data infrastructure, and some companies are advanced than others in tackling this issue.

HEALTH CARE USE & POLICY STUDIES – Conceptual Papers

PHP316
THE NEW TECHNOLOGY COST-EFFECTIVENESS CHECKLIST: INTRODUCING A PRACTICAL GUIDELINE FOR THE SELECTION OF HEALTH TECHNOLOGIES
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BACKGROUND: The increasing focus on healthcare costs, aging of populations and rising costs of drug development require an effective approach to ensure the rational uptake of new and difficult-to-handle technologies by health systems. Health stakeholders need cost-effective and appropriate and effective healthcare with enduring results at a reasonable cost, particularly in environments where resources are scarce. In spite of much research, methodologies and recommendations, a simple solution to make budget allocations on drug development that would be needed by many decision makers. APPROACH: A user-friendly and read-do checklist could facilitate the assessment of cost-effectiveness of technologies, particularly new, innovative high cost drugs. The aeronautical industry (pre-flight safety checklist), World Health Organization/Harvard School of Public Health (pre-surgical safety checklist) and public health services (pre-disaster or disease preparedness checklists) have successfully prevented and reduced air traffic accidents and morbidity and mortality secondary to surgical interventions, diseases and natural disasters through the implementation of safety checklists.

PRACTICAL IMPLICATIONS: In pharmacoeconomics, as in aviation, medicine and public health, a checklist can help ensure consistency and expert opinion. It is unclear how these rankings would relate to the preferences of life if the intention of the two therapies are different, yet they would compete for the same resources within the health care system. The ranking used is created based on expert opinion. It is unclear how these rankings would relate to the preferences of the patients or the general public. The scale relies on clinical trials as the evidence base. What matters for reimbursement agencies, payers and health care providers is how well the new treatment opportunity performs in clinical practice, in relation to existing therapeutic alternatives. CONCLUSIONS: There are limitations to the ESMA-MCBS at present as a measure of value. One important aspect that would merit further study to validate how well the scale is able to discriminate between more and less valuable therapies as perceived by reimbursement bodies, by for instance comparing the rankings of therapies according to different scales: managed-entry agreements and risk-sharing arrangements to reduce the cost of drugs.

CONCLUSIONS: A generic “New Technology Cost-Effectiveness Checklist”, intended to be modified as needed to fit local requirements, could guide evidence-based decision making in resource-limited settings. In turn, it may become the tool to reach the universal goals of patients, providers, payers and policy-makers to (1) get the best drug and technology quality at the lowest cost and with reasonable access, and (2) enhance health system partnerships and solutions towards improved individual and population health outcomes.

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ASSESSING THE ESMA MAGNITUDE OF CLINICAL BENEFIT SCALE FROM A HEALTH ECONOMICS PERSPECTIVE
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OBJECTIVES: Recently the ESMA Magnitude of Clinical Benefit Scale (ESMO-MCBS) has been introduced. The scale is supposed to assist decisions about value and cost-effectiveness of new cancer therapies. This is achieved by classifying therapeutic advances according to their relative clinical benefit according to pre-defined criteria. The objective of the present study was to investigate the scale from a health economic perspective. METHODS: We conducted a systematic literature review in order to identify relevant methods and generate comments on the implementation of the scale. RESULTS: Several issues that make the scale problematic were identified. Firstly, the scale makes a difference between drugs on the basis of the difference in outcomes of relevant comparator drugs. Secondly, there is no rigorous approach for setting the reference level, which is not based on clinical outcomes but instead on economic outcomes. Moreover, the scale is not sensitive to the context in which the drugs are used. Finally, the scale does not consider the cost-effectiveness of the therapy. CONCLUSIONS: The ESMA-MCBS is not a reliable tool to assess the clinical benefit of new cancer therapies. Future work should focus on improving the scale by addressing these limitations.

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ECONOMIC SANCTIONS AND MARKET ACCESS FOR PHARMACEUTICALS: CASE STUDIES WITH RUSSIA, CUBA AND IRAN
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OBJECTIVES: The objective of this study was to analyze the impact of imposed and/or withdrawn economic sanctions on various countries on access to innovative pharmaceuticals, market access, and health outcomes. Recent geopolitical and pharmaceutical market dynamics related to Russia, Cuba, and Iran in light of the introduction or removal of sanctions on these markets. Intellectual property regulations, healthcare financing, and other market players challenge pharmaceuticals. Numerous economic, political, and social vari- ations across nations limit the transferece of HTA institutionalization models that have been implemented elsewhere. The “Knowledge to action” (KA) model has proven to reduce the “evidence-practice” gap through a systematic method of linking evidence to implementation and monitoring processes. The objective of

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RECENT UPDATE TO RUSSIA’S ESSENTIAL DRUGS LIST AND SEVEN NOSONOLOGIES: CLINICAL DIFFERENTIATION AND LOCAL MANUFACTURING IMPLICATIONS FOR NEW DRUG INCLUSION
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OBJECTIVES: The objective of this study was to assess implications of the recent update to Russia’s Essential Drugs List (EDL) and Seven Nosologies (VZN) on the access of the local pharmaceutical market in the context of various economic pressures.

METHODS: This study was based on the review of current and past iterations of the EDL and VZN, various policy changes, as well as economic and health outcome indicators. In addition, a pragmatic literature review was undertaken to assess the impact of the EDL and VZN updates on the current market access environment in Russia.

RESULTS: The 2015 EDL, which was previously updated in 2012, includes an additional 50 therapies, some of which are reimbursed through the VZN. Five new medicines were added, including treponemal, a cure for Gaher’s disease, and a second-line therapy for multiple myeloma, bringing the total to 23 therapies since its implementation in 2008. The 2013 decision to require reimbursement for all innovations was later overturned. However, VZN reimbursement for medicines reimbursed through the VZN are reimbursed at the federal or state level while the rest are paid out-of-pocket. CONCLUSIONS: The expansion of the EDL and VZN have made some innovative therapies available to certain populations that were previously unable to access these high-cost treatments. In addition, due to economic uncertainties, laws have been enacted to restrict the admission of foreign drugs to state procurement if equivalent INNs are available through local manufacturers.

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HEALTH ECONOMICS IN IMMUNIZATION DECISION-MAKING – RESULTS FROM A SYSTEMATIC LITERATURE RESEARCH AND A STAKEHOLDER SYMPOSIUM IN GERMANY
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BACKGROUND: Immunization decision-making (IDM) is usually based on multiple sources of evidence. Health economics (HE) has become increasingly relevant in IDM as decision-makers need to consider economic perspectives. There are two approaches among stakeholders on how to implement HE into IDM. METHODS: We conducted a systematic literature review in order to identify relevant methods and advantages of considering HE in IDM. The review was conducted for a stakeholder symposium in Germany. RESULTS: The literature evidence was used to prepare a national stakeholder symposium in January 2015 on which representatives from academia, politics, industry, administration and patient-support groups were able to discuss different options on how to implement HE into IDM. CONCLUSIONS: Based on the literature review, we make four recommendations: (i) a consideration of the most efficient vaccination strategy, (ii) identification of the most efficient vaccination strategy, (iii) identification of critical input parameter, (iv) budget-impact-analysis, and (v) decision-making based on an incremental cost-effectiveness threshold. A recently conducted survey showed that most European countries consider HE in IDM. This is done (a) most frequently via an informal appraisal, (b) rarely by using a cost-effectiveness threshold (4 countries), and (c) never by applying multiple-criteria decision-analyses. After key-note lectures, group-works and panel discussions, the majority of stakeholders had the opinion that in Germany the advantages of (i) to (iii) should be taken into account and decisions should be derived from an informal appraisal. DISCUSSION: Most of the invited stakeholders acknowledged the use of HE in IDM. There was consensus that in Germany a cost-effectiveness threshold is no option. However, HE might be considered in IDM to compare different vaccination strategies and highlight the potential (economic) benefits of vaccination.