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 innovative technologies by health systems. Health stakeholders want safe, appropriate and effective healthcare with ending 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 or decisions will 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 pharmaco-economics, as in aviation, medicine and public health, a checklist can help ensure consistency and completeness in carrying out the complex technology selection task, implementation, the decision maker’s communication and consistency of information and data, facilitating the decision-making process and determining the most cost-effective options. This checklist could also be a useful tool to negotiate value added services, 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 decisions 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 partnerships and solutions towards improved individual and population health outcomes.

PHP317

ASSESSING THE ESMO MAGNITUDE OF CLINICAL BENEFIT SCALE FROM A HEALTH ECONOMICS PERSPECTIVE

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OBJECTIVES: Recently the ESMO Magnitude of Clinical Benefit Scale (ESMO-MCBS) has been introduced. The scale is supposed to assist decisions about value and cost-effectiveness of cancer therapies. This scale, 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 economics perspective.

METHODS: We conducted an appraisal of the building blocks of the scale in order to assess potential limitations to using the instrument to inform policy.

RESULTS: Several issues that make the scale problematic were identified, including: the absence of a process of concern was: ESMO-MCBS uses multi-scale weights on different topics, depending on if the intent of the therapy of to be curative or not. It is impossible to compare two cancer treatments which both have effect on survival and quality 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 ESMO-MCBS at present as a measure of value. One important aspect that would merit further study is 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 ESMO-MCBS to rankings based on estimated gains in survival and quality-adjusted survival.

PHP318

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 innova- tive pharmaceuticals, market access, and health outcomes. Recent geopolitical and pharmaceutical market dynamics related to Russia, Cuba, and Iran are considered.

METHODS: This study examined the current health care financing options and market access implications of pharmaceuticals in Russia, Cuba, and Iran in light of the introduction or removal of sanctions on these markets. Intellectual property regulations, healthcare financing, and ef- fectiveness criteria are amongst other challenges to market access. Economic 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

PHP319

RECENT UPDATE TO RUSSIA'S ESSENTIAL DRUGS LIST AND SEVEN NOSOLOGIES: 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 molecules were included, including trexoludil, a cure for Gaucher’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 remove the financial responsibility of the WHO and other international authorities for local drug manufacturing in Russia 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.

PHP320

HEALTH ECONOMICS IN IMMUNIZATION DECISION-MAKING – RESULTS FROM A SYSTEMATIC LITERATURE REVIEW 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 economic evidence is seen as an important instrument to help increase the transparency of how decisions are made among stakeholders on how to implement HE into IDM. METHODS: We conducted a systematic literature review in order to identify relevant methods and approaches of considering HE in IDM. Furthermore, an overview of IDM in several European countries was compiled based on literature. The generated 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.

RESULTS: Based on the literature review five core advantages from considering HE aspects in IDM were identified: (I) modelling of future vaccine related public health effects; (II) identification of the most efficient vaccination strategy; (III) identification of the most efficient vaccination strategy; (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 multi-criteria decision-analyses. After key-note lectures, group-works and panel discussions, the majority of stakeholders had the opinion that in Germany the current 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.

PHP321

HOW TO INSTITUTIONALIZE THE “KNOWLEDGE TO ACTION” FRAMEWORK FOR HEALTH TECHNOLOGY ASSESSMENT?

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OBJECTIVES: The institutionalization of health technology assessment (HTA) methodologies and practices is fundamental to establish HTA as an integral part of HTA systems 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