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I. Different views on number vaccinations needed against A(H1N1)

Source: Associated Press and EMEA



A single dose of swine flu vaccine is enough to immunise adults and children over 10 against the pandemic strain, the World Health Organization said on 30 October 2009.

The global body's expert group known as SAGE said that while more data are needed on children between 6 months and 10 years, countries that have made vaccinating children a priority can administer a single dose to this age group in order to ensure that as many as possible are immunised quickly. The expert group recommended a single dose of vaccine in adults and adolescents from 10 years of age and above, provided this use is consistent with regulatory authorities' indications. More study is advised on effective dosage regimens for immuno-suppressed persons, for whom two doses of vaccine may be needed.

The expert group, which met for three days in Geneva at the end of October, said medical regulators should have the final say on which vaccines can be administered as a single shot.

But its recommendation is an important indication for those regulators - particularly in the developing world - that haven't yet decided how many doses should be required.

Meanwhile, the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA) has reviewed early data from clinical studies for the three pandemic vaccines authorised so far, Celvapan, Pandemrix and Focetria. The Committee maintained its recommendation adopted in September 2009, that these vaccines be preferably used as two doses, at least three weeks apart. However, for Pandemrix and Focetria, the limited data currently available indicate that one dose may be sufficient in adults.

II. Increasing numbers of fake A(H1N1) vaccines sold over the internet

Source: EurActiv

European medicine authorities are growing increasingly alarmed by the number of bogus swine flu remedies being sold over the internet. The news comes as Members of the European Parliament (MEPs) gear up to debate new rules on counterfeit medicines.

The European Union is cracking down on the sale of fake online medicines as part of a regulatory overhaul of the pharmaceutical sector. MEPs will debate the proposals in the coming weeks, but several leading parliamentarians have indicated that the EU executive's decision not to legislate against fake medicines sold over the internet is a major weakness in the draft new law.

The European Medicines Agency (EMA) is warning that criminal gangs are trying to cash in on the H1N1 flu pandemic by selling fake or low-quality antiviral medicines and vaccines online.

Some fake drugs contain no active ingredients while others are laced with sugar, rat poison and other medicines, according to industry sources. The EMA says these products present a serious health risk for those who buy them.



The temptation to buy illegal medicines over the internet has been heightened by concerns that not all European governments have stockpiled enough medicines to treat the entire population.

A European Commission spokesperson said customs officials are working to stop the import of fake medicines into Europe and are checking parcels of medicines ordered online.

To guard consumers and patients against counterfeit medicines, the pharmaceutical industry, via one of the European associations representing its interests, EFPIA, has launched a pilot scheme for a 2-D barcode system. The barcode is applied to each pack of medicine and is then scanned by the pharmacist at the point of sale. This reveals immediately whether the pack is genuine and if it has previously been dispensed. The trial will conclude in November and industry groups are pushing for a harmonised and interoperable system to be rolled out in all 27 EU countries.

However, pharmacists and wholesalers have previously expressed concern that any system for verifying medicines should not add disproportionately to their cost base or workload. There is also debate among industry groups as to which form of barcode would be most practical. Some argue for a radio frequency identification system, but problems with accuracy and the potential for radio waves to change the properties of medicines could make this impractical. Manufacturers and wholesalers prefer 2-D barcodes which are easily scanned and can contain detailed encrypted information. Pharmacists (including those represented by EAHP) underline that personal information from customers must be safeguarded, together with sensitive commercial data on what medicines pharmacists dispense, so as to avoid commercial exploitation of the data collected by pharmacists by third parties.

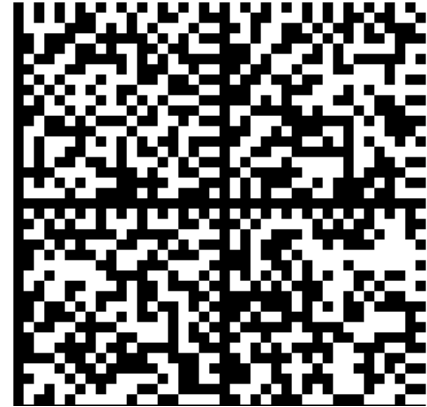
III. Data matrix system to help reduce risk of counterfeit medicines reaching patients

Source: EFPIA

The European Federation of Pharmaceutical Industry and Associations (EFPIA), the voice of the research-based pharmaceutical industry in Europe, on 20 October 2009 unveiled its pilot project to check medicines and so help reduce the risk of counterfeit medicines being dispensed to patients. The verification system is being piloted in conjunction with project partners Apoteket AB, the Swedish pharmaceutical retailer and local Swedish wholesalers Tamro & Oriola-KD.

Using a small data matrix - similar to a barcode - to individually number each pack of medicine, the system can provide the pharmacist with an almost instantaneous verification as to whether that a pack has been previously dispensed. A message will immediately alert that the pack may be counterfeit.

The system is being trialled in 25 retail pharmacies in and around Stockholm and will be able to check more than 100,000 products. The data matrix includes information on the product code, batch number, the expiry date and will contain a unique, randomised serial number that identifies packs individually. The trial is expected to run until late November 2009. The system is part of EFPIA's response to the European Commission's proposal for mass serialisation of data about medicinal products as part of measures to better protect EU citizens from the serious threats posed by counterfeit medicines. EFPIA hopes the system can offer the basis for a cost-effective, harmonised and interoperable system across Member States.



EAHP welcomes this initiative which will serve another important purpose: patient safety in hospitals. The data matrix, if and when adopted by drug makers, could also contain the drug's route of application, the name and quantity of active substance(s) and the manufacturer's name, as EAHP has requested of the pharmaceutical industry. The EAHP believes such a system would significantly reduce the number of adverse drug reactions.

More information: <http://www.eahp.eu/Advocacy/Bar-coded-unit-doses>

IV. The European Parliament reviews a draft directive on pharmacovigilance



On Thursday 5 November 2009, the European Parliament Health and Environment Committee will start discussing the draft Pharmacovigilance Directive.

Ahead of the debate, EAHP met with other members of the European Public Health Alliance (EPHA) with the intention of establishing their common opinions then communicating them to Members of the European Parliament (MEPs).

EAHP had already published its comments on the European Commission's draft proposal when the latter released it for an open consultation; the EAHP document is available here: <http://www.eahp.eu/EAHP-EU-Monitor/EAHP-answer-to-the-EC-consultation-on-Pharmacovigilance>.

EAHP reiterated its call for more transparency in the system of collecting and reviewing data on adverse drug reactions and re-affirmed that it does not support several measures

proposed by the European Commission, which are likely to weaken the European pharmacovigilance system, instead of strengthening it:

- generalisation of premature market authorisation;
- end of compulsory public funding of pharmacovigilance activities;
- strengthening the firms' stranglehold on the collection and interpretation of data, hence endangering the public systems of pharmacovigilance in Member States;
- centralising of dilution data at the European level in a "megabase" is unworkable.

EAHP and other members of EPHA suggest the following actions to improve European pharmacovigilance:

- Enhancing communication with the public and patients: public information and education campaigns, through the EMEA and national agency websites, health centres and patient organisations, etc., on the importance of adverse drug reactions reporting should be carried out and it should be a key part of training for health professionals
- Improving patient information leaflets
- Introducing a symbol to indicate new medicines under surveillance
- Encouraging direct reporting of Adverse Drug Reactions by patients and healthcare professionals
- Opting for rigorous pre-authorisation studies in place of post-authorisation risk management systems
- Providing authorities with the means to act independently from industry
- Stimulate additional longer-term research on specific medicines
- Encourage twinning of knowledge transfer in pharmacovigilance between countries

The EAHP hopes that the Commission's proposals will be significantly amended by MEPs in the public interest.

V. EU launches a consultation on the revision of the Clinical Trials Directive

Source: European Commission



On 12 October 2009 the European Commission Directorate General Enterprise and Industry (DG ENTER) launched a public consultation on the revision of the so call Clinical Trials Directive.

This assessment will consider options for improving the functioning of the Clinical Trials Directive with a view to making legislative proposals, if appropriate, while taking the global dimension of clinical trials into account.

Requirements for the conduct of clinical trials in the EU are provided for in Directive 2001/20/EC, later amended in Directive 2005/28/EC. Clinical trials

submitted in any marketing authorisation application in the EU are required to be conducted in accordance with the Clinical Trials Directives. If the clinical trials are conducted outside the

EU, but submitted in an application for marketing authorisation in the EU, they have to follow the principles which are equivalent to the provisions of the Clinical Trials Directive.

A European database – EudraCT – contains all ongoing or completed interventional clinical trials of medicinal products falling within the scope of directives. This database gives the competent authorities of the Member States, EMEA and the Commission the necessary information to communicate on clinical trials and to maintain oversight of clinical trials and the development of investigational medicinal products (IMP). It provides for enhanced protection of clinical trial subjects and patients receiving IMPs.

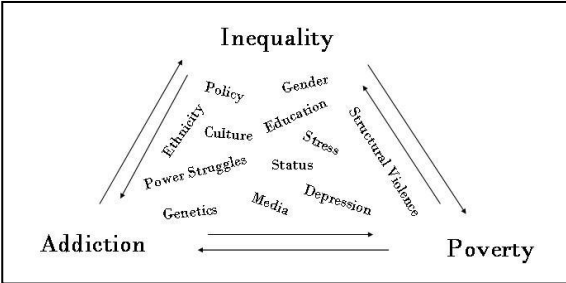
Community legislation states that certain information contained in EudraCT is to be made accessible to the public. This public accessibility concerns clinical trials with paediatric as well as non-paediatric participants. It encompasses protocol-related information and result-related information, and it covers both negative and positive results.

The public consultation document is published here:
http://ec.europa.eu/enterprise/pharmaceuticals/clinicaltrials/docs/2009_10_09_public-consultation-paper.pdf

Interested parties are invited to comment by 8 January 2010.

VI. The European Commission tackles health inequality

Source: European Commission and the European Voice



The European Commission said on 20 October 2009 it intends to put the issue of health inequality at the centre of the EU's agenda in a bid to close the gap in life expectancy between rich and poor Europeans.

In a non-binding policy document, the Commission said that it would like to see

Member States co-ordinate policies more closely in a wide range of policy areas that affect health.

It also wants to collect data regularly from each country and invest funds in further research.

A recent Eurostat report revealed that, in 2007, the average life expectancy of women differed by eight years across the 27-member EU. The gap for men was even larger, at 14 years. Infant mortality ranges from around 3 per 1,000 live births to more than 10 per 1,000. It also found that, in some new Member States, the gap between national life expectancy and the EU average has increased in the past two decades.

The reasons for the gap include income, education, living and working conditions and access to healthcare. The Commission said that, at this stage, it intends to collect data from around Europe in order to compare the situation in different regions and seek the causes of gaps. The first report is expected to be published by 2012.

Until then, the Commission recommends that Member States move the issue up their national agendas.

The Commission itself has limited resources itself to fund public-health programmes.

The EU already has as a goal an improvement in the number of active, healthy years that Europeans live. That aim is expressed in the 'healthy life years' indicator included in the Lisbon Strategy, a development programme adopted in 2000 with the aim of enriching human resources in the European economy.

VII. European Commission launches a European partnership for action against cancer

Source: European Commission



On 30 September 2009 the President of the European Commission and Commissioner Androulla Vassiliou officially launched the partnership for action against cancer in Brussels.

Three million people are diagnosed with cancer every year in the EU. It is the second biggest cause of death in both men and women. The Partnership aims to draw together relevant organisations to share expertise and to identify challenges in order to reduce the number of new cancer cases in the EU by 15% by 2020.

The Partnership aims to support countries in their efforts to tackle cancer by providing a framework for identifying and sharing information, capacity and expertise in cancer prevention and control. It aims to engage a wide range of stakeholders, including non-governmental organisations, researchers, patient groups, industry and national authorities across the EU, in a collective effort and with a common commitment to addressing cancer. This partnership approach will also help avoiding scattered actions and the duplication of efforts by contributing to better use of the limited resources available.

The Commission policy paper on Action against Cancer, adopted in June 2009, sets out the aims, objectives and actions of the partnership. After the launch event, preparatory meetings for the partnership are planned later in the autumn.

VIII. News in brief

1) Merck takes over Schering-Plough and Pfizer, Wyeth

The European Commission ruled on 23 October 2009 that Merck's merger with Schering-Plough would not harm competition as it approved the pharmaceutical company's takeover of its rival Schering-Plough.

The deal announced in March 2009 will unite the maker of asthma drug Singulair with the maker of allergy medicine Nasonex.

The \$41.1 billion acquisition of smaller Schering-Plough will allow Merck to leapfrog to No. 2 worldwide in prescription medicine, just behind Pfizer Inc., which Wyeth bought on 17 October 2009 for \$68 billion. The new Merck-Schering company would have about \$42.4 billion in annual sales.

The two companies hope to fully close the deal in the fourth quarter following shareholder approval on 7 August 2009. The deal still needs approval from the U.S. Federal Trade Commission.

2) Update on the spread of the A(H1N1) virus

As of 11 October 2009, there have been more than 399,232 laboratory-confirmed cases worldwide of pandemic influenza H1N1 2009 and over 4735 deaths have been reported to the World Health Organisation(WHO).

As many countries have stopped counting individual cases, particularly of milder illness, the case count is significantly lower than the real number of cases that have occurred. WHO is actively monitoring the progress of the pandemic through frequent consultations with the WHO Regional Offices and Member States and through monitoring of multiple sources of data.

Influenza activity continues to increase in the northern temperate zones across the world. In North America, the United States is now experiencing nationwide rates of Influenza-Like Illness (ILI) well above seasonal baseline rates with high rates of pandemic H1N1 2009 virus detected in clinical laboratory specimens. Canada is reporting increases in ILI rates for the third consecutive week with some provinces now reporting above average infection rates. Mexico also reports high intensity and active transmission in some areas of the country. Western Europe and northern Asia are experiencing increased rates of ILI, well above baseline in some countries, but activity is generally not as widespread as in North America.

More information: http://www.who.int/csr/don/2009_10_16/en/index.html

3) Nobel Prize in chemistry: revealing the ribosome

The 2009 Nobel Prize in Chemistry has been awarded to Ada E. Yonath, Weizmann Institute of Science, Rehovot, Israel, Venkatraman Ramakrishnan, MRC Laboratory of Molecular Biology, Cambridge, United Kingdom and Thomas A. Steitz, Yale University, New Haven, CT, USA for studies of the structure and function of the ribosome.

This is the 101st chemistry Nobel to be awarded since 1901, and Professor Yonath is only the fourth woman to win. The prize is to be shared equally between the three scientists, who all contributed to revealing the ribosome's huge and complex molecular structure in detail. The work of the three new Laureates has led to a better understanding of the molecular basis of translation and may have wider implications for human health and medicine. Their structural studies have revealed how antibiotics can bind to ribosomes in different ways to disrupt protein synthesis — and this may lead to the development of new antibiotics in the fight against multiresistant bacteria.

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Comments and suggestions are welcome: ed@eahp.eu

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