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Is it Possible to Estimate the Welfare Economic Loss to Society of Not Having Value-Based Differential Pricing for Multi-Indication Pharmaceuticals: An Empirical Analysis in Denmark, Norway, and Sweden

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OBJECTIVES

The absence of payment models to accommodate a value-based pricing (VBP) system capable of reflecting the differential value of pharmaceuticals across indications poses a risk of inadequate reimbursement for multiple-indication pharmaceuticals approved by the European Medicines Agency (EMA) (1). The aim of this project was to evaluate whether it is possible to empirically estimate the welfare economic loss in terms of quality-adjusted life years (QALY) and life-years (LY) due to the absence of VBP payment models for multi-indication pharmaceuticals in Denmark, Norway, and Sweden.

METHODS

As a case-example, three multi-indication pharmaceuticals identified through EMA, manufactured by different companies, with a total of 18 indications were selected for each country (2). Data from the national Health Technology Assessment (HTA) organizations in the three countries (NoMA, DMC, TLV) were used to extract relevant outcomes including the national reimbursement decision, annual number of patients, incremental QALYs, and LYs compared to existing treatment, representing the opportunity costs in terms of QALYs and LYs that could have been gained if these indications were recommended/reimbursed rather than not recommended (3,4,5). Data was collected from 2012-2023.

RESULTS

Publicly accessible information pertaining to multiple-indication pharmaceuticals are available through webpages for EMA, NoMA, DMC and TLV (Table 1), including reimbursement decision, number of patients, incremental QALYs, and LYs. Consequently, it becomes possible to estimate QALYs and LYs lost, that otherwise would have been gained if indications were reimbursed. However, there are gaps and uncertainties in the publicly available data. Initial results (Table 2), which is only based on the not recommended indications for the three pharmaceuticals', revealed a total loss of 323 QALYs and 396 LYs for the population in the three countries.

TABLE 1: OVERVIEW OF HTA DECISIONS

Medication, name	Number of EMA indications	Indications applied for									Indications not applied for		
		Recommended			Not recommended			In process					
		NO	DK	SE	NO	DK	SE	NO	DK	SE	NO	DK	SE
Ibrutinib	4	1	3	2	3	0	0	0	1	0	0	0	2
Olaparib	8	3	2	4	0	2	0	5	2	0	0	2	4
Brentuximab Vedotin	6	3	4	2	1	1	0	1	0	0	1	1	4

TABLE 2: ESTIMATED LOSS OF QALYS AND LYS

EMA indication	Decision			Total number of patients*			LY loss			QALY loss		
	NO	DK	SE	NO	DK	SE	NO	DK	SE	NO	DK	SE
Ibrutinib												
Indication A	No	Yes	Yes	46	50	89	86	0	0	76	0	0
Indication B	No	In process	No info§	22	24	42	63	-	-	50	-	-
Indication C	Yes	Yes	Yes	77	83	148	0	0	0	0	0	0
Indication D	No	Yes	No info§	15	16	29	43	0	-	34	0	-
Olaparib												
Indication A	Yes	Yes	Yes	31	34	60	0	0	0	0	0	0
Indication B	Yes	No	Yes	65	70	125	0	84	0	0	65	0
Indication C	Yes	No	Yes	65	70	125	0	42	0	0	40	0
Indication D	In process	In process	No info§	58	63	111	-	-	-	-	-	-
Indication E	In process	Not applied	No info§	30	32	58	-	-	-	-	-	-
Indication F	In process	Not applied	No info§	57	62	110	-	-	-	-	-	-
Indication G	In process	Yes	Yes	30	32	58	-	0	0	-	0	0
Indication H	In process	In process	No info§	30	32	58	-	-	-	-	-	-
Brentuximab Vedotin												
Indication A	In process	Not applied	No info§	22	24	42	-	-	-	-	-	-
Indication B	Yes	Yes	Yes	1	3	2	0	0	0	0	0	0
Indication C	Yes	Yes	No info§	5	5	10	0	0	-	0	0	-
Indication D	Yes	Yes	No info§	17	18	33	0	0	-	0	0	-
Indication E	Not applied	Yes	Yes	3	3	6	-	0	0	-	0	0
Indication F	No	No	No info§	25	27	48	38	41	-	28	30	-
Total, per country				599	650	1153	230	167	0	189	135	0
Total						2402			396			323

*The number of patients has been extracted from Norway, and subsequently multiplied by a factor corresponding to the population sizes of Denmark and Sweden to estimate the number of patients in these countries (1,08 for Denmark and 1,93 for Sweden). § TLV is not listing ongoing assessments based on manufacturer applications on their webpage. Hence, the absence of a published assessment could mean that the assessment is still in process or that manufacturer has not applied or has withdrawn the application.

DISCUSSION

A notable strength of our study lies in the utilization of publicly available data showing the national HTA organizations' own assessment of QALYs and LYs from each indication that could have been gained if indications were recommended/reimbursed rather than not recommended. Website information from NoMA, DMC and TLV is incomplete, however, and for many indications, only sparse information is publicly available. Therefore, it is not possible to make precise calculations of lost QALYs and LYs, but estimates can be made relying on fair assumptions. To illustrate, many indications are not registered on the TLV website potentially due to withdrawals or direct implementations, thus introducing uncertainties in the results for Sweden. Also, NoMA list numerous indications as "in process", potentially related to conditional approval where future market access status is uncertain.

CONCLUSIONS

The results demonstrate that lack of payment models to accommodate VBP for multi-indication pharmaceuticals may result in a measurable welfare loss to society in terms of QALYs and LYs lost. However, the societal loss may be associated with other causes as well, emphasizing the need for further research. Implementing VBP policies has the potential to mitigate welfare loss and improve patient access to multi-indication pharmaceuticals.

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