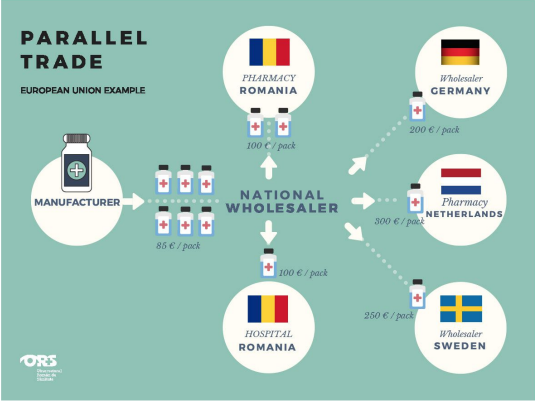
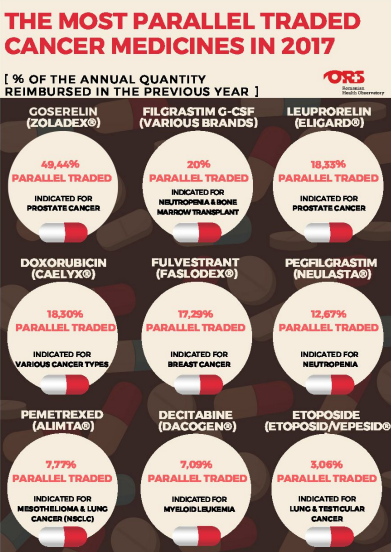


# MAGNITUDE OF CANCER DRUGS PARALLEL TRADE FROM ROMANIA TO EUROPEAN UNION COUNTRIES IN 2017

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## RESULTS (continued)

23 cancer drugs were reported by patients or healthcare professionals as having supply issues on the Ministry of Health website. 11 of them were parallel traded during the analyzed period; for two of them the parallel traded quantity exceeded 18% of the average annual reimbursed quantity (see Table 2).

The impact of parallel trade on cancer patients was estimated considering several indicators: shortages of the product reported on the Ministry of Health website, lack of generic alternative with the same strength/form, market share of the product in the previous year. The results are presented in Table 3.

Study limitations: the analysis focused exclusively on the cancer drugs reimbursed under the National Oncology Program. To illustrate the possible effects of this limitation we included in the analysis a cancer drug – Lanreotid – which is not reimbursed under the National Oncology Program but its shortage was reported on the Ministry of Health website.

## CONCLUSIONS

During 2017, parallel trade of cancer drugs from Romania was significant in terms of quantity. Expressed as a percentage of the average annual reimbursed quantity, parallel traded quantities for five cancer drugs exceeded 15%. National and EU level policies are needed to avoid the negative effects of parallel trade on patients' access to treatment.

## OBJECTIVES

Parallel exports of medicines from low-price European Union (EU) countries to high-price EU countries can lead to low stocks in the former. This study shows for the first time the extent of parallel trade of cancer drugs exported from Romania, during March – December 2017, and estimates the impact on cancer patients.

## METHODS

Parallel exports officially notified to the Romanian National Agency for Medicines and Medical Devices between March 2017 and December 2017 were obtained and analyzed.

Pharmaceuticals reimbursed under the publicly-funded National Oncology Program which were exported through parallel trade were identified. Quantities were expressed as a percentage of the annual average volumes reimbursed by the Romanian National Health Insurance House in the previous year (2016). Calculations were made separately for each pharmaceutical form/dosage. Generic alternatives were considered.

## RESULTS

We first obtained results regarding the most parallel traded drugs from Romania, in all disease areas. During the analyzed period, a total number of 14,46 million therapeutic units in various pharmaceutical forms were parallel traded from Romania.

It is impossible to estimate the total financial value of the parallel trade using only publicly available data, but other reports appreciate the total value of parallel trade market in Romania as being "important" (Romanian Competition Council, 2017) and reaching one fifth of the total value of the Romanian pharmaceutical market.

The study focus is on cancer medicines. Price differences for the same pharmaceutical products between Romania and the main countries of destination for parallel trade are significant, as listed in Table 1.

39 INN of the 113 National Oncology Program's medicines analyzed were at least once parallel traded from Romania during March 2017 – December 2017, summing 136,925 therapeutic units in various pharmaceutical forms.

The study identified one cancer drug for which 49% of the average annual reimbursed quantity was exported through parallel trade from Romania, four cancer drugs for which more than 15% of the average annual reimbursed quantity was parallel traded and three cancer drugs for which quantities between 7%-12% were parallel traded (see infographic above).

Table 1. Price differences between Romania and the main countries of destination for parallel trade

International Nonproprietary Name (INN)	BRAND NAME	Price difference GERMANY vs ROMANIA	Price difference NETHERLANDS vs ROMANIA	Price difference DENMARK vs ROMANIA	Price difference SWEDEN vs ROMANIA
LANREOTID	SOMATULINE AUTOSOL 20MG	2,9 x price RO			
LEUPORELIN	ELIGARD 21.5MG	4,6 x price RO	3,2 x price RO	3 x price RO	
	ELIGARD 40 MG	4,4 x price RO	3 x price RO	3 x price RO	
BORTEZOMID	VELCADE 3.5 MG		1,2 x price RO	1,4 x price RO	1,2 x price RO
VINORELBIN	NAVELBINE 20 MG	2,8 x price RO			
	NAVELBINE 30 MG	2,7 x price RO			
DASATINIB	SPRYCEL 20 MG	2,1 x price RO	0,7 x price RO	1,9 x price RO	1,6 x price RO
	SPRYCEL 50 MG	1,8 x price RO	1,3 x price RO	1,7 x price RO	1,4 x price RO
	SPRYCEL 70 MG		1,3 x price RO	1,7 x price RO	1,4 x price RO
	SPRYCEL 150 MG	3,5 x price RO	4,9 x price RO	3,1 x price RO	0,8 x price RO
TEMZOLOMID	TEMZOLOMIDE 20 MG	10 x price RO			0,6 x price RO
	TEMZOLOMIDE 150 MG	7,4 x price RO			2,1 x price RO
	TEMZOLOMIDE 150 MG	5,3 x price RO			1,4 x price RO
TOPIRCAMUR	HYCAMTIN 5 MG		2 x price RO		3,1 x price RO

Table 2. Cancer drugs with shortage issues and their parallel trade status

International Nonproprietary Name (INN)	Brand Name	Quantity parallel traded in 2017 expressed as % of the quarterly quantity reimbursed in the previous year	Quantity parallel traded in 2017 expressed as % of the annual quantity reimbursed in the previous year
Leuporelin	Eligard	73,30%	18,30%
Bortezomid	Velcade	39,30%	9,83%
Vinorelbin	Navelbine	14,50%	3,62%
Dasatinib	Sprycel	13,31%	3,33%
Topotecam	Hycamtin	6,91%	1,73%
Lanreotid	Somatuline	153%	38,25%
Nilotinib	Tasigna	1,88%	0,47%
Imatinib	Glivec	0,04%	0,01%
Anastrozol	Enzamidex	0,45%	0,11%
Temozolomid	Temozolomide	7,17%	1,80%
Mycophenolat	Myfortic	0,88%	0,20%
Enzalutamid	Xtandi	not reimbursed in the previous year	not reimbursed in the previous year
Olaparib	Lynparza	not parallel traded	not parallel traded
Tamoxifen	Tamoxifen	not parallel traded	not parallel traded
Procabazin	Natulán	not parallel traded	not parallel traded
Tretinoin	Vesanoind	not parallel traded	not parallel traded
Bleomycin	Bleomycin Medac	not parallel traded	not parallel traded
Vinblastin	Vinblastina	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
Ondansetron	Emeset	not parallel traded	not parallel traded
Lapatinib	Tyverb	not parallel traded	not parallel traded

Table 3. Impact of the parallel trade of cancer drugs on Romanian patients

International Nonproprietary Name (INN)	Brand Name	Quantity parallel traded in 2017 expressed as % of the quarterly quantity reimbursed in the previous year	Estimated Impact on cancer patients	Number of Romanian wholesalers which are offering the product for parallel trade	Countries of destination
Lanreotid	Somatuline	153%	Considerable	8	information not available
Dasatinib	Sprycel	13.31%	Considerable	9	Germany, Netherlands, Sweden, Denmark, Finland
Topotecam	Hycamtin	6,91%	Significant	9	Netherlands, Austria, Sweden, Denmark
Leuporelin	Eligard	73,30%	Significant	9	information not available
Vinorelbin	Navelbine	14,50%	Significant	6	information not available
Temozolomid	Temozolomide	7,17%	Low	5	Germany
Bortezomid	Velcade	39,30%	Low	7	Germany, Finland