

# 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

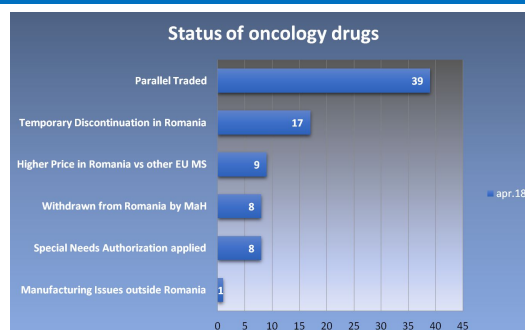
Available administrative data for 113 INNs, corresponding to 534 products, from the National Oncology Program were analyzed in terms of availability on the market, price status and parallel trade status. In addition, 2683 complains of shortages filled in by patients and HCP during 2015-2017 were analyzed.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

### RESULTS

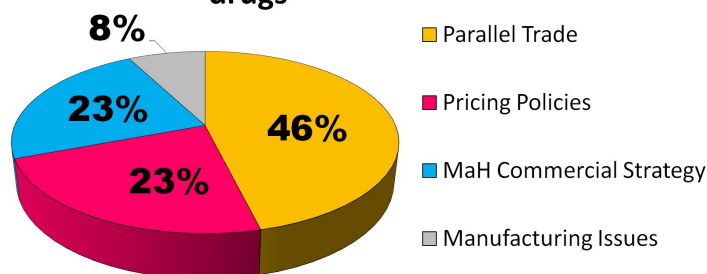
From the cancer medicines analyzed, 23 products were temporary unavailable on the Romanian market, 16 had their market authorization withdrawn by the MaH, 39 were at least once parallel traded, 16 products were more expensive than in the referenced EU countries thus not complying with the national regulations 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

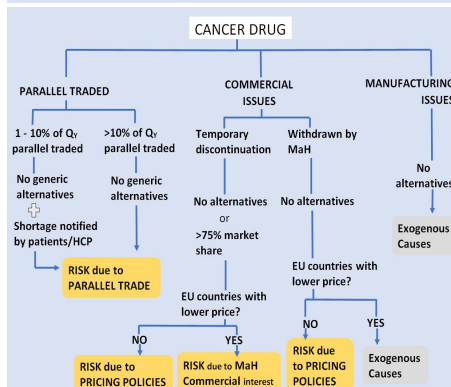
Cancer drugs status should be continuously monitored to identify those with a high shortage risk and to enable early mitigation actions of the highly negative impact on patients. Policy tools and frameworks can be developed to implement proactive mechanisms if data on parallel trade, available stocks 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



### Early detection of cancer drugs at high shortage risk



### Cancer drugs for which shortages were reported

International Nomenclature Name (INN)	Brand Name	Quantity parallel traded in 2017 represented as % of the quantity marketed in the reference year	Quantity parallel traded in 2017 represented as % of the quantity marketed in the reference year
Lapatinib	Epigard	73.30%	18.30%
Bortezomib	Velcade	39.30%	9.83%
Vincristin	Navelbine	14.50%	3.62%
Dasatinib	Sprycel	13.31%	3.33%
Topotecan	Hyctanin	6.91%	1.73%
Letrozole	Somatone	15.3%	38.25%
Nilotinib	Tasigna	1.88%	0.47%
Imatinib	Glivec	0.04%	0.01%
Anastrozole	Endoxan	0.45%	0.11%
Temozolomid	Temozolomid	7.17%	1.80%
Mycophenolat	Myfortic	0.88%	0.20%
Erlotinib	Tarceva	not reimbursed in the previous year	not reimbursed in the previous year
Ligandir	Ligandir	not parallel traded	not parallel traded
Tamoxifen	Tamoxifen	not parallel traded	not parallel traded
Procarbazine	Nabalan	not parallel traded	not parallel traded
Etravirin	Yescard	not parallel traded	not parallel traded
Bleomycin	Bleomycin Medac	not parallel traded	not parallel traded
Vindesine	Vindesine	not parallel traded	not parallel traded
Cyclophosphamid	Endoxan	not parallel traded	not parallel traded
Dactinomycin	Cosmegen	not parallel traded	not parallel traded
Melphalan	Alkeran	not parallel traded	not parallel traded
Oestradiol	Emosect	not parallel traded	not parallel traded
Lapatinib	Tyverb	not parallel traded	not parallel traded



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