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Please note that the next EU monitor will be released at the end of September 2010

I. EMA summonsed by European Ombudsman to provide documents on anti-obesity medicines

Source: EurActiv



The EU's medicines regulator is under fire from the European Ombudsman for refusing to grant Danish researchers access to documents on two anti-obesity drugs so they can conduct independent analysis.

Researchers claim studies supporting some medicines is biased and want to validate the evidence behind the weight-loss drugs.

However, the European Medicines Agency (EMA) says the files are commercially sensitive and must remain confidential.

The Ombudsman, P. Nikiforos Diamandouros, has called on the EMA to grant access to clinical study reports and trial protocols, dismissing the agency's argument that drugmakers' commercial interests should be prioritised.

The Danish scientists at the centre of the complaint, which began in October 2007, said patients' welfare should trump concern for the commercial interests of the pharmaceutical industry.

During his investigation, the Ombudsman inspected the relevant reports and protocols and concluded that the documents did not contain information on the composition of the anti-obesity medicines, nor did they contain other commercially confidential information. In his view, their disclosure would consequently not undermine commercial interests.

The Ombudsman criticised the EMA's refusal to grant access to the reports as an instance of "maladministration" and called on the agency to disclose the documents or provide a convincing explanation as to why access cannot be given. The EMA must reply by 31 August 2010.

Obesity drugs are a source of considerable controversy, with a number of leading medicines taken off the market amid safety concerns. Acomplia has been linked to psychiatric disorders, while sibutramine was suspended due to apparent connections with increased risk of heart attacks and strokes.

Neither the EMA nor the Ombudsman specified which anti-obesity drugs the current transparency case relates to.

This is not the first case against the medicines regulator to hit the headlines this year, despite the agency's public campaign to put transparency at the heart of its work.

The EMA came under pressure last month in a separate case relating to controversial acne medication. An Irish citizen had requested access to reports linking the drug to suicidal tendencies but the EMA refused, saying EU transparency rules do not apply to adverse reactions to medicines.

The Ombudsman disagreed, saying the medicines agency's work has a direct impact on the health of citizens and it should give the widest possible access to documents when requested.

The EMA has until 31 July to respond to the criticism arising from the acne drug controversy. In an initial response, the agency said it had launched a range of transparency initiatives and public consultations since the original complaint in 2008.

II. OECD Health Data 2010 report shows growth in health spending

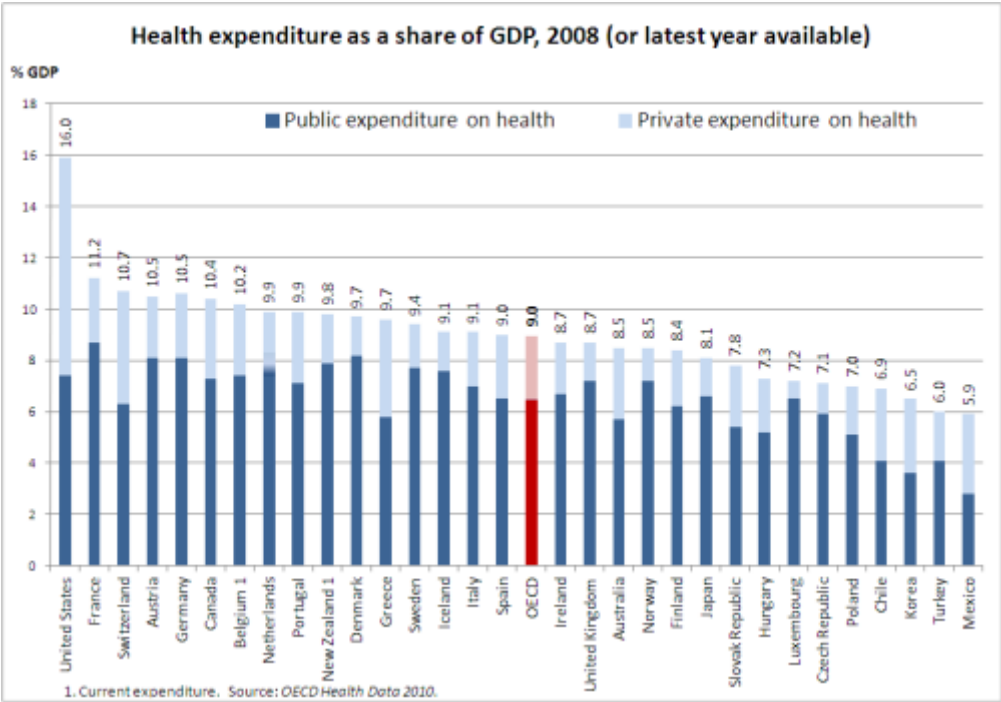
Source: OECD



In a report released on 29 June 2010 the Organisation for Economic Co-operation and Development (OECD) showed that total spending on healthcare in OECD countries has been rising faster than economic growth. The average spend on health as a percentage of GDP rose from

7.8% in 2000 to 9.0% in 2008. Factors pushing health spending up - technological change, rising expectations and population ageing - will continue to drive costs higher in the future.

In some countries the recent economic downturn, with GDP falling and healthcare costs rising, led to a sharp increase in the ratio of health spending to GDP. In Ireland, the percentage of GDP devoted to health increased from 7.5% in 2007 to 8.7% in 2008. In Spain, it rose from 8.4% to 9.0%.



The United States spent \$7,538 per person on health in 2008, well over double the \$3,000 average of all OECD countries. The next biggest spenders, France and Switzerland, spent much less than the U.S. per capita but still some 50% more than the OECD average.

Governments of most OECD countries shoulder the lion’s share of healthcare costs. The share of government expenditure devoted to health increased in most countries, rising from an average of 12% in 1990 to an all-time high of 16% in 2008. Given the urgent need to reduce their budget deficits, many OECD governments will have to make difficult choices to sustain their healthcare systems: curb the growth of public spending on health, cut spending in other areas, or raise taxes.

New medical technologies are improving diagnosis and treatment but they also increase health spending. **OECD Health Data 2010** shows that there has been rapid growth in the supply and use of computed tomography (CT) scanners and magnetic resonance imaging (MRI) units used for diagnostic purposes. MRI units per capita more than doubled on average across OECD countries between 2000 and 2008, reaching 13 machines per million population in 2008, up from 6 in 2000. The number of CT scanners rose to 24 per million population, up from 19 in 2000. The number of MRI units per capita is much greater in Japan, the United States, Italy and Greece than in other countries. These countries, along with Australia and Korea, also have more CT scanners.

MRI and CT scanners are expensive to buy and to operate. There are big differences in their use per capita - far more in the United States than in Canada, France or the Netherlands. The rapid growth in these diagnostic procedures over the past decade in the United States has raised concerns that some imaging may not be useful. To reduce unnecessary procedures and cut costs, many OECD countries are trying to promote rational use of costly medical technologies.

These are some of the findings from OECD Health Data 2010, a comprehensive source of comparable statistics on health and health systems across the 31 OECD countries (including Chile as a new member this year) and 3 prospective members (Estonia, Israel and Slovenia).

OECD Health Data 2010 is available **online** to subscribers of SourceOECD, the OECD online library.

III. **Shortcut to eye treatment in the UK: EMA wants the EU to intervene**

Source: EuropeanVoice



A UK bid to cut its drugs spending has alarmed Europe's most senior medicines official, who believes that the European Commission should intervene.

Thomas Lönngren, the executive director of the European Medicines Agency (EMA), said on 26 June 2010 he is concerned at the possibility that the UK will encourage the use of a bowel-cancer medicine to treat degeneration of the eye.

The medicine, Avastin, has not gone through the rigorous testing procedure required for licensed use in ophthalmology, but the UK is now assessing whether it could be an adequate, cost-effective alternative to the much more expensive standard eye treatment.

Lönngren, whose agency has a key role in ensuring that medicines prescribed in the EU have been adequately tested, says he is "unhappy" with the possibility of such "off-label" use. For a Member State to encourage the use of a pharmaceutical for an indication for which it is not licensed would be a breach of EU legislation, he said.

As Member States struggle to limit their healthcare spending – in the face of ever-tighter budgets and ever-growing demand – they are increasingly keeping expensive new medicines off the market, or insisting on price cuts. They frequently justify their decisions through the emerging discipline of 'health-technology assessment', which incorporates non-medical considerations into appraisals.

But Lönngren said that if a medicine has been approved through the EU's authorisation procedures, it is fit for purpose.

He believes that if there are problems at Member State level, they should be tackled by the European Commission.

Christina Fasser of Retina International, which represents eye patients, also expressed concern at treatment by an off-label drug in some EU countries in an effort to reduce costs, “despite the availability of a drug that has undergone scrupulous testing”. She said that patient groups in the EU “are concerned that, in times of economic pressure, patient safety may be compromised.”

The European Patients' Forum also insisted that assessments of health technology “cannot be used as a pretext for tough decisions if public confidence is to be maintained” and called for involvement of patients and their organisations in these processes – which, it said, “is not yet happening in many EU countries”.

IV. Pfizer sanctioned for failing to report adverse drug reactions

Source: Reuters



The U.S. Food and Drug Administration warned Pfizer Inc on 10 June 2010 for failing to quickly report serious and unexpected potential side effects from its drugs already on the market.

In a 12-page warning letter to Pfizer Chief Executive Jeffrey Kindler, the FDA cited numerous examples involving some of the company's top-known brands, including impotence drug Viagra, cholesterol pill Lipitor and seizure medicine Lyrica.

The delays in reporting side effects date back as far as 2004 and have grown in recent years, according to the FDA's letter that was released by Pfizer on 10 June 2010.

Ronald Pace, director of the FDA's New York office, told Pfizer in the letter dated May 26 that it had not properly documented or investigated reported problems in patients after the drugs were approved for use.

"FDA expects drug manufacturers to establish and implement reasonable mechanisms to assure that all serious and unexpected experiences are promptly recorded and investigated," Pace wrote.

Pace asked Kindler to arrange a meeting between the company and the agency over the violations. Pfizer said it received the letter June 3.

The FDA conducted a 6-week inspection of Pfizer's New York headquarters in July and August of 2009, where agency inspectors found system-wide lapses at the world's largest drugmaker.

The patient reports "contained serious and unexpected adverse events... that were not submitted until they were identified during the FDA inspection," Pace wrote. Efforts to fix the problem "have been shown to be ineffective," he added.

In a statement, Pfizer said it would work with the FDA to satisfy the agency "and to assure optimal surveillance and reporting of post-marketing adverse events."

But it also said that such individual reports are just one part of its overall monitoring of the drugs it sells and that it "believes we provide complete and accurate data to determine the benefit and risk profile for all of our medicines, and to enable their safe and appropriate use."

In its letter, the FDA cited multiple examples of reporting lapses.

For example, while Viagra and similar medications are known to cause serious visual problems, including blindness, Pfizer failed to report cases related to its drug within the agency's 15-day deadline "by misclassifying and/or downgrading reports to non-serious without reasonable justification."

And with Pfizer's now withdrawn painkiller Bextra, FDA granted the company a waiver allowing 60 days to forward any complaints, a window of time the drugmaker still missed.

The FDA said Pfizer initially blamed the problems on a new computerized system to handle the reports, saying staff were not properly trained. In a September 2009 response to the agency, Pfizer told the agency it would update user manuals, better train its staff in the computerized reporting system and take other action.

Despite those steps, the FDA said in its letter that the company's actions were "inadequate."

Pfizer told the FDA that its reporting improved after May 2009, but did not include any data backing up that claim, the FDA said. Additionally, the company did not prove to the FDA that it trained all the employees it said it would.

According to the FDA, the company's delays in telling the agency about reported complaints have only grown. About 4 percent of Pfizer's 80,560 reports were sent late from March 2006 through December 2008 compared with 9 percent from December 2008 to June 2009, the letter said.

Additionally, the FDA stated that Pfizer did not immediately tell the FDA about thefts and significant losses of its medications. FDA's Pace requested an immediate meeting and asked for the problems to be fixed within 15 days, or an explanation provided if it would take longer. He also called for Pfizer to submit a revised plan to fix the problems. Failure to fix the problems could result in legal action without notice and the FDA could delay action in approving the company's pending drugs, among other penalties, Pace said in the letter.

V. **Priorities of the Belgian Presidency**

Source: Belgian government



Under the Belgian Presidency, the Council will enter into policy discussions on the way in which Member States and the Commission together manage public health risks, in particular as a result of evaluation of the influenza pandemic.

Based on a communication by the Commission, the Council will adopt conclusions on nuclear medicine and radioisotopes.

The Council will continue negotiations on the draft directive relating to cross-border healthcare.

Particular attention will be devoted to the question of professionals from the healthcare sector, to the social factors determining health, to the fight against cancer and chronic illnesses, as well as to solidarity and innovation in the proprietary medicinal products sector.

The Council will continue to work on legislative initiatives constituting the "pharmaceutical package". Particular attention will be paid to proposals aimed at combating the counterfeiting of medicines, and pharmacovigilance.

At an international level, the Belgian Presidency will prepare for and coordinate the European Conference on the WHO Framework Convention on Tobacco Control.

More information:

www.eutrio.be

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Comments and suggestions are welcome: ed@eahp.eu

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