EARLY HEALTH TECHNOLOGY ASSESSMENT (HTA): LESSONS LEARNED FROM A RUSSIAN BIOTECHNOLOGY COMPANY

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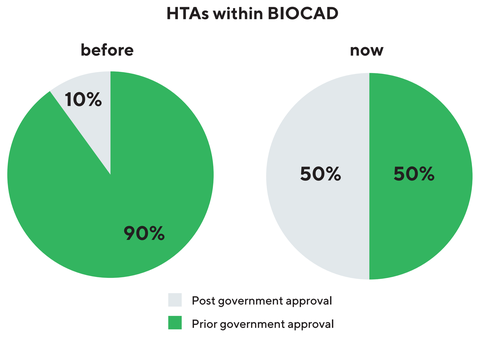
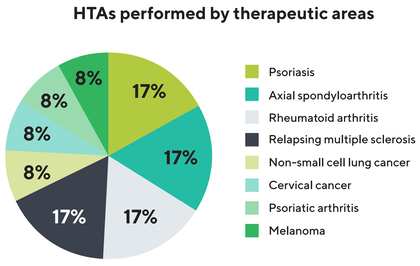
BACKGROUND

Early HTA is an iterative evaluation alongside Phase I and II clinical trials used to reinforce pharmacoeconomic evidence in early-stage clinical development. Although rapidly developing, most health economics studies in Russia are carried out post drug approval.

OBJECTIVES

- To analyze the internal HTA process in a Russian biotechnology company (BIOCAD);
- To identify best practices and gaps.





MATERIALS & METHODS

We analyzed BIOCAD's internal HTA process to improve project selection, and future reimbursement and market access strategies. For our analysis, we selected BIOCAD's innovative products currently in phase I and II trials or those planned for phase II and III trials.

RESULTS

We selected 9 case studies (7 drugs, most of them have more than 1 indication). The best practices we determined:

- Conducting brief pharmacoeconomic evaluation of a drug prior to clinical trial planning was the best practice. It facilitated trial design in regards to defining the comparator, outcome measures (including HRQoL estimates), patient profile, and trial duration, and incorporated clinical and health economics evidence into the decision making on pricing, reimbursement, and market access strategy.
- Early dialogs with HTA bodies allow for the integration of HTA requirements (e.g. choice of comparators, relevant outcomes, quality of life, patient groups) in the study design and the economic evaluation. That helps to improve the quality and appropriateness of the data generated in clinical trials in view of future reimbursement dossier.
- For a biotechnology company focusing on particular therapeutic areas, it is important to consider the portfolio HTA. Evaluating all drugs under development in the same area helps identifying potential relative impact and informing stakeholders on the drug value to better manage product portfolio and uncertainty. BIOCAD has already applied this methodology for relapsing multiple sclerosis and rheumatoid arthritis cases.

We identified the gaps we need to address to mitigate risks associated with market access and reimbursement.

- Pricing without accounting for HTA requirements results in inaccurate sales forecasts, inappropriate market access strategy, delayed listing and reimbursement.
- Lacking HTA when prioritising potential indications (especially relevant for countries like Russia where listing is not indication-based) or choosing preferred route of administration may lead to errors in market access and reimbursement strategy, need for additional trials, and delays in bringing drug to patients.

CONCLUSION

Although early HTA is brief and may involve many assumptions, it helps making vital decisions on drug value, trial design, pricing, and market access strategy.

	Drug	BCD-085, Russia	BCD-100, Russia	BCD-089, Russia	BCD-132, Russia	BCD-054, Russia	BCD-085, Europe	BCD-100, Europe
Challenges	Absense of indication prioritisation	+						
	Unbalanced population characteristics	+						
	Absense of HRQoL measures	+		+		+		
	Inconsistency between pricing and HTA requirements	+	+					
	Inconsistency between clinical trial design and HTA requirements (choice of comparator and outcomes)		+	+		+		
	Choice route of administration based on financing channel			+		+		
	Engagement in clinical trial protocol development only from phase III				+		+	+
Best practices	Early dialogues with HTA bodies		+					
	Initiation of national or multi-HTA consultations						+	+
	Portfolio analysis			+	+	+		
	Pricing in line with HTA requirements			+	+	+	+	+
	Prioritisation of indications				+			
	Clinical trial protocol approval by HTA unit (choice of comparator, outcomes, population, trial duration)				+		+	+
	Prioritisation of countries for market access						+	+

BIOCAD
Biotechnology Company