

National Pharmaceutical Supply Group response to Public Consultation on EC Proposals of Counterfeit Medicines

The Submitting Group

The NPSG provides a national strategic focus in the relationship between hospital pharmacists, with their operational knowledge of NHS requirements, and the NHS Purchasing and Supply Agency (NHS PASA), in matters relating to the procurement and supply of medicines to the NHS secondary care market in England.

The Response

It is essential to protect the classical supply chain from counterfeit medicines and the NPSG supports this. It is also essential however that any measures taken do not paralyse the efficient and speedy working of the business processes within the supply chain and that responses are proportionate.

4.1.1 *Subject all actors of the distribution chain to pharmaceutical legislation*

We support this proposal although we are concerned about workload issues here for regulators. This could significantly increase regulator costs. There also appears to be a requirement for WDL holders to audit their suppliers. We question the practicality of this and are again concerned about the workload implications. We would also request that any final decision about the qualification requirements for a qualified person be checked against the level of qualification existing now within the NHS.

4.1.2 *Tightening rules on inspections*

We support this proposal.

4.1.3 *Improving product integrity through a unique seal from the manufacturer to the retailer or wholesaler, using a risk-based approach, supported by a ban on repackaging*

This measure would have serious implications for parallel imported medicines where the labelling on the foil inners needs to be amended. Any seal would be relatively easy to falsify and we are not sure of the benefit that would arise from this extra cost. Is there any evidence that products which bear this seal now are less likely to be the subject of counterfeiting?

Seals would be useful to avoid pharmacy dispensing staff opening packs to verify the contents. The right to open and reseal should be available to PI suppliers.

The NHS undertakes a significant amount of repackaging for legitimate clinical reasons, such as to produce emergency packs containing small amounts of a medicine used by mental health crisis resolution teams. Giving manufacturer's original packs to such patients would not be in their best interests. These packs may also be produced by a different corporate body to the one delivering the clinical service, and so there will need to be flexibility to allow others than just the market authorisation holder and the end-user to open the packaging.

4.1.4 *Centrally accessible record to facilitate traceability of batches throughout the distribution chain*

Whilst appearing desirable in principle it is difficult to see how this proposal could be made to work. Any documentation is potentially forgeable and the data requirements of a central database for every product would be huge, difficult to manage and liable to error. It is likely that verification would be so problematic that people would not undertake it. Recording batch numbers only occurs in a small minority of Trusts as the time involved and the difficulty in ensuring the data is accurately recorded outweigh the benefits.

4.1.5 *Mass serialisation for pack-tracing and authenticity checks on a case-by-case basis*

This proposal is potentially even more complex in terms of data management than proposal 4.1.4. The costs of such a scheme would be high and it is difficult to see how it would improve security.

4.1.6. *Increasing transparency concerning authorised wholesalers through a Community database*

We support this proposal.

4.2. *Tightening requirements for the import/export/transit (transshipment) of medicinal products*

We support this proposal.

4.3.1 *Requirement of a mandatory notification procedure for manufacturers/importers of active substances*

We support this proposal.

4.3.2. *Enhancing audit and enforceability of GMP*

We support this proposal.

4.3.3. *Enhancing GMP inspections*

We support this proposal.

NPSG

7 April 2008