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General Practitioners Committee

By email: sanco-pharmaceuticals@ec.europa.eu

25 April 2012

Dear Sir/Madam

Consultation on concept paper for implementation of Directive 2011/62/EU

The British Medical Association (BMA) is an independent trade union and voluntary professional association which represents doctors and medical students from all branches of medicine all over the UK. With a membership of over 143,000 worldwide, we promote the medical and allied sciences, seek to maintain the honour and interests of the medical profession and promote the achievement of high quality healthcare. The BMA is registered on the European Commission register of interest representatives.

We welcome the opportunity to respond to the public consultation on the implementation of the '*Delegated Act on the detailed rules for a unique identifier for medicinal products for human use, and its verification*.' The BMA supports measures that will reduce the risk of counterfeit medicines entering the supply chain. The proposals as outlined in this EU Directive recommend a sensible use of technology that has the potential to yield a number of additional benefits, including quickening the process of identifying batch problems in medicinal stock. Further to this, we would especially welcome the development of this technology to serve a dual purpose in recording batch numbers and expiry dates on individual medical records.

While we support the principle of this Directive, the BMA's General Practitioners Committee have expressed some concerns on the proposals as they currently stand:

- The stock identification systems that are already in place across the UK are largely manual, and as such, the possible workload implications in implementing this Directive could be considerable.

- A scoping of expected initial costs in purchasing the necessary equipment is not dealt with in this Directive. This cost of this electronic equipment could be a considerable expense at a time of economic austerity.

- Detailed provision for items such as vaccines, or personally administered (PA) items, are not explored in this directive.

- For non-dispensing doctors, a verification system would need to be agreed to allow for items supplied from the doctor's bag.

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We hope that our submission is useful.

Yours faithfully

Head of NHS GPs Division