REIMBURSEMENT POLICIES REGARDING RARE DISEASES IN CENTRAL AND EASTERN EUROPEAN COUNTRIES

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OBJECTIVES

The purpose of this study is to gather information on reimbursement policies regarding rare diseases in Central and Eastern European (CEE) countries. The aim is also to demonstrate whether there are separate reimbursement requirements or approaches to therapy used in the treatment of rare diseases.

METHODS

The interviews among HTA and Market Access experts from 19 CEE countries: Albania, Bosnia and Hercegovina, Bulgaria, Croatia, Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Moldova, Montenegro, North Macedonia, Poland, Romania, Serbia, Slovakia, Slovenia, and Ukraine were conducted. The requirements for reimbursement and health policy in rare diseases were examined and compared among all specified countries.

RESULTS

In most of the CEE countries, there is no clear policy related to rare diseases. Uncommon disorders are often neither specifically recognized, nor treated in reimbursement legislation. Drugs for rare diseases usually do not have unique formal requirements for reimbursement application. Nevertheless, from 19 reviewed countries only 8 do not use any significant separate approach to rare diseases and/or orphan drugs: Albania, Bosnia & Hercegovina, Estonia, Moldova, Montenegro, Poland, Slovenia, and Ukraine. Other countries have already applied special treatment for rare diseases in the reimbursement process (Figure 1), but this “special treatment” differs significantly among the countries. Some countries do not use the cost-effectiveness ratio (ICER) threshold for orphan drugs or the cost-effectiveness threshold is more favourable to orphans than to other molecules (Bulgaria, Czechia, Latvia, Serbia and Slovakia). Others have separate legislation and reimbursement process for rare diseases (e.g. Lithuania, North Macedonia). A few countries have a separate budget for orphans (e.g. Serbia, North Macedonia, Croatia). The main differences in the approach to orphans compared to other drugs are presented in Table 1.

Table 1. The main difference in the approach to orphans compared to other drugs in CEE countries

COUNTRY	THE MAIN DIFFERENCE IN THE APPROACH TO ORPHANS COMPARED TO OTHER DRUGS
BULGARIA	There is no ICER threshold (3xGDP/capita) defined for orphan drugs
CROATIA	National Plan for Rare Diseases treatment and additional budget for rare diseases
CZECH REPUBLIC	With EMA Orphan designation ICER threshold is not the crucial criterium also other reimbursement criteria are considered
GREECE	Orphan drugs do not need to have a positive reimbursement decision in 5 European countries before submitting. Moreover, orphan drugs can be reimbursed on a patient basis
HUNGARY	Acceptability of cost-effectiveness or importance of the role of equity
LATVIA	For rare diseases, the ICER threshold must be below 300,000 EUR (instead of <52,300 EUR for others)
LITHUANIA	Separate legislation for orphan drugs for very rare diseases, but the treatment decisions refer to a particular patient
NORTH MACEDONIA	Separate legislation for rare diseases - National Rare Disease Program with a separate budget. Shorter timelines for the reimbursement process for orphans
ROMANIA	The separate process with specific criteria for rare diseases. Orphan drugs receive additional points compared to other molecules in the reimbursement process
SERBIA	Dedicated national rare diseases budget. The informal ICER threshold (3xGDP/capita) is more flexible for orphans
SLOVAKIA	No ICER threshold for orphan drugs indicated for therapy of rare diseases

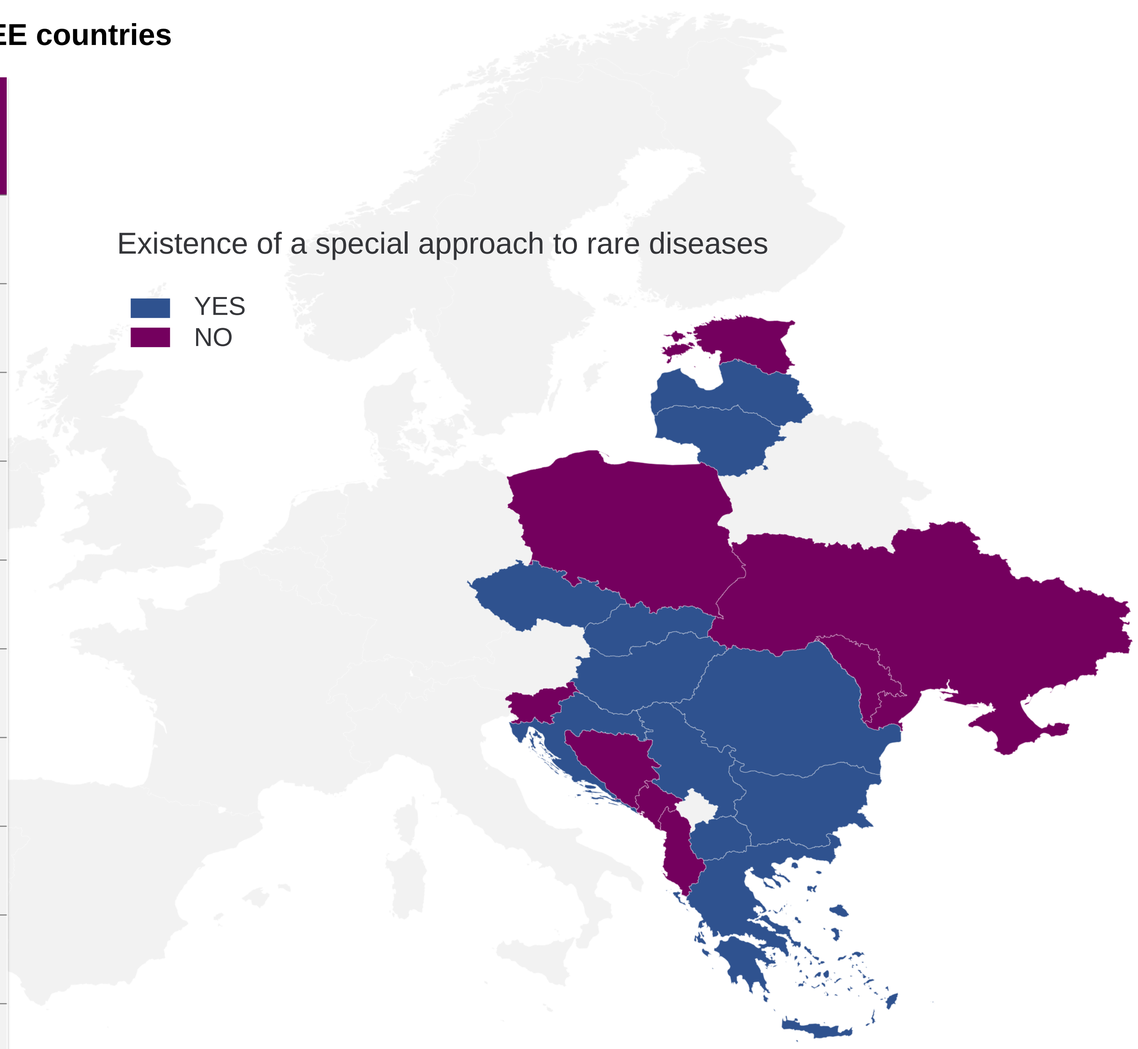

Figure 1. Specific approach to orphan drugs and/or rare diseases

CONCLUSION

Rare diseases for which diagnosis and treatment methods are often lacking, and access to data is limited due to small populations, are still treated equally with common diseases in the area of pricing and reimbursement in some CEE countries. Several countries did not apply a formal specific approach to orphan drugs or other therapies dedicated to the treatment of rare diseases. Nevertheless, most CEE countries use a more favourable approach in the reimbursement process to orphans even if it is not reflected in the legislation.

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