O'Neill report on antimicrobial resistance: funding for antimicrobial specialists should be improved

Richard Price

A landmark report into the global problem of antimicrobial resistance (AMR) has delivered wide ranging advice to international governments and agencies, including the need to improve funding for AMR specialities, such as those within the medical, nursing and pharmacy fields.

The recommendation comes within the long-awaited **O'Neill report** which was commissioned in 2014 by UK Prime Minister David Cameron and the Wellcome Trust and published on 19 May 2016. Economist Jim O'Neill led the compilation of the report.

10 headline recommendations are selected for inclusion in the report's Executive Summary, of which the 7th is 'Improve the numbers, pay and recognition of people working in infectious disease.'

Explaining the rationale for the recommendation, the report states: 'focusing on AMR-related specialties is often less rewarding financially and in terms of prestige than other areas of science and medicine. To change this we need an urgent rethink and improved funding to improve career paths and rewards in these fields.' Other recommendations in the report include:

- ▶ A 'massive' global public awareness campaign

The report suggests this should be in the order of up to 100 m USD a year.

- ▶ Improving hygiene at a global level to prevent the spread of infection

This should include expanding access to clean water and sanitation in parts of the world where this cannot be taken for granted.

- ▶ Reducing unnecessary use of antimicrobials in agriculture

Agricultural practice in the USA is picked out for criticism. Improvement can be achieved by the use of targets, milestones, legal restrictions and greater transparency to consumers about antibiotic use in their meat.

- ▶ Improved global surveillance

The WHO is suggested as best placed to give oversight to such improvement and coordination

- ▶ Rapid diagnostics to reduce unnecessary use of antibiotics

The report suggests a Global Innovation Fund for AMR to support such technological development.

- ▶ Development of vaccines and alternatives

- ▶ The creation of a Global Innovation Fund for AMR

To be endowed with two billion US\$ over 5 years.

- ▶ An improved incentive environment for new antibiotics

The report suggests a system of market entry rewards of around one billion US\$ per drug for effective treatments

- ▶ Leadership by the G20 and UN in delivering an enhanced global response to the AMR threat

Commenting on the O'Neill report, Tajda Miharija Gala, EAHP Vice-President, and spokesperson on AMR issues, commented:

'This report is a very welcome entry to the urgent debate on what more needs to happen at the global level to successfully meet the AMR threat. Many of the recommendations can be wholeheartedly supported by the European Association of Hospital Pharmacists, such as the need to improve funding for antimicrobial specialist pharmacists in hospitals.

As applies to achieving any significant change, if Governments are serious about improving prudent use of antibiotics in the hospital sector, then it is of vital importance that they assign leadership responsibilities. Specialist pharmacists should be key parts of antibiotic stewardship programmes in hospitals across Europe.

I hope forthcoming Council conclusions about antimicrobial resistance, to be formed under the Dutch Presidency of the EU, will reflect seriously on the solid recommendations of the O'Neill report, as well as the input they are receiving from healthcare professional stakeholders.'

NEW RESEARCH COLLABORATION FORMED TO STUDY MEDICINES SHORTAGES IN EUROPE

A new pan-European initiative has been formed to investigate causes, impacts and potential solutions to the shortages of

medicines experienced across all European countries.

Taking place under the long-established European Union (EU) programme **Cooperation in Science and Technology (COST)**, the network of interested researchers and individuals so far spans 20 countries and a multiplicity of professional backgrounds and expertise.

The programme will last for four years and will operate via a series of working groups investigating such issues as the landscape of medicines shortages; manufacturing-related shortages; logistics-related shortages; therapeutic options and substitutions; and the impact of shortages on outcomes.

The Chair of the 'Action' is Professor Helena Jenzer from the Bern University of Applied Sciences, Switzerland, with Dr Roberto Frontini, the immediate past President of EAHP, as deputy chair.

Commenting on the new Action, EAHP Board Member and spokesperson on medicines shortages, Aida Batista remarked:

'On behalf of EAHP, I send my strongest congratulations to Prof Jenzer in bringing together this project on the pressing topic of medicines shortages. With patient care being harmed on a daily basis by supply shortages, this kind of collaboration to shine a light on the causes and available remedies is to be much welcomed. We send our best wishes to the participants and look forward to forthcoming outputs.'

To make sure your country is involved, contact your national COST coordinator.

POLITICAL AGREEMENT ACHIEVED ON FUTURE EU MEDICAL DEVICES REGULATION

It has been announced that after nearly four years of deliberation, political agreement between the European Parliament and EU Governments has been reached on the legal texts of a new medical device regulatory regime for the EU.

The full texts of the agreed regulations had not been released at the time of writing, and will still require confirming votes in both the European Parliament and the structures used by representatives of national Governments. Nonetheless, the announcement of the agreement remains significant given the protracted debate thus far between EU institutions about the detail of the proposals.

One of the major sticking points had been difference of view on the reprocessing of medical devices for single use. Quoted on the website of the Regulatory

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Affairs Professionals Society, Jérôme Unterhuber, spokesman for the Council of the EU (the coordinating body for EU national governments) said:

“The Dutch Presidency of the Council and the representatives of the European Parliament agreed that reprocessing and further use of such devices will only be possible where it is explicitly authorised by national law and will be subject to strict rules ensuring safety. For reprocessed single-use devices all the responsibilities of the original manufacturer go over to the reprocessor. The Parliament had originally asked to allow reprocessing of single-use medical devices unless it is banned by member states.”

Beyond new rules around reprocessing of single use devices, the Regulation also aims to achieve:

- ▶ Additional scrutiny during the conformity assessment procedure for high risk medical devices and in vitro diagnostic medical devices;
- ▶ Strengthening of the clinical data requirements related to medical devices;
- ▶ Strengthening of the designation and monitoring processes governing notified bodies;
- ▶ New classification rules for in vitro diagnostic medical devices;
- ▶ The obligation for manufacturers and authorised representative to have a person responsible for regulatory compliance continuously at their disposal;
- ▶ Authorised representatives to be held legally responsible and liable for defective products placed on the EU market;
- ▶ Increased traceability of medical devices following the introduction of a Unique Device Identification (UDI) system;
- ▶ Increased transparency via the establishment of EUDAMED III with information from several databases concerning economic operators, CE Certificates of Conformity, conformity assessment, clinical investigations, the UDI system, adverse event reporting and market surveillance made available to the public.

EUROPEAN COMMISSION LAUNCH PUBLIC CONSULTATION ON PROFESSIONAL REGULATION

The Directorate General of the European Commission with responsibility for free movement of professionals (DG GROW) has launched a public consultation to seek stakeholder opinions on the proportionality of professional regulation across Europe.

Over the past 2 years, all EU Member States have been encouraged by the European Commission to conduct what is termed ‘mutual evaluation’ as a means of “screening their regulatory arrangements for professions and ensuring that they are ‘proportionate’ to legitimate public interest objectives, without creating unnecessary regulatory burden and labour market restriction.”

18 of the 28 EU countries, plus Norway, have now submitted ‘National Action Plans’ on professional regulation on the basis of this mutual evaluation exercise.

The Commission now seeks to know what stakeholder opinion is on:

- ▶ the specific changes to professional regulation proposed by the Member States;
- ▶ other changes that should be made but which have not been proposed; and,
- ▶ whether the Member States’ review of their professional regulation landscape was ‘sufficiently robust’.

The consultation will remain open until 19th August 2016.

WORLD HEALTH ASSEMBLY AGREES ACTIONS ON MEDICINES SHORTAGES

Delegates to the 69 World Health Assembly have agreed a range of measures aimed at addressing the global shortage of medicines and vaccines, especially for children.

Delegates agreed to develop ways to forecast, avert and reduce shortages. These include notification systems, better ways of monitoring supply and demand, improving financial management of procurement systems to prevent funding shortfalls, and improving affordability through price negotiations and voluntary or compulsory licensing of high-priced medicines.

Other highlights from the World Health Assembly meeting include the adoption of a WHO Framework on Integrated, People-Centred Health Services, which calls for a fundamental shift in the way health services are funded, managed and delivered. Delegates requested WHO to develop indicators to track progress toward integrated people-centred health services.

COMMISSION LAUNCHES FOUR CONSULTATIONS ON APPLICATION OF CLINICAL TRIALS REGULATION

The European Commission has opened four separate public consultations, each examining a distinct issue, or set of issues, related to implementation of EU

Regulation 536/2014 (‘the Clinical Trials Regulation’).

1. Consultation on risk proportionate approaches to clinical trial regulation

The first consultation seeks stakeholder opinions on how best to apply the ‘risk proportionate’ approach to regulation of clinical trials envisaged in Regulation 536/2014.

Regulation 536/2014 provides for less stringent rules or adaptations with regards to monitoring, traceability of the Investigational Medicinal Product (IMP) and content of the Trial Master File (TMF), to those clinical trials which pose only a minimal additional risk to subject safety (as defined in Article 2(3) of the Regulation) compared to normal clinical practice.

The consultation covers such issues as how identification of risk levels should be conducted and the application of risk proportionate approaches to safety report.

The deadline for response is 31 August 2016.

2. Public consultation on ‘Summary of Clinical Trial Results for Laypersons’

A second consultation interrogates the application of Article 37 of the Clinical trial Regulation (EU) No 536/2014 which requires that sponsors provide a summary of clinical trial results in the EU Portal and Database, in a format understandable to laypersons.

The consultation seeks stakeholder opinion on the recommendations formed by an expert group on what primary elements should be covered in a lay summary, and other guidelines such as format, language and a recommended template.

The deadline for response is 31 August 2016.

3. Definition of IMPs and use of Auxiliary Medicinal Products (AMPs)

A third consultation examines the definition of ‘Investigational Medicinal Product’ with a particular focus given to how common understanding about the term and concept of ‘Auxiliary Medicinal Products’ can be established. Different types of AMP are explored, such as rescue medication and challenge agents.

The deadline for response is 31 August 2016.

4. Public consultation on the revision of ‘Ethical Considerations for Clinical Trials on Medicinal products conducted with Minors’

A fourth consultation is now published exploring aspects of change that

Regulation (EU) No 536/2014 ushers in in respect to the participation of children in clinical trials. This includes greater emphasis on understanding informed consent as a continual process, new recommendations in respect to consent in emergency situations and the provision of age appropriate information.

The deadline for response is 31 August 2016.

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