The EAHP EU Monitor is a weekly round up of news relevant to hospital pharmacy in Europe.

You can subscribe to the EAHP EU Monitor ***here.*** [1]

European Commission consults on changes to GMP guidelines

The European Commission has opened a consultation on proposed changes to European guidelines on Good Manufacturing Practices for Medicinal Products.

The primary proposals for changing guidelines relate to:

- improved guidance on prevention of cross-contamination;

- a new complementary toxicological assessment guidance;
- changes to guidance on the qualification of suppliers (to reflect the legal obligation of manufacturing authorisation holders to ensure that active substances are produced in accordance with GMP);
- changes to clarify and harmonise expectations of manufacturers regarding the testing of starting materials; and
- guidance to manufacturers on notification of restrictions in supply.

Comments and suggestions are invited by the Commission until **18 July 2013** and should be sent by email to: ADM-GMDP[at]ema.europa[dot]eu [2] and SANCO-pharmaceuticals-D6[at]ec.europa[dot]eu [3]

More information **here.** **[4]**

EMA CHMP adopts opinions on new leukaemia, eye, arthritis, and diabetes medicines

The European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP) has published a number of opinions on a range of potential new medicines arising from its January meeting.

The Committee adopted a positive opinion regarding the conditional marketing authorisation for Pfizer Inc.'s bosutinib in the European Union (EU) for the treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) (TKIs) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.

The CHMP has also recommended marketing approval for Jetrea (ocriplasmin), developed by Belgium's ThromboGenics and licensed outside the USA, for the treatment of adults with vitreomacular traction. The drug is the first non-surgical treatment option for VMT, a condition which can cause decreased vision and the distortion of images. Sufferers currently have to have a vitrectomy, where the vitreous humour is removed surgically and which requires the patient to be in a 'head-down' position for seven-14 days and has a recovery period of four to six weeks.

However, the CHMP has issued a negative opinion on another eye drug, namely Santhera Pharmaceuticals' Raxone (idebenone) for the treatment of Leber's hereditary optic neuropathy, which causes progressive vision loss.

Other highlights of the meeting saw the CHMP recommend the green light for Novartis' cryopyrin-associated periodic syndromes drug Ilaris (canakinumab) as a treatment for frequent acute gouty arthritis. It also backed expanded approvals for AstraZeneca/Bristol-Myers Squibb's diabetes drugs Onglyza (saxagliptin) and Komboglyze (saxagliptin/metformin)

and AbbVie's blockbuster Humira (adalimumab).

The CHMP also issued positive recommendations on new generics of Boehringer Ingelheim's hypertension combo Micardis HCT (telmisartan/hydrochlorothiazide) from Actavis and Krka and the latter's copy of Lundbeck's Alzheimer's disease drug Ebixa (memantine).

More information **here** [5].

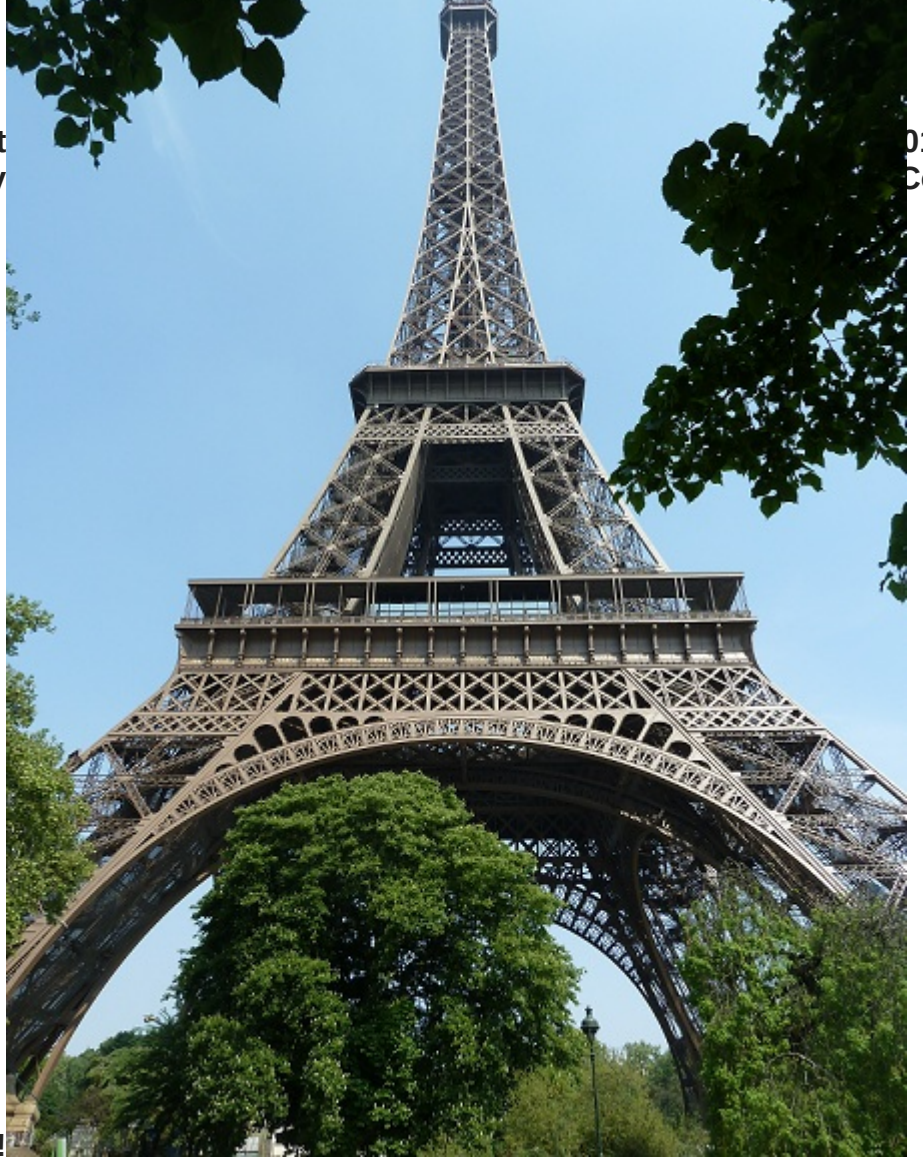
EJHP: Report of SEFH event on Pharmacogenetics

The online first edition of EJHP this week published a report on an event held by the Spanish Association of Hospital Pharmacists (SEFH) on the topic of Pharmacogenetics.

The event aimed to help hospital pharmacists better understand the basic concepts and potential clinical applications of pharmacogenetics to hospital pharmacy practice, examining clinical implementation across Europe and considered clopidogrel as a particular case study.

Read the full article **here** [6].

18th Congress of the EAHP: Don't miss the 1st February early bird registration fee!

Hospit  **013 deadline for achiev** **Congress of the EAHP!**

The Congress takes place from Wednesday 13th to Friday 15th March, at the Palais des Congres Conference Centre, Paris. The Congress is a busy schedule of: keynote speeches; operational, therapeutic and conceptual seminars; workshops; satellite events; poster presentations and exhibits covering the breadth of hospital pharmacy practice in Europe.

This year's Congress has the overall theme "Improving patient outcomes: a shared responsibility"

Registration information **here** [7].

Programme information **here** [8].

21 January 2013

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] https://www.eahp.eu/contact/ADM-GMDP/ema.europa/eu
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