Europe paying a heavy price for chronic diseases, finds new OECD-European Commission report

Richard Price

A new joint report from the European Commission and the Organisation for Economic Co-operation and Development (OECD) estimates that the premature deaths of 550 000 working-age people across European Union countries from chronic diseases, including heart attacks, strokes, diabetes and cancer, cost EU economies EUR 115 billion or 0.8% of GDP annually. This figure does not include the additional loss in terms of lower employment rates and productivity of people living with chronic health problems.

The report, entitled 'Health at a Glance', also explains that while earlier diagnosis and better treatments have substantially increased the share of people surviving these diseases, many countries – including the United Kingdom, Ireland and especially some Central and Eastern European countries – lag behind in terms of cancer survival rates.

'Many more lives could be saved if standards of care are raised to the best level across EU countries', said OECD Secretary-General Angel Gurría, launching the report in Brussels with European Commissioner for Health and Food Safety Vytenis Andriukaitis. 'More needs to be done to reduce inequalities in access and quality of care, and European health systems must become more efficient in channelling resources where they have the most impact on health outcomes, including on prevention'.

Health at a Glance: Europe 2016 shows slow growth in health spending in many EU countries in 2015, collectively accounting for 9.9% of EU GDP. Germany, Sweden and France each spent around 11% of GDP on health care, closely followed by the Netherlands and Denmark (at 10.8% and 10.6%, respectively). Countries in the Eastern part of the EU tend to spend much less, with shares ranging from 5% to 6% of GDP.

In all countries, the health spending share of GDP is projected to increase in the coming years due mainly to population

ageing and the diffusion of new diagnostic and therapeutic technologies.

ECDC REPORT THAT 1 IN 7 PEOPLE LIVING WITH HIV IN THE EU/EEA ARE NOT AWARE OF THEIR HIV STATUS

Almost 30 000 newly diagnosed HIV infections were reported by the 31 European Union and European Economic Area (EU/EEA) countries in 2015, according to data published this week by the European Centre for Disease Prevention and Control (ECDC) and the WHO Regional Office for Europe. ECDC further estimates that currently around 122 000 people living with HIV across the region are unaware of their infection. The estimated time between HIV infection and diagnosis is four years.

European Commissioner for Health and Food Safety, Vytenis Andriukaitis, said: *'HIV/AIDS continues to be a serious problem in Europe. The Commission is committed to helping Member States reach the Sustainable Development Goal target of ending HIV/AIDS and Tuberculosis by 2030 and reducing Hepatitis. ECDC's estimate that one in seven people living with HIV are unaware of their status is particularly worrying: people who do not know they are infected cannot benefit from life-saving treatment, and can continue to transmit the virus to others. This is why easy and accessible testing is so important. The European Commission supports HIV testing by working together with Member States and civil society on joint projects, funded by the EU Health Programme, on prevention and linkage to care'.*

'The facts we know about the HIV epidemic in the EU/EEA, are based on the number of new diagnoses reported each year, which represents the cornerstone of European HIV surveillance', explains ECDC Acting Director Andrea Ammon. 'But we also know that these figures do not reflect the true picture. ECDC estimates that currently around 122 000 people in the EU/EEA are infected with HIV but are not aware of their infection – that is every 1 in 7 people living with HIV in the region'.

AUTHORS OF PLOS ONE STUDY SUGGEST CURRENT ORPHAN DRUG LEGISLATION MAY BE SKEWING MEDICINE RESEARCH PRIORITIES TOO FAR

A recent study by two UK academics suggests that orphan medicine regulation, in place across the EU and more globally, designed to incentivise investment in treatments for rare diseases, could be making orphan products so profitable that investment in broader indications is being stifled. The study comes at a time when the European Commission has been considering stakeholder views on potential revisions to the orphan medicine regulatory framework.

According to the authors' analysis of 83 publicly quoted companies, which together market nearly 200 orphan drugs, compared with control companies matched by size, country and R&D investment, orphan drugs companies are five times more profitable and have a 10 percent to 15 percent higher market valuation.

All of the world's 10 most expensive medicines have orphan status, with Alexion Pharmaceuticals Inc.'s Soliris (eculizumab), for treating atypical hemolytic uremic syndrome and paroxysmal nocturnal hemoglobinuria, heading the list, at more than \$400 000 per year.

'Although these (10 drugs) are prescribed to fewer patients, their high prices can result in revenues equivalent to traditional blockbusters', said Dyfrig Hughes, professor of pharmacoeconomics, and co-director of the Centre for Health Economics & Medicines Evaluation at Bangor University, Wales.

Almost one-third of drugs approved for rare diseases now exceed \$1 billion in annual sales. The global orphan drugs market is expected to reach \$176 billion by 2020, accounting for 19 percent of prescription drug sales. The European Medicines Agency (EMA) has authorised 123 orphan drugs since EU legislation was enacted in 2000.

For Hughes, who has acted as an external expert for the EMA's Committee of Orphan Medicinal Products, incentives have tipped the balance, allowing companies to make excessive profits. *'This may have had the adverse and unintended consequence of directing R&D resources away from other areas of unmet clinical need, such as antibiotics', he said.*

MEPS SEEK IMPROVEMENTS TO EU PAEDIATRIC MEDICINES REGULATION

A group of Members of the European Parliament (MEPs) are seeking to influence the European Commission's current considerations on whether to revise the

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EU's regulation on Paediatric medicine development with a set of their own suggestions for improvement.

The group of 7 MEPs includes the Chair of the European Parliament's Health Committee, Giovanni La Via (European Peoples Party, Italy), and representatives of other political groupings in the Parliament.

They consider that while the EU's 2007 Paediatric Regulation has boosted research into childhood medicine, there is still scope for further improvements. The benefits they note the Regulation as achieving include:

- ▶ Obliging companies to conduct a Paediatric Investigation Plan (PIP) for each new molecule they want to market;
- ▶ Improving the level of information available on the paediatric use of approved medicines; and,
- ▶ Increasing the relative number of paediatric clinical trials.

However, the MEPs express hope that more may yet be achieved via amendments to regulation to improve the research landscape for paediatric oncology and neonatology. Supporting their view, they cite the fact that childhood cancer remains the first cause of death by disease in children aged one year and over and 6000 young people die of cancer each year in Europe.

Among the barriers in this respect, include the suggestion that for those cancers that only occur in children, little financial incentive exists for the pharmaceutical industry to bring new treatments to market. The MEPs also consider that the Regulation's obligations on companies to conduct paediatric medicine development should be based on a drug's mechanism of action matched to a tumour's biology rather than on indication limiting the drug's use to a specific type of cancer.

The MEPs tabled a resolution to this effect, to be voted on by a full plenary meeting of the European Parliament. The resolution attracted over 80 proposed amendments, including one calling for the Paediatric Regulation to be amended to ensure *'that promising trials in the paediatric population cannot be terminated early due to disappointing results in the target adult population'* tabled by MEPs Dame Glenis Willmott (UK, Socialist & Democrat Group) and Elena Gentile (Italy, Socialist & Democrat Group).

EDQM OPEN CONSULTATION ON AUTOMATED DOSE DISPENSING GUIDELINES

The European Directorate for the Quality of Medicines and Healthcare (EDQM) has opened a consultation on prospective

European guidelines on Automated Dose Dispensing. The consultation will close on the 24th February 2017.

The purpose of the guidelines is to harmonise the standards and approaches to automated dose dispensing across Europe, to help ensure that this service is provided to a consistently high standard which ensures the safe supply of medicines to patients. The guidelines are intended to be utilised by pharmacies and manufacturers involved in automated dose dispensing, as well as by national authorities in countries where this service is provided.

Commenting on the consultation, Aida Batista, EAHP Director of Professional Development and Patient Safety policy lead, remarked: *'Automatic Dose Dispensing can be a powerful tool for patient safety as well as medication adherence. However, there are common challenges to be met in respect to its introduction and use. Therefore, EDQM's initiative to produce guidelines to help ensure this service is provided to a consistently high standard across Europe, is to be welcomed. EAHP encourages engagement by hospital pharmacy in the EDQM project and will be making its own response to the survey'*.

EUROPEAN COMMISSION OPEN CONSULTATION ON AN EU ACTION PLAN TO TACKLE ANTIMICROBIAL RESISTANCE

Ahead of launching a new 5-year action plan to tackle Antimicrobial Resistance (AMR) the European Commission has opened a consultation to collect stakeholders' perceptions on a range of available actions. The consultation is open to all citizens and will close on 28th April 2017.

Three new positions published on hot topic of biosimilar interchangeability

The European Society for Medical Oncology (ESMO), the USA's Food and Drug Administration (FDA) and a collection of scientists from national medicines regulators have each made new and important interventions to current debates about biosimilar interchangeability. The public positioning comes as an increasing number of biosimilar products coming to market in an environment where cost pressures highlight the need to use less expensive medicinal products where this can be done without detriment to patient treatment or safety.

In the case of small and large chemical medicines, moving patients to cheaper generic versions of the originator product has been a long-standing and successful means to reduce a health system's medicines bills. In the case of biologic medicines

however, the level to which a reference product and a biosimilar product can be considered interchangeable is sometimes made subject of debate. Because of this, healthcare professional organisations and regulators are increasingly making known their positions on the matter.

The USA's medicines regulator, the FDA, opened the new year by publishing long-awaited draft guidelines on the interchangeability of a biosimilar with its reference product. The draft guidelines call for developers of biosimilars to produce a switching study (or studies) to demonstrate that the risk in terms of safety or diminished efficacy between a biosimilar and its reference product is not greater than the risk of using the reference product without such switch. In short, an interchangeable product is expected to produce the same clinical result as the reference product in any given patient. Achieving the status of 'interchangeable' is especially important in the USA as only such designated biosimilars can then be substituted for the reference product by a pharmacist without the intervention of a health care provider.

The FDA consultation is open for comments by interested parties until the 20th March 2017.

Meanwhile, the ESMO has made an intervention into the current discussions on biosimilar interchangeability and substitution by publishing a formal position paper. The paper embraces the opportunity biosimilars provide in keeping medicines costs sustainable for health systems, but also strongly emphasises the need for physicians to retain authority in respect to any switch of a patient between reference and biosimilar product, or between different biosimilars.

The ESMO position paper states: *'Automatic substitution, which might be practice for generics, should... be avoided in the field of biosimilars. Interchangeability and switching should only be permitted if: (1) the physician is well-informed about the products; (2) the patient is fully briefed by the physician and (3) a nurse is closely monitoring the changes and tracking any adverse events'*.

Also entering the debate, a collection of authors drawn from the European medicines regulatory community have recently published a paper in the Journal BioDrugs with the statement: *'Our conclusion is that a switch between comparable versions of the same active substance approved in accordance with EU legislation is not expected to trigger or enhance immunogenicity. On the basis of current knowledge, it is unlikely and very difficult to substantiate that two products, comparable on*

a population level, would have different safety or efficacy in individual patients on a switch. Our conclusion is that biosimilars licensed in the EU are interchangeable’.

The authors are drawn from regulatory agencies in Finland, the Netherlands, Germany and Norway.

Finally, the European Commission continue to follow matters closely, and to assist national discussions has published a ‘Q&A’ document about biosimilars in seven different languages. Entitled ‘*What I need to know about Biosimilar Medicines - Information for patients*’, the document seeks to explain in simple language such issues as extrapolation and provide links to reputable sources of further information. The published languages are English, German, French, Spanish, Portuguese, Italian and Polish.

FIP publication: Strategies for medicines information should be included in national medicines policies

A new publication by the International Pharmaceutical Federation (FIP) has set out an agenda for improving the provision of medicines information internationally. *Medicines information: Strategic development* sets out a vision for collaboration and action towards ensuring high quality medicines information around the world, through the use of specific recommended strategies.

The document also:

- highlights the dangers of scenarios where medicines information systems tolerate inaccuracy, or become overwhelming, biased, unhelpful or simply not well understood;
- conveys key goals of goals for the strategic development of medicines information as including medication

safety and pharmacovigilance, rational prescribing and dispensing, and health literacy;

- provides case studies of national medicines information strategies in countries such as the United States, United Kingdom and Finland

OECD make intervention to international debate about medicines prices

The OECD has published a report raising concern at the pressures being placed on public health spending as a result of rising prices for medicines. The report draws particular attention to the struggle payers face in meeting the high cost of medicines that are targeted to very small populations, a trend likely to be exacerbated by the growth of ‘personalised’ or ‘precision’ medicine.

The report ‘New Health Technologies: Managing Access, Value and Sustainability’ also singles out a simultaneous problem, in respect to new treatments for wide populations, such as for hepatitis, which might be very effective, but remain unaffordable to many who would benefit in almost all OECD countries because of their high budget impact.

The report therefore recommends that the prices paid for technologies ‘*must reflect their real-world health benefits compared with alternatives, and be adjusted based on evidence about their actual impact.*’ Seeking important changes to existing procedures, the OECD suggest that payers must be equipped with the necessary powers to adjust prices and withdraw payment for ineffective technologies.

In order to achieve a necessary re-balancing of power between payers and manufacturers, the report authors recommend heightened transparency and co-operation between payers and international

joint procurement initiatives, as tested in Europe and Latin America. Pricing agreements, which link the final price paid to the actual performance of the drug, as used in Italy and England, may also be effective if management and administration costs are controlled and the clinical data and evidence collected made widely available to the scientific community.

Finally, the report also evidences the causes of concern from the trend of many biomedical technologies being approved and adopted based on limited evidence of their safety and effectiveness. The report finds assessment of their performance in real world conditions to be rare which ‘compromises safety, is wasteful and no longer sustainable.’

Therefore the report recommends greater efforts to ‘harness the potential of health data more effectively. Use of personal health data creates major opportunities for health system improvement, research and disease surveillance, but requires the right governance frameworks

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to realise these benefits while managing the privacy risks.’

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