Access to Medicines, Care, and Services for Multiple Sclerosis Patients in Central and Eastern European Countries: A Comparative Analysis

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OBJECTIVES	RESULTS						
To compare the access of patients with multiple sclerosis (MS) to disease-modifying treatments (DMTs), care, and services in Central and Eastern European countries (CEECs).	 Access to pharmacotherapy for MS There are no distinctions in the legal requirements for the P&R for MS drugs. The criteria for pharmacoeconomics analysis/HTA report is presented in Table 2. In all CEECs included in the study, the available DMTs were fully reimbursed; GCI is shown on Table 3. Other services and Support for MS patients All countries provide access to different services and support for MS patients depending on patients' disability level; Romania, Estonia, and Serbia ensure complete inpatient care, physiotherapy, and rehabilitation for MS patients; 						

METHODS

A 2-part questionnaire-based survey was conducted among experts from six CEECs – Bulgaria, Estonia, Poland, Romania, Serbia, and Slovakia over 4 months (01.12.2022 – 01.04.2023) **(Table 1)**

Table 1. Structure of the questionnairePart 1. Access to pharmacotherapy forMS

1. The legal requirements for P&R of medicinal products for MS;

2. The criteria for pharmacoeconomics analysis/HTA report required for the medicinal products;

3. Availability of MPs for MS (authorized in the EU) in the reimbursed lists of each country and the in pharmacotherapeutic guidelines in comparison with the European one; 4. Financial burden of MS therapies for the health insurance funds in each country; Administrative procedure for prescribing and dispensing of medicines for MS - criteria for treatment initiation continuation; and type of prescriptions/protocols; validity of the protocols/prescriptions.

- Financial burden: 2019 2021, DMTs' costs increased over time. Highest MS expenditures observed were in Poland (€1.15 billion in 2021) (**Figure 1,2**);
- The administrative procedures for prescribing and dispensing MS drugs does not exhibit significant differences among the countries.

Table 2. Requirements for conducting HTA

Slovakia Poland Serbia Bulgaria Estonia Romania Availability of HTA guideline ++++Pharmacoeconomic analysis CEA,CUA, CEA,CUA, CEA,CUA, CEA,CUA, CEA,CUA, CMA applied CMA CMA CMA CMA 2, 3, 5 or 3xGDP/cap No official 3xGDP/capita No official No official ICER threshold $10 \times GDP/$ threshold threshold threshold ita capita Is modeling obligatory? ++ + + +meta-analysis is carried out in Meta-analysis of conducted accordance with Cochrane clinical trials is requested guidelines if necessary Are the HTA appraisals from other

NHIFs completely covered all diagnostic tests and procedures.

Assessed by the number of authorized DMTs and included in their Positive Drugs Lists, the best access icant to MS therapy have Bulgaria (84,21%), Poland (78,95%), and Slovakia (78,95%) **(Table 3).**

Part 2. Other services and Support for MS patients

Other resources utilized for MS patients (for medical and assistive equipment, home care etc.)
 Supporting and educational programs for MS patients, availability of centers for comprehensive MS care etc.

	countries valuable for the final decision?	+	+		+	+	_	-	
r า	Assessment of social and economic burden of the disease, its rarity and		+		+	_	-	-	
r	seriousness			_	• •				
Table 3. Multiple sclerosis medicines included in the national positive drug lists									
>	Country:		Bulgaria	Serbia	Poland	Slovakia	Estonia	Romania	
ו	Number of drugs included in PDL		16	12	15	15	11	11	
f	Number of drugs included in PT	G EU:	19	19	19	19	19	19	
ć	GCI:		0,8421	0,6316	0,7895	0,7895	0,5789	0,5789	
	Figure 1. Total costs for MS drugs	F	Figure 2. Total costs for MS drugs in %						
	1 400 000 000,00				8,00% 6,23%				
					6,93% 6,33%				
, ,	1 200 000,00								
	1 000 000,00				6,00% 4,42%				
5	8,29 7,236				5,00%			4,49%	
	800 000 000,00	81 156 40 57/		L	3,87%	3,63%			



- The study revealed differences in MS patients access to DMTs, care, and services amongst included countries.
- Improving access to MS therapy needs an evaluation of the longterm impact of the barriers as well as frequent feedback from MS patients and stakeholders.



*Official data solely concerning the costs of drugs for Multiple Sclerosis in Serbia is currently unavailable.

Abbreviations: MS – Multiple Sclerosis; CEA – Cost-effectiveness Analysis; CUA – Cost-utility Analysis; GCI - Guideline Compliance Index; HTA – Health Technology Assessment; DMD's – Disease-modifying drugs, P&R – Pricing and reimbursement; GDP – Gross Domestic Product; ICER – Incremental cost-effectiveness ratio; EU – European Union; PDL – Positive Drug List; PTG – Pharmacotherapeutic guidelines; NHIFs – National Health Insurance Funds.