OECD—delivering quality health services: a global imperative

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The Organisation for Economic Co-operation and Development (OECD) together with WHO and the World Bank Group recently published a report calling for urgent action from governments, clinicians, patients, civil society and the private sector to help rapidly scale up quality healthcare services for universal health coverage.

With many countries around the world failing to provide the right care, at the right time that delivers clinical value to patients, is safe, and meets the needs and preferences of patients, the report addresses the necessity to step up the game to achieve universal health coverage by 2030. Simply ensuring coexistence of infrastructure, medical supplies and healthcare providers will not be sufficient to tackle inaccurate diagnosis, medication errors, inappropriate and unnecessary treatment or the lack adequate training.

Five elements, namely healthcare works; healthcare facilities; medicines, devices and other technologies; information systems and finances, have been identified as crucial for a quality system. In addition, to a good foundation also a high level of intervention through standard setting, education and performance-based incentives will in accordance with the report add to the improvement of the quality of care. Innovative interventions have been developed in a number of regions. These experiences, however, need to be shared more widely, especially with low-income and middle-income countries.

The call to action of OECD, WHO and the World Bank addresses governments, health systems, patients and healthcare workers. Hospital pharmacists as part of the latter group should participate in quality measurement and improvement with their patients, embrace a practice philosophy of teamwork, regard patients as partners in the delivery of care and commit themselves to providing and using data to demonstrate the effectiveness and safety of the care. These contributions will however only be effective if all actors work together towards an integrated approach.

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WHO—MEDICINES REIMBURSEMENT POLICIES IN EUROPE

WHO recently released a report on 'Medicines reimbursement policies in Europe' analysing different approaches throughout the WHO European region. Data were collected by means of a literature review, qualitative interviews in selected case study countries and a questionnaire completed by competent authorities including those collaborating in the Pharmaceutical Pricing and Reimbursement Information network.

Variations in expenditure and system organisation were found. Differences were notable in particular between outpatient and inpatient services. Since co-payment is mostly not mandated for the inpatient sector, the report focused mainly on the reimbursement policies for the outpatient sector. In this regard, it looked at the financial burden of co-payments that exists particularly for patients in lower-income countries. More detailed information was gathered for Azerbaijan, Finland, Greece, Kyrgyzstan, the Republic of Moldova, the Netherlands, Scotland/UK, Spain and Turkey in the context of the case studies, which focused either on country-specific reimbursement policies or progress towards universal health coverage.

Overall, the report highlights that there is no 'one size fits all' model when it comes to reimbursement policies that could be used throughout the WHO Europe region. Nonetheless, principles such as prioritisation, evidence-based decision-making, real-world data generation, transparent and smooth processes, making use of the efficiency of lower-priced medicines, patient involvement in decision-making, systematic and regular evaluations and strategic design of policy measures were identified as tools for the improvement of affordable access to medicines.

NEWS FROM THE EUROPEAN MEDICINES AGENCY

July's round-up of the European Medicines Agency's (EMA) activities features a review of bacterial lysate medicines, recommendations of the Pharmacovigilance Risk Assessment Committee (PRAC) on Xofigo, information on the Brexit preparedness of marketing authorisation holders and an update on the new clinical data publication policy.

Communications

EMA has started a review of bacterial lysate medicines since recent studies have cast doubt on its effectiveness in reducing the number and severity of respiratory infections in adults and children who experience repeated infections. The review will determine if the marketing authorisations for the medicines containing bacterial lysate should be maintained, varied or suspended across the EU.

PRAC has recommended restricting the use of the cancer medicine Xofigo (radium-223 dichloride) to patients who have had two previous treatments for metastatic prostate cancer (prostate cancer that has spread to the bone) or who cannot receive other treatments. This restriction confirms the PRAC's previous interim recommendation that the medicine must not be used with Zytiga and prednisone/prednisolone. Xofigo should not be used with other systemic cancer therapies, except for treatments to maintain reduced levels of male hormone (hormone therapy).

Brexit preparedness

With the date of Brexit fast approaching, the EMA is continuously working on raising awareness among marketing authorisation holders. This is achieved through information notices on legal issues and guidance documents that are regularly updated. Earlier this year, the EMA gathered data via a survey on the potential of supply shortages for centrally authorised products. Findings show that regulatory planning is on track for more than half of the centrally authorised products with an important step in their regulatory processes in the UK.

Clinical data publication

The first report on EMA's policy on the publication of clinical data has been released. It features 50 medicines for which clinical data were published since the adoption of the policy. The results of a user survey of the clinical data website are also included in the report. It summarises the reasons of the different user groups for accessing the data and their views on its usability. Importantly, it shows that very few respondents disagree with EMA's rationale for developing the policy. In addition, most respondents strongly agree that publishing clinical data increases public trust in EMA's decision-making and

that it allows the reassessment of clinical data.

EDQM RELEASES ANNUAL REPORT

The European Directorate for the Quality of Medicines and HealthCare (EDQM) published its annual report showcasing the major highlights of the past year, including updates and new additions to the European Pharmacopoeia, strengthening the cooperation with the EMA and continuing to lead the work of the European Network of Official Medicines Control Laboratories (OMCLs).

The European Pharmacopoeia provides legal and scientific benchmarks for pharmacopoeial standards, which contribute to delivering high-quality medicines in Europe and beyond. In the past year, EDQM reached an important milestone for biotherapeutic products by adopting the first monograph on a monoclonal antibody (mAb):infliximab concentrated solution (2928). In addition, 222 monographs were revised to incorporate regulatory changes and scientific progress.

Also, the work of the OMCLs, which are a result of a collaboration with the European Union, continued to ensure mutual recognition of test results, harmonisation of working methods and sharing of expertise, laboratory resources and data. Cooperation was also fostered with international partners such as the Health Surveillance Agency of Brazil and the Chinese Pharmacopoeia Commission to promote co-operation on the safety and quality of medicines.

Guidelines for the preparation, use and quality assurance of blood component and on the quality and safety of tissues and cells for human application were adopted in the area of healthcare in accordance with the mission of EDQM. As a directorate of the Council of Europe, EDQM aims at protecting public health by enabling the development, supporting the implementation and monitoring the application of quality standards for medicines and their safe use.

FIP REPORT HIGHLIGHTS IMPACT OF PHARMACY INTERVENTIONS ON ADHERENCE IN THE ELDERLY

The International Pharmaceutical Federation (FIP) released a report focusing on the role of the pharmacist in promoting adherence among elderly patients. The report evaluates a number of pharmacy interventions such as new medicines services, more counselling when a medicine is supplied again, dosage administration aids and reminder systems.

By reviewing evidence in literature and compiling case studies from Australia, Belgium, Denmark, Ireland, the Netherlands, Singapore, Spain and Switzerland, an overview on relevant interventions and programmes to improve medication adherence in the elderly population was collected. The report highlighted the importance of the interaction between multiple intervention methods. In this regard, three interlinking elements were identified, namely the effective communication with the patient and his/her carer by all members of the healthcare team; the need to simplify the taking of medicines for older patients and sustaining the effort by continuously providing input to the patient's needs.

Despite the key role that the pharmacist plays in improving the adherence of elderly patients, shortcomings were identified by the report. In particular, due to professional differences and the isolation of the pharmacy from the other health professions involved in the management of patients' limitations to the scope of interventions were found. Collaboration in a more integrated way was mentioned as a solution to this problem.

In 2016, the European Association of Hospital Pharmacists (EAHP) released its position paper on an ageing society, which also touches on the uptake of hospital pharmacist roles in medication reconciliation and review. As highlighted in this paper, hospital pharmacists can foster patient adherence through improved medicines management during admission, inpatient stay and discharge.

WHO COMPETENCY FRAMEWORK ON AMR

Three years ago, WHO launched its global action plan to tackle antimicrobial resistance (AMR). To support the efforts of this action plan, WHO released a Competency Framework for Health Workers' Education and Training on AMR. This document contains a matrix menu of core and additional knowledge, skills and attitudes for health workers in the field of human health. It is designed to be used as a reference guide and applied according to local priorities and needs.

On the one hand, the framework makes suggestions for the training of prescribers and non-prescribers such as (hospital) pharmacists, nurses and laboratory technicians in the fields appropriate use of antimicrobial agents; infection prevention and control; diagnostic stewardship and surveillance; as well as awareness raising. On the other hand, it addresses information on the knowledge, skills and attitudes of all healthcare works and of public health officers/health services managers.

As its main theme, the competency framework highlights the need for an interprofessional approach based on the principle that reacting to AMR requires a shared understanding, and effective collaboration and communication among health workers. The use of antimicrobial stewardship teams is encouraged. In particular, public health officers and health services managers should be enabled to determine and implement best approaches to antimicrobial stewardship, which helps to optimise clinical outcomes while minimising unintended consequences of antimicrobial use.

ENVI COMMITTEE CALLS FOR MORE ACTION ON AMR

The European Parliament's Environment, Public Health and Food Safety (ENVI) Committee backed two measures aiming at fighting the use of antimicrobials in the European Union. These include the Own Initiative (INI) report on the European One Health Action plan against antimicrobial resistance and the Proposal for a Regulation on veterinary medicinal products. The ENVI Committee adopted the reports on these matters unanimously.

The INI report underlines that the growing threat posed by antibiotic-resistant bacteria can be tackled through the 'One Health' approach proposed by the European Commission's AMR action plan. In this regard, Members of the European Parliament urge the European Commission and Member States to restrict the sale of antibiotics for both human and veterinary use and to remove prescription incentives. In addition, they call for the promotion of preventive measures, an increase in 'health literacy' and heightened efforts to raise awareness of the perils of self-medication and over-prescription. Future research and development priorities should be supported through an EU priority pathogen list for both humans and animals and incentives should be created to stimulate investment in new substances.

The Proposal for a regulation on veterinary medicinal products aims at fighting the abuse of the use of antibiotics in husbandry, which are used particularly to boost animal performance. It suggests restricting the preventive use of antibiotics in veterinary medicine and drawing up a list of 'critical' antibiotics that can only be

used in the field of human medicine. The Regulation also encourages innovation in the area of antimicrobials through incentives such as longer periods of protection for the technical documentation of new drugs.

ECDC REPORTS RISE OF CARBAPENEM-RESISTANT ENTEROBACTERIACEAE

The European Centre for Disease Prevention and Control (ECDC) has released a new rapid risk assessment on carbapenem resistance highlighting the threat to patients and healthcare systems in all European Union and European Economic Area countries. The report outlines the growing rise of carbapenem-resistant Enterobacteriaceae (CRE) since the 1990s, which often are a cause of urinary tract infections and bloodstream infections.

Particularly high resistance levels were reported in Italy, Greece and Romania. To prevent the spread of CRE, which is usually associated with prolonged hospital stays, high treatment costs, treatment failures and high mortality, prevention and control measures are recommended by the rapid risk assessment. These include actions related to limited treatment options and high mortality; actions to prevent transmission of CRE in hospitals and other healthcare settings; actions to prevent spread of CRE into the community; actions to prevent cross-border spread; actions to reduce risks for healthcare systems.

Similarly to EAHP's position on AMR, also the rapid risk assessment by ECDC suggests the implementation of antimicrobial stewardship programmes and the use of hygiene measures for the prevention and control of the emergence and spread of CRE and other multidrug-resistant bacteria in the hospital setting. In addition, the report highlights the need for new antibacterial agents (antibiotics) active against prevalent multidrug-resistant bacteria such as CRE.

Section 6: Education and Research

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