



UEMO

UNION EUROPÉENNE DES MÉDECINS OMNIPRATICIENS/MÉDECINS DE FAMILLE

EUROPEAN UNION OF GENERAL PRACTITIONERS/FAMILY PHYSICIANS

## UEMO BULLETIN N°06 – SEPTEMBER 2017

Dear UEMO Members,

This bulletin is focused on a variety of EU-related health topics including the manufacturing for Medicines, AMR, Biosimilar medicines, Mr Juncker's 2017 State of the Union and many more.

We hope you enjoy reading this issue!

Yours sincerely,

*Aldo L'UPO*

UEMO President

### EU NEWS

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- ❖ INTEGRATE Joint Action – Strategies To Prevent And Treat Hiv, Hepatitis, Tb And Stis In Europe
- ❖ European Leaders Set New Roadmap To Achieve 2030 Agenda And Improve 900 Million People's Health And Well-Being
- ❖ AMR: Time Is Running Out, We Need Action Now
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### UEMO NEWS

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## PATIENT SAFETY: COMMISSION ADOPTS ACTS ON GOOD MANUFACTURING PRACTICES FOR MEDICINES



18<sup>TH</sup> SEPTEMBER

On September 18th, the European Commission adopted two legal acts aimed at improving patient safety in the EU through good manufacturing practices (GMP) that ensure the highest quality of medicines for human use.

The first act is an [implementing directive](#) that sets out principles and guidelines of GMP in medicines where the manufacture or import is subject to a manufacturing authorization: see Article 40 of the Community code Directive (2001/83/EC).

The second act is a [delegated regulation](#) that sets out GMP for investigational medicinal products, as required by the Clinical Trials Regulation (536/2014/EU), and detailed arrangements for inspections. This legal act ensures the highest quality of medicinal products used in clinical trials and prepares the smooth entry into force of this Regulation.

The principles and guidelines for GMP set out in these acts take into account recent updates to the well-established EU rules on the safety of medicines.

Whether a medicinal product is already on the market, or still undergoing a clinical trial, the newly adopted acts aim to ensure the highest level of quality for medicines for the benefit of the patients as well as consistency between the GMP requirements for both types of medicinal products.

### Find out more:

- ❖ [Medicinal products for human use](#)
- ❖ [Clinical Trials Directive](#)

## INTEGRATE JOINT ACTION - STRATEGIES TO PREVENT AND TREAT HIV, HEPATITIS, TB AND STIS IN EUROPE



19<sup>TH</sup> SEPTEMBER

The opening conference of the INTEGRATE Joint Action "From HIV testing and linkage to care to integration of HIV, Hepatitis, TB & STIs" took place on 19 September in Brussels. The meeting examined the results and policy implications of two EU co-financed



projects – OptTEST (Optimising testing and linkage to care for HIV across Europe) and Euro HIV EDAT (Operational knowledge to improve HIV early diagnosis and treatment among vulnerable groups in Europe) and discussed how the INTEGRATE Joint Action can build on the work of these and other relevant EU projects related to HIV, Hepatitis, TB and STIs testing and linkage to care. See programme.

## **INTEGRATE**

INTEGRATE Joint Action is a three year project (2017-2020) receiving 80% co-funding under the third EU Health Programme. It brings together 29 partners from public health institutions, hospitals, NGOs and universities in Croatia, Denmark, Estonia, Greece, Hungary, Ireland, Italy, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia, Spain, UK and Serbia. The main aim of the Joint Action is to integrate early diagnosis and linkage to prevention and care of HIV, viral hepatitis, TB and STIs in EU countries by 2020.

### **OptTEST: main outcomes**

- A standard definition of linkage to care
- Development and testing tools to overcome provider barriers to IC-guided testing
- Evaluation of cost-effectiveness of HIV testing strategies in three pilot countries (France, Estonia, Spain)
- A searchable database showing the most common legal and regulatory barriers

- An advocacy tool kit with tips on how to overcome these and other barriers such as stigma

### **Euro HIV EDAT: main outcomes**

- Operational data and guidelines to scale up testing and linkage to care programmes and improve their effectiveness, including an updated guide helping community-based voluntary counselling and testing (CBVCT) services, improve testing and linkage to care for MSM and migrants
- A Toolkit for the implementation of checkpoints, available in several languages
- An HIV-Testing strategy using oral fluid samples and online communication of test results for MSM and migrants in 6 European countries

### **Find out more:**

- ❖ [The European Commission – HIV-AIDS](#)
- ❖ [INTEGRATE](#)
- ❖ [OptTEST project](#)
- ❖ [Euro HIV EDAT project](#)



**EUROPEAN LEADERS SET NEW  
ROADMAP TO ACHIEVE 2030  
AGENDA AND IMPROVE 900  
MILLION PEOPLE'S HEALTH AND  
WELL-BEING**



07<sup>TH</sup> SEPTEMBER

Health leaders gathered at the annual meeting of the WHO Regional Committee for Europe. In Budapest, Hungary on 11–14 September 2017 they took decisions on health priorities that will have an impact on the health and well-being of about 900 million people in the WHO European Region, including in the European Union, central and eastern Europe, the Caucasus and central Asia.

Life expectancy has reached over 77 years on average across the Region and infant mortality is the lowest ever. However, gaps remain between countries. Life expectancy ranges from over 83 years to 71 years, and infant mortality from as low as 2 per 1000 children born alive to 22.

“As the health status of Europeans is steadily improving, we need to focus on achieving better, more equitable, sustainable health and well-being for each

and every one at all ages. This is what we call universal health coverage and this is what will help us advance the Sustainable Development Agenda for health,” says Dr Zsuzsanna Jakab, WHO Regional Director for Europe. “From now on, governments will be able to use the new European roadmap to implement the 2030 Agenda, building on Health 2020, Europe’s policy framework: this gives us a common direction to better serve all our citizens’ health and well-being.”

**Europe’s progress on Health 2020 promising towards achieving SDGs**

In their second phase of Health 2020 implementation, countries of the Region are making progress in setting up national policies and plans that address its core values. This in turn will provide a stepping stone towards achieving the Sustainable Development Goals (SDGs) in the Region. By 2016:

- 98% of the Region’s 53 countries reported having a policy or strategy to address the reduction of health inequities, an increase of 10% since 2010.
- 93% of countries indicated that they had a national health policy aligned with Health 2020, 35% more than in 2010.
- 86% of countries have implementation plans and 89% accountability mechanisms, both increasing since 2010 – by 40% and 44% respectively.

**Wide-ranging agenda to cover major health challenges and opportunities**



All the priorities of this year's Regional Committee meeting have a bearing on achieving Health 2020 and the SDGs. Topics range from enhancing access to medicines to making the health workforce fit for purpose; from improving emergency preparedness and response to working together for health and reducing the death toll from polluted environments.

### **Leaving no one behind by expanding access to medicines**

Medicines are the main contributor to out-of-pocket health payments in the Region. For the most vulnerable, life-saving drugs may be impossible to afford, especially long-term treatments for noncommunicable diseases. In several economies in transition, a 1-month hypertension course can cost up to a month's wages, mostly paid out of pocket.

The latest data for the Region shows considerable variation in pharmaceutical spending between countries, ranging from less than 10% of total health care expenditure in northern Europe, to more than 30% in central Europe and central Asia. The Regional Committee will consider a document on improving affordable access to effective, high-quality and safe medicines, lower medicine prices and improved procurement processes.

### **Transforming Europe's health workforce**

The sustainable health workforce framework for action, expected to be adopted at the Regional Committee

meeting, aims at enabling European countries to transform their workforce sustainably. One of the main challenges is making sure that the right people with the right skills are in the right place in the right numbers for an effective health system. With the new framework for action, countries are called to improve workforce planning and retention of health workers; high-income countries are discouraged from actively recruiting health workers from lower-income countries.

### **Celebrating the 10th anniversary of the International Health Regulations (IHR)**

In the past 10 years, the world has faced a number of global health emergencies with repercussions for the Region: Ebola, Middle East respiratory syndrome coronavirus, poliovirus, yellow fever, Zika virus and others. The IHR have improved information flow from one country to another, enabled more timely interventions, improved international collaboration and reduced interference with travel and trade.

#### **Find out more:**

- ❖ [More information about WHO Europe activities](#)





## AMR: TIME IS RUNNING OUT, WE NEED ACTION NOW



27<sup>TH</sup> SEPTEMBER

The shocking statistic that 44% of the general population across Europe still does not know that antibiotics are ineffective against the common cold virus brings into sharp focus the enormous challenge that antimicrobial resistance (AMR) presents.

AMR is one of the biggest threats to modern medicine and the global economy, yet millions of people are unaware of its potentially catastrophic implications.

In his Review on Antimicrobial Resistance published in May 2016, economist Lord Jim O'Neill warned that by 2050 AMR could lead to 10 million deaths a year and a 2–3.5% reduction in gross domestic product (GDP), which would ultimately result in a £100trillion cost to the global economy. According to the World Bank, unless adequate collective action is taken, the annual costs of AMR could be as large as those of the global financial crisis that started in 2008.

These stark warnings have led to unprecedented political commitment on a global scale and impressive projects are now underway or being planned. These include consumption surveillance programmes; infection prevention and control initiatives; partnerships with veterinary associations to promote a One

Health approach (a concept that recognises that the health of humans, animals and ecosystems are interconnected), and numerous projects to develop antibiotics, vaccines or alternative treatments.

But despite this, up to 50% of all antibiotics currently prescribed globally are unnecessary. Too many patients, unaware of the looming crisis, still feel their illness is somehow validated if they are prescribed an antibiotic, whether they need it or not. Urgent action is required to fundamentally change this mindset, and time is running out.

In its National Action Plan on AMR, the World Health Organization (WHO) identified five strategic objectives.

- Improve awareness and understanding;
- Strengthen knowledge through surveillance and research;
- Reduce incidence of infection;
- Optimise use of antimicrobial medicines;
- Ensure sustainable investment for R&D and implementation of control measures.

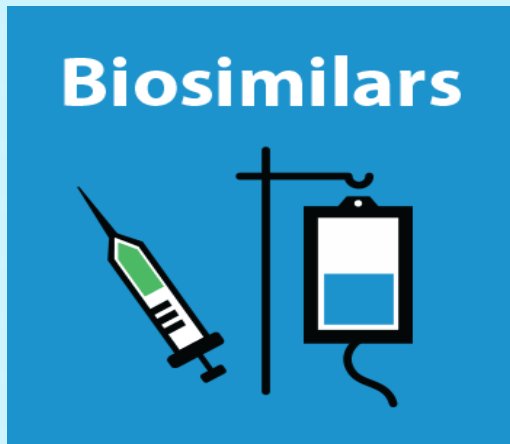
Much effort is underway across Europe. The European Medicines Agency (EMA) has joined forces with the European Centre for Disease Prevention (ECDC) and the European Food Safety Authority (EFSA) in a bid to make the EU a best practice region in the fight against AMR through research, development and innovation.

### Find out more:

- ❖ [Antimicrobial Resistance – Summary. April 2016](#)



## BIOSIMILARS: A SIMILAR FRONTIER



27<sup>TH</sup> SEPTEMBER

Biologics, drug products made from living organisms, have revolutionized the treatment of life-threatening illnesses and chronic diseases, including cancer, rheumatoid arthritis, diabetes, and autoimmune disorders. The market for biologics continues to increase and is expected to reach \$390 billion by 2020 and represent 28% of the value of the world's pharmaceutical products. In 2014, 10 of the top 25 drugs in the United States were biologics. Biologics play a significant role in patient care, but because of the high cost of these medications, they may be inaccessible to patients and increase health care costs.

The emergence of biosimilars (a biological product that is highly similar to the reference product and only has minor differences in clinically inactive compounds, and no meaningful differences in terms of safety, purity, and potency from the reference product) into the EU market gives clinicians more affordable options that are safe and effective.

### PHARMACOLOGY

For a product to gain approval as a biosimilar, a manufacturer must be able to

show the pharmacokinetic (PK) and pharmacodynamic (PD) similarities and differences between the proposed biosimilar product and the reference product. Through comparative, head-to-head studies with the reference product, the manufacturer also must demonstrate that small changes to the biosimilar do not affect its profile or immunogenicity.

Biologics and biosimilars are made from living organisms such as bacteria, yeast, and mammalian cells, rather than from the simpler atomic units of small molecule generics, and as a result they are not as easy to copy and will have a degree of microheterogeneity. The large size and complexity of the molecules and the inherent variability of the manufacturing process make it difficult to be identical to the reference product.

### PLACE OF BIOSIMILARS IN THERAPY

Biosimilars afford clinicians the potential to provide cost-saving alternatives for life-changing medications and managing chronic diseases.

Pharmacists can play a critical role in supporting the use of biosimilars in health systems by interpreting data; navigating pharmaceutical contracts; and educating patients, physicians, and other health care professionals.

Postmarketing pharmacovigilance is critical to the overall acceptance of biosimilars. Health systems must ensure that appropriate mechanisms are in place to track the unique adverse events associated with biosimilars.

### Find out more:

- ❖ [Biosimilars in the EU, information for healthcare professionals.](#)



## STATE OF THE UNION: THE FUTURE OF HEALTH IN EUROPE



13<sup>TH</sup> SEPTEMBER

In his State of the Union address 2017, European Commission President Jean-Claude Juncker presented his vision stating that the wind is back in Europe's sails. By stressing that Europe must be a Union of equality, he sent a strong message about equity as a fundamental basis of a Union of values. His statement reinforces the need for more EU engagement in the field of health.

In line with the five proposed scenarios for the Future of Europe, President Juncker made a bold suggestion for his own sixth scenario. This included institutional reforms without Treaty changes such as a combined European Commission and European Council President; a Commission Vice-President for economy and finance, using qualified majority voting instead of unanimity in tricky areas including tax and social policy; and transnational voting lists for European Parliament elections. This year's address offered a detailed policy blueprint for his final two years in office, in which he clearly hopes to shape his legacy.

**Will the Commission re-chart the course to reduce health inequalities?**

First and foremost, President Juncker acknowledged that the European Union should be based on equity, which is the cornerstone of any EU action addressing inequalities. He referred to the need to strengthen the social dimension of Europe, urging national governments to adopt the Commission's proposal on the European Pillar of Social Rights before the end of 2017. More specifically on health, he highlighted the added value of EU action on vaccination, where better European cooperation could prevent avoidable deaths from measles:

“In a Union of equals, there can be no second-class citizens. It is unacceptable that in 2017 there are still children dying of diseases that should long have been eradicated in Europe. Children in Romania or Italy must have the same access to measles vaccines as other children right across Europe. No ifs, no buts. This is why we are working with all Member States to support national vaccination efforts. Avoidable deaths must not occur in Europe.”

These concerns were highlighted in the political debate following the speech, with MEP Philipp Lambert, co-chair of the Greens, emphasising that social, environmental and health standards should be upheld in the future EU Trade policy. EPP member Andrey Kovatchev stressed the need to maintain EU protection in the area of public health, echoing a statement signed by more than 70 MEPs from all the major political groups, calling for continued EU health action and enhanced cooperation between EU Member States. A call to the European Commission to step up coordinated EU action to tackle cross-border health challenges has now gathered support from over 200 organisations as part of the current EU:





Do More for Health campaign. This health call fits into the alternative, civil society 6th scenario, developed by almost 300 non-government organisations.

With 70% of Europeans wanting the EU do more on health in a recent Eurobarometer survey, what better way is there to answer the almost constant call to 'bring Europe closer to its citizens' than by making it more relevant to their daily lives? President Juncker's positive appreciation for Europe's role in protecting health in his State of the Union address is the start of the development of a more positive vision, assuring the Commission's co-ordinating role and paving the way for future action on health at European level.

#### Find out more:

- ❖ Join the campaign calling on the EU to do more for health [here](#).

### RECOMMENDATIONS FROM EUROPEAN BREAST GUIDELINES



European women's probability of developing breast cancer over a lifetime is approximately 1 in 8\*. A woman's individual risk of breast cancer may be

higher or lower than this average, depending on a number of factors, including age, family history, reproductive history (such as menstrual and childbearing history), race/ethnicity, and others.

The ECIBC is developing recommendations for breast cancer screening and diagnosis. Over the course of the next two years, approximately 90 evidenced-based recommendations regarding screening and diagnosis will be developed and published on this site as they become available. Supplemental recommendations will be developed and updated as new evidence and priorities emerge. Future recommendations will cover other aspects of breast cancer.

Each recommendation is specifically tailored to the needs of citizens and patients, health professionals, and policy makers. All recommendations are based on the female population at 'average' and 'below average' risk of developing breast cancer.

#### Find out more:

- ❖ [issue recommendations as a healthcare professional](#)



## UEMO NEWS

### EUNETHTA JA<sub>3</sub> ASSEMBLY & FORUM IN AMSTERDAM



13-14<sup>TH</sup> SEPTEMBER

The EUnetHTA Forum provides a framework for updates and decisions relevant to the Consortium and a platform for networking, regular network-wide scientific discussions and exchange of experience. The Forum consists of the EUnetHTA Consortium Partners, Collaborating Stakeholders (as per definition provided in the guide for applicants for the Joint Action) and other organisations concretely involved in the activities of EUnetHTA JA<sub>3</sub>.

Daniel Widmer (UEMO) represented the Health Care Providers group on a presentation: “Stakeholder involvements to date in EUnetHTA JA<sub>3</sub>” and as part of the panel on further development of stakeholder involvement with all four pillars

#### Find out more:

- ❖ [Short presentation video of the event](#)
- ❖ [Event's leaflet](#)

### EFPC CONFERENCE IN PORTO



24-26<sup>th</sup> SEPTEMBER

The 2017 European Forum for Primary Care (EFPC) conference took place in Porto from 24 to 26 September with the title: The Citizen Voice in Primary Care; a social commitment to 'health for all'!

The main topic of the conference was: how to make sure that care at community level will be provided in close collaboration with citizens and communities.

D. Widmer (UEMO) represented the HTAN Healthcare Provider Pillar of the HTAN Stakeholder Pool. He presented the role & mandates (DG Sanco, EUnetHTA, Member-States), mapping current status and future steps. He also discussed cross-pillar communication, interactions and topics of interest.

#### Find out more:

- ❖ More about the [EFPC](#).



## UEMO AT SMART-2017 IN BARCELONA



21st OCTOBER

The “SMART-2017” Project is the third edition of a pan-European study sponsored by the European Commission under the title “Benchmarking Deployment of eHealth among General Practitioners 2017”. The main purpose of this study is comparing the results with the previous waves on the level of adoption and implementation of health applications, networks and services by GPs, through a survey of GPs focused on the use of ICT and eHealth applications in their day-to-day work. The purpose of the meeting was mainly to define the process for the data collection as well as the UEMO’s role in the survey. The UEMO was represented by Marie-Christine Bonnamour.

## UEMO 50<sup>TH</sup> ANNIVERSARY CELEBRATION FALL GENERAL ASSEMBLY 2017



26-28 OCTOBER

We are pleased to announce that the Fall UEMO General Assembly will take place in Paris, France on 26th – 28th October 2017. Furthermore, on 26 October the UEMO will celebrate its 50<sup>th</sup> anniversary!

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