HTA REQUIREMENTS IN CENTRAL AND EASTERN EUROPEAN COUNTRIES

Karolina Skóra, Joanna Augustyńska, Michał Seweryn, Agnieszka Leszczyńska

EconMed Europe, Cracow, Poland

OBJECTIVES

Our research is aimed to determine the Health Technology Assessment (HTA) requirements for applying for public funding of new therapies in Central and Eastern European (CEE) countries.

METHODS

Interviews among HTA and Market Access experts from CEE countries were conducted. Nineteen countries were included: Albania, Bosnia and Hercegovina, Bulgaria, Croatia, Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Moldova, Montenegro, North Macedonia, Poland, Romania, Serbia, Slovakia, Slovenia, and Ukraine. The requirements for reimbursement application and implications of HTA were examined and compared among all specified countries. In addition, the need for local clinician opinion and local data collection was also explored.

RESULTS

In all analyzed CEE countries, the budget impact (BI) analysis is required. In 14 countries reimbursement decisions are also obligatory based on cost-effectiveness (CE) analyses (Bulgaria, Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Montenegro, North Macedonia, Poland, Serbia, Slovakia, Slovenia, and Ukraine). Areas, where discrepancies across countries were found, include medical evidence requirements. Usually, in countries where CE is obligatory, the medical part is also needed, but a systematic review of the literature (SLR) is obligatory only in a few (Czech Republic, Greece, Lithuania, Poland, and Slovakia). Instead of SLR, in Montenegro, North Macedonia, Serbia and Slovenia clinical opinion is needed.

Most countries require the preparation of all HTA analysis de novo taking into account local HTA requirements and local data but some model their reimbursement decision-making policy on HTA documentation used in other countries. In Romania, the HTA dossier comprises a summary of UK/Scottish, France and German HTA files recommendations and a so-called “budget impact” - but it is only a simple calculation. In Bulgaria, local data are not obligatory, they usually rely on international analysis. Only five countries require a full HTA dossier including BI, CE and SLR: Czech Republic, Greece, Lithuania, Poland and Slovakia (table 1).

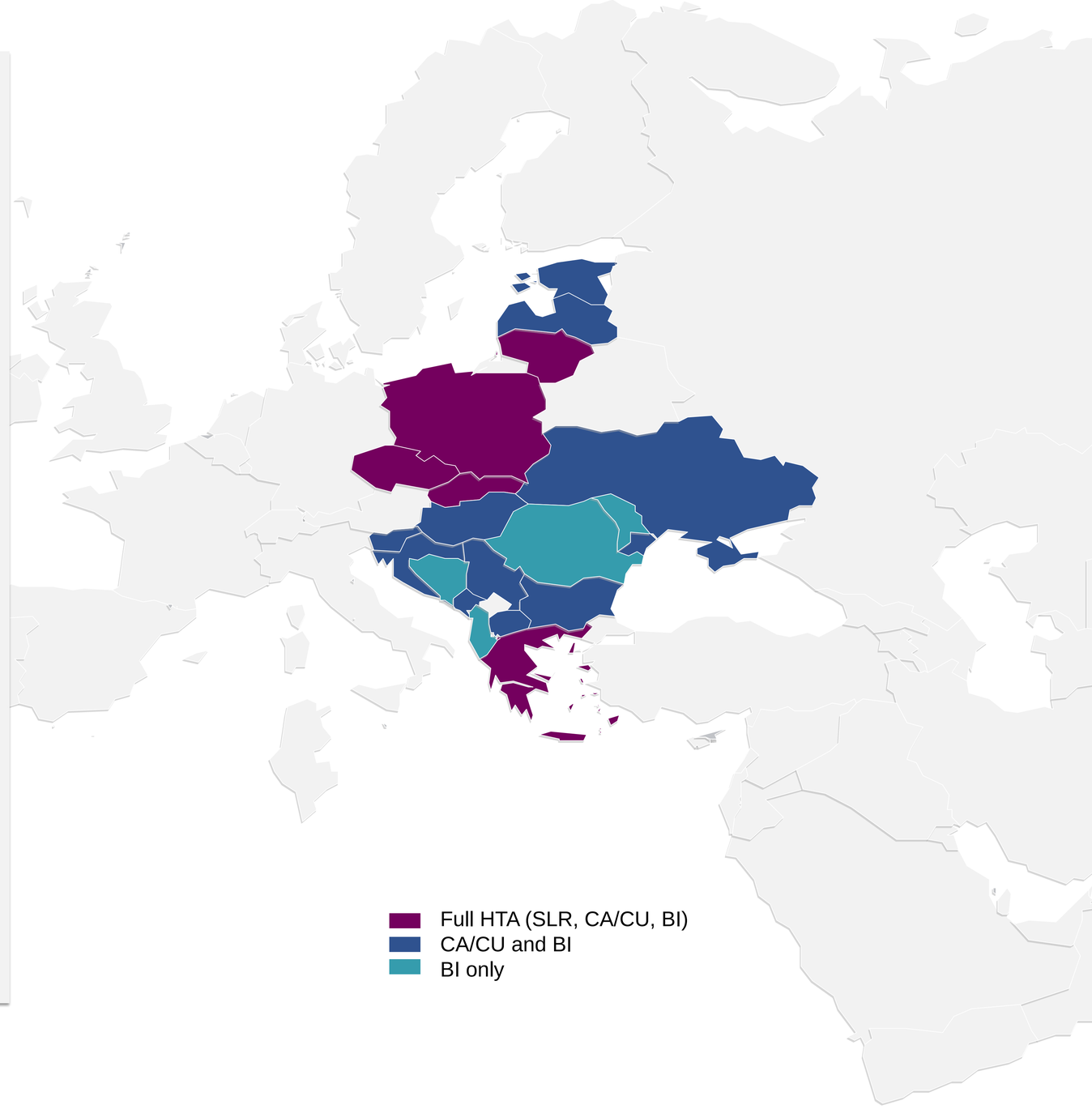

Table 1. Obligatory CEE countries HTA requirements

Country/ Document	ALB	BIH	BGR	HRV	CZE	EST	GRC	HUN	LVA	LTU	MDA	MNE	MKD	POL	ROU	SRB	SVK	SVN	UKR
BI	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
CE/CU			■		■	■	■	■	■	■		■	■	■		■	■	■	■
SLR					■		■			■				■			■		
Others				a)						b)		a)	a)		c)	a)		a)	

a) KOL clinical opinion is needed; b) Similar to Scottish requirements; c) The HTA dossier comprises a summary of UK/Scottish, France and German HTA files recommendations and budget impact

CONCLUSION

Although all analyzed countries use HTA evaluation to make reimbursement decisions, the scope and extent differ among countries. BI is the basic form of HTA documentation required by all countries, whereas SLR is performed only by a few. However, considering the diversity of the included CEE countries, the differences in health systems and healthcare expenditure, basic pricing and reimbursement requirements for a new therapy are quite similar in this region.

Abbreviations: ALB – Albania; BGR – Bulgaria; BI – Budget impact; BIH – Bosnia and Herzegovina; CE/CU – cost-effectiveness/utility analysis; CZE – Czech Republic; EST – Estonia; GDP – gross domestic product; GRC – Greece; HRV – Croatia; HTA – Health Technology Assessment; HUN – Hungary; ICER – Incremental cost-effectiveness ratio; LTU – Lithuania; LVA – Latvia; MDA – Moldova; MKD – North Macedonia; MNE – Montenegro; N/A – not available; POL – Poland; ROU – Romania; SLR – systematic literature review; SRB – Serbia; SVK – Slovakia; SVN – Slovenia; UK – United Kingdom; UKR - Ukraine

Ask a question: k.skora@econmed.eu, Karolina Skóra, BD Vice President

EconMed Europe, Cracow, Poland

www.econmed.eu/en www.linkedin.com/company/econmed-europe-sp-z-o-o

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