZOMIDUM	VELCADE 3.5 MG		1,2 x price RO	1,4 x price RO	1,2 x price RO
Topotecan	Hycamtin	6.91%	1.73%	VINORELBINUM	NAVELBINE 20 MG	2,8 x price RO			
Lanreotid	Somatuline	153%	38.25%		NAVELBINE 30 MG	2,7 x price RO			
Nilotinib	Tasigna	1.80%	0.47%	DASATINIBUM	SPRYCEL 20 MG	2,1 x price RO	0,7 x price RO	1,9 x price RO	1,6 x price RO
Inotilab	Gilevec	0.04%	0.01%		SPRYCEL 50 MG	1,8 x price RO	1,3 x price RO	1,7 x price RO	1,4 x price RO
Anastrozol	Enzamide	0.45%	0.11%		SPRYCEL 70 MG		1,3 x price RO	1,7 x price RO	1,4 x price RO
Temozolomid	Temozolomide	7.17%	1.80%		SPRYCEL 100 MG	3,5 x price RO	4,9 x price RO	3,1 x price RO	0,8 x price RO
Mycophenolat	Myfortic	0.88%	0.20%	TEMOZOLOMIDUM	TEMOZOLOMIDE 20 MG	10 x price RO			0,6 x price RO
Enzalutamid	Xtandi	not reimbursed in the previous year	not reimbursed in the previous year		TEMOCAL 100 MG	7,4 x price RO			2,1 x price RO
Chlaparib	Lynparza	not parallel traded	not parallel traded	TOPOTECUMUM	Hycamtin 1 MG		2 x price RO		3,1 x price RO
Tamoxifen	Tamoxifen	not parallel traded	not parallel traded						
Procicabuzin	Nabutan	not parallel traded	not parallel traded						
Tretinoin	Veanoid	not parallel traded	not parallel traded						
Bleomycin	Bleomycin Medac	not parallel traded	not parallel traded						
Vinblastin	Vinblastin	not parallel traded	not parallel traded						
Cyclophosphamid	Endocan	not parallel traded	not parallel traded						
Dactinonin	Cosmegen	not parallel traded	not parallel traded						
Melphalan	Alkeran	not parallel traded	not parallel traded						
Ondansetron	Emszet	not parallel traded	not parallel traded						
Lapathib	Tyerb	not parallel traded	not parallel traded						

Early detection of cancer drugs at high shortage risk



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