Press release – embargo immediate

London, 2 July 2013

Cost before care – what price patient safety?

French Drug Regulator speaks out to highlight risks of therapeutic substitution

In its recent report, "When is a Medicine Not a Medicine?", the European Alliance for Access to Safe Medicines (EAASM) highlighted the dangers to patients when cost is put before quality care. In three case studies, the report highlighted examples of patients being harmed and, indeed, killed, when these cost-cutting measures go wrong. Since then, there have been well publicised reports from the USA, of the horrendous damage done to patients due to failings in so-called "compounding laboraties".

Now, in response to a question from Gilbert Barbier (Member, French Senate, Jura Department) the French Drug regulator (ANSM) has clarified the situation, saying:

1. **There is not a single country in the world that has authorised the substitution of Lucentis with Avastin.**
2. **Pharmacovigilance data shows that the use if Avastin causes more toxicity than the use of Lucentis .**
3. **These two products are radically diffent; this is as to compare Aspirin with Paracetamol, they are not considered as equivalent and substitutive.**

The Agency further stated that whilst substitution is not forbidden, the risk is to be borne by those taking the decision on substitution.

Speaking following the ANSM's comments, Jim Thomson (Chair EAASM) said;

" The ANSM has made its position abundantly clear. It has stated categorically that these two medicines are not the same and that not a single country has authorised the substitution. Indeed, it has placed the responsibility firmly at the door of healthcare practitioners (HCPs) who decide to go down the route of substitution."

On the face of it, it would appear that the ANSM's comments about risk and responsibility, should be sufficient to reassure patients but this is really not the case. Thomson explained why still, on a daily basis, they are put at risk:

"When making the decision to use a substitute medicine, the patient should have his or her options clearly and fully explained and should be asked for written consent. We know from our ongoing research in the UK that this is far from the reality in the NHS. In fact, decisions are being made purely on the basis of cost, mistakes are being made and when things do go wrong, there is little or no reporting, unless the circumstances are particularly grave. That is clear evidence of systemic failure and we call on Drug

Regulators to take note of and support the ANSM's serious concerns and very clear position on this serious patient safety issue".

ENDS

Notes to Editors

When is a Medicine Not a Medicine can be obtained at:
http://www.eaasm.eu/when-is-a-medicine-not-a-medicine-report.

For further comment, please contact jim.thomson@eaasm.eu +44 (0)7901 800608

About EAASM

The European Alliance for Access to Safe Medicines (EAASM) is a pan-European patient safety organisation, campaigning for the exclusion of counterfeit and substandard medicines from the supply chain and to improve patient safety in Europe. The Alliance represents different stakeholders, at its core are patient groups, and thus it represents many millions of patients. The EAASM was founded in 2007 and works as a non-profit organisation.

The Debate in France

Detailed coverage of the French debate can be found via the following linked video. The times of the questions and answers are indicated for reference.

http://videos.senat.fr/video/videos/2013/video18749.html

Question (14:11) Gilbert Barbier (member of the Senate of France, representing the Jura department):
Answer (30:55 – 35 :02) Dominique Maraninchi Dominique (Directeur général des médicaments génériques, homéopathiques, à base de plantes et des préparations de l'Agence nationale de sécurité du médicament et des produits de santé (ANSM)) :