Antimicrobial resistance: antibacterial clinical development pipeline

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The WHO released a report that provides an overview on the antibacterial agents in clinical development. It is a follow-up action related to the list of priority antibiotic resistance pathogens that was drawn up as part of WHO's Global Action Plan on Antimicrobial Resistance. The report shows a serious lack of new antibiotics, since most of the drugs currently in the clinical pipeline are modifications of existing classes of antibiotics and are thus short-term solutions.

The analysis focused on 62 antibacterial products (51 antibiotics and 11 biologicals) that were as of May 2017 in phases I–III of clinical development and had not yet received a market authorisation for human use. In addition, to classifying the antibacterial products by type, pathogen category, phase of clinical development and expected activity against priority pathogens, the report also analysed their innovativeness. Only 8 out of the 33 antibiotics that are being developed for priority pathogens fulfilled at least one of the four criteria that were used to assess innovativeness. These criteria include (1) absence of cross-resistance to existing antibiotics, (2) new chemical class, (3) new target and (4) new mechanism of action.

Overall, the report shows that the antibacterial agents currently in clinical development are insufficient to mitigate the threat of antimicrobial resistance (AMR). Consequently, more investment is needed in basic science, drug discovery and clinical development. Furthermore, the report calls for more innovative products as these are required against pathogens with no cross-resistance or co-resistance to existing classes.

In addition to the presentation of the findings, the report also highlights the important role of antimicrobial stewardship. The development of new antibiotics is not sufficient to mitigate the threat of AMR, wherefore it needs to go hand in hand with infection prevention and control activities. As outlined in the European Association of Hospital Pharmacists' (EAHP) position paper on AMR activities fostering the appropriate use of existing and future antibiotics should be

undertaken by stewardship teams in which also hospital pharmacists are involved.

Stay tuned for more information on the upcoming European Antibiotic Awareness Day that will be supported by EAHP as well as on the new hospital toolkit that will be released by the European Centre for Disease Prevention and Control (ECDC) shortly.

U-PGX: IMPLEMENTING PHARMACOGENOMICS IN EUROPE

The Ubiquitous Pharmacogenomics (U-PGx) project, which is funded by the European Union's (EU) Horizon 2020 grant, aims at implementing pharmacogenomics (PGx) in seven EU sites/countries and evaluating patient benefit and cost-effectiveness using a randomised clinical trial design. Overall, the project seeks to address major challenges and obstacles for the implementation of PGx testing in patient care by taking into account the diversity of health systems and citizens in Europe.

Pharmacogenomics, the study of genetic variability affecting an individual's response to a drug, plays the central role in this project. Its use allows personalised medicine and reduction in 'trial and error' prescribing leading to more efficacious, safer and cost-effective drug therapy. However, despite the advances made in PGx and the availability of PGx tests, application remains very limited.

U-PGx will specifically investigate if the emerging approach of pre-emptive genotyping of an entire panel of important PGx markers is cost-effective and results in a better outcome for patients. With the pre-emptive PGx testing approach data on multiple important pharmacogenes are collected prospectively and embedded into the patients' electronic record. Typically, it alerts prescribers and pharmacists through electronic clinical decision support systems when a drug is ordered or dispensed for a patient with an at-risk genotype. The new model of personalised medicine through pre-emptive PGx testing will be conducted at a large scale in Austria, Greece, Italy, Slovenia, Spain, the Netherlands and the UK.

To meet this goal, the U-PGx Consortium combines existing PGx guidelines and novel health information technology solutions. For this study, existing PGx

guidelines (84 drug-gene pairs comprising 13 genes) from the Dutch Pharmacogenetics Working Group have been translated into all local languages of the countries involved (from Dutch to English, German, Greek, Slovenian, Spanish and Italian) by certified professionals. The guidelines will be published as a series in the international high-ranked journal *Genome Medicine* in order to facilitate their use in patient care.

FIP GLOBAL SURVEY: PHARMACY AT A GLANCE

The World Congress of Pharmacy and Pharmaceutical Sciences saw the launch of 'Pharmacy at a glance: 2015–2017'—a global survey of the International Pharmaceutical Federation (FIP). It provides readers with information on the state of the pharmacy profession at global level for both community and hospital pharmacy services. Data on the distribution of pharmacists in different sectors and access to pharmacies, models of generic medicines dispensing/substitution and the availability of medicines online are summarised in eight infographics out of which two are specifically dedicated to hospital pharmacies.

Regarding hospital pharmacies, the study investigated the scope of practice by surveying the extent of implementation of a set of activities and services. These were clustered in four groups addressing the influence on procurement and prescribing, the preparation and delivery of medicines, monitoring of medicines use as well as other activities and services. It was investigated if these services are available and if they can be considered as part of mainstream hospital pharmacy practice.

The most common services reported were the provision of support to emergency departments (by 69 out of 72 respondents), reporting of adverse reactions to medicines (by 68 out of 72 respondents) and the participation in pharmacy and therapeutic committees (by 68 out of 72 respondents). The responsible use of medicines is adhered to through the implementation of antibiotic stewardship initiatives as well as infection control and prevention strategies. Recently introduced technical innovations—such as clinical PGx testing—are services that are not yet available within the majority of the participating hospital pharmacies.

COMMISSION EXPERT PANEL TASKED WITH THE DEVELOPMENT OF THREE NEW OPINIONS

The Expert Panel on effective ways of investing in health of the European Commission has been tasked with the development of three opinions relating

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to pricing models for innovative medicines; access to healthcare in the EU; and assessing the performance of health systems. The opinions should be presented in the second semester of 2017 as they will feed into further policy work of the European Commission.

The Expert Panel on effective ways of investing in health is an interdisciplinary and independent group. It was established by the European Commission to develop non-binding advice which aims to provide the necessary evidence that will support the EU countries in delivering high-quality care and making their health systems more resilient and efficient while improving accessibility to all.

Opinion on innovative payment models for high-cost innovative medicines

Sustainability of health systems, patient access and affordability impact the development and the timely authorisation of innovative medicines. Since the European Commission is committed to ensuring accessibility of patients to innovative medicinal products and is interested in exploring possible synergies between various bodies in the EU, it has tasked the Expert Panel with the drafting of an opinion on innovative payment models for high-cost innovative medicines.

The opinion should clarify methodologies and provide a tool for national competent authorities by identifying the gaps of current models and proposing areas for further development for those authorities willing to increase their resilience. To this end the Expert Panel will:

- ▶ Analyse the current role of the national pricing and reimbursement authorities to improve access on innovative medicines, focusing on the scope to explore new ways of setting prices for specialty medicines in terms of improving access;
- ▶ Answer the question of how health outcomes can be reflected on price setting, looking in particular to the role of real world data for innovative payment models;
- ▶ Elaborate on a theoretical framework of health system performance assessment in the area of pharmaceuticals.

Opinion on benchmarking access to healthcare in the EU

The recommendation that establishes the European Pillar of Social Right includes a principle on access to good quality preventive and curative healthcare. In order to guide the improvement of access to

healthcare in EU Member States the Expert Panel has been asked to suggest quantitative benchmarks/targets on access to healthcare based on the unmet needs for medical examination indicators; to propose a qualitative benchmark, based on principles and policy levers, and to discuss the possible utilisation of EU funds and/or other mechanisms to support the improvement of access to healthcare.

Opinion on tools and methodologies for assessing the performance of primary care

The third opinion will focus on the primary care sector and evaluate how strong primary care can contribute to consolidating the overall health system's performance. In this regard, the Expert Panel should provide views on dimensions and domains for assessing the performance of primary care and specific existing or new indicators for a better understanding of the performance of primary care.

In addition, it should determine how the analysed indicators are fitted for policy-making and whether they allow the identification of specific levers and policy actions to respond to the highlighted issues. The findings should provide advice for an EU agenda on performance assessment of primary care and will also contribute to the work of the Expert Group on Health Systems Performance Assessment.

PHARMACISTS IN EMERGENCY DEPARTMENTS STUDY PUBLISHED

The Pharmacists in Emergency Departments study analysed the future-enhanced clinical role of pharmacists in England due to the concerns about maintaining appropriate clinical staffing levels in these departments. The findings of the study support the case for extending the clinical role of pharmacists.

The study investigated if emergency department attendees could be clinically managed by pharmacists with or without advanced clinical practice training. Pharmacist data collectors working in 49 sites in England identified patient attendance at their emergency department and recorded anonymised details of 18 613 cases. The findings were each categorised into one of four possible options: cases which could be managed by a community pharmacist; could be managed by a hospital pharmacist independent prescriber; could be managed by a hospital pharmacist independent prescriber with additional clinical training; or medical team only (unsuitable for pharmacists to manage).

Out of the recorded cases, 726 (3.9%) were judged suitable for clinical management by community pharmacists, 719 (3.9%) by pharmacist prescribers, 5202 (27.9%) by pharmacist prescribers with further training, and 11 966 (64.3%) for medical team only. Overall, the study concluded that 36% of emergency department cases could potentially be managed by a pharmacist. General medicine and orthopaedics turned out to be the areas of greatest potential for pharmacist management.

AMR: JOINT INTERAGENCY ANTIMICROBIAL CONSUMPTION AND RESISTANCE ANALYSIS

The second joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of AMR in bacteria from humans and food-producing animals was recently published by the ECDC, the European Food Safety Authority, and the European Medicines Agency.

The report analyses data from 2013 to 2015 which were obtained through five different surveillance/monitoring networks managed by the agencies to collect annual data on the consumption of antimicrobial agents and the occurrence of AMR in bacteria in both humans and food-producing animals in the EU/EEA Member States and in Switzerland. The presented results show that there are still important differences across the EU in the use of antibiotics in animals and humans. The situation varies depending on the country and on the type of antibiotic, but overall the use of antibiotics is higher in food-producing animals than in humans.

The conclusions of the second report are in line with those of the first report published in 2015. However, the increase in the number of countries reporting antimicrobial consumption data in both humans (30, previously 28) and food-producing animals (29, previously 26) allowed for a more sophisticated analysis due to the availability of better quality data.

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