

**Response to Public Consultation in Preparation
of a Legal Proposal to
Combat Counterfeit Medicines for Human Use**

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**Key Ideas for Better Protection of Patients
Against the Risk of Counterfeit Medicines**

**As Proposed by the European Commission,
Enterprise and Industry Directorate-General,
Consumer Goods,
Pharmaceuticals**

**Submission from Reckitt Benckiser International Ltd.
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1. Executive Summary

The European Commission have commenced a consultation on measures to prevent counterfeiting of medicinal products, given that they constitute a potential threat to public health.

The EC have identified active ingredient suppliers and brokers as a potential route into the legitimate pharmaceutical market and have moved to include them within pharmaceutical legislation, require their registration and maintain a database of them.

The Regulatory authorities would have to perform GMP inspections of them.

Manufacturers would also have to increase control of active ingredients by using more modern methods and would legally have to perform audits of these suppliers.

Additional measures for manufacturers and wholesalers include improving product traceability (including access to databases of batch-specific information), tightening up and mandating GMP/GDP requirements and generally increasing transparency of the industry as a whole.

Reckitt Benckiser agrees with all elements of the proposals that relate to active ingredient suppliers / brokers.

Control measures need to be proportional to the risks; and need to take into consideration the different profiles of prescription medicines and Over-the-Counter (OTC) medicines. In relation to the enhanced traceability, the proposals of unique product seals and single item traceability seem appropriate for the products at which they are primarily aimed (expensive prescription products – ‘life-style’ or life-saving drugs) but are not seen as necessary for OTC, mass-market products. Current systems are fit for purpose for OTC medicines already.

The requirements for increased control of active ingredients tend to have already been adopted by Reckitt Benckiser but it is stressed that that does not mean they should be made compulsory, as they are not applicable to all active ingredients.

With regard to the database access, again it is stressed that this is not appropriate or proportional to OTC products that are unlikely to be targeted by counterfeiters (the potential return does not warrant the risk).

2. Background

The European Commission have stated that recent analysis of European Union statistics demonstrate that counterfeit medicinal products have become an increasing threat to public health, through the provision of sub-standard or dangerous counterfeit products.

Whilst initially targeting 'life-style' drugs (e.g. Viagra) for their ease of access to users, counterfeiters now appear to be moving into life-saving medicines, including those used to treat cancer and heart disease, given their relative high cost and thus high returns available to the unscrupulous.

This trend is thought to be on the increase.

Included in this assessment of threat are the active pharmaceutical ingredients, their producers and their import into the EU, as this area is thought to be one means of accessing the mainstream, legitimate pharmaceutical supply chain being used by the counterfeiters.

Other elements of the problem that have been identified are:

- i). deficiencies in supply chain integrity, with a lack of clarity as to whether current pharmaceutical legislation covers all participants, for example, active pharmaceutical ingredients' brokers and traders
- ii). medicinal products not intended for use in the EU but which pass through it's borders (i.e. in transit or intended for export only)
- iii). current legislation being open to interpretation by Member States who then go on to adopt different measures to tackle the problem locally, thereby potentially damaging the single market / free movement ethos

3. The European Commission Proposals

The following measures are being proposed by the European Commission to better protect patients in the EU from counterfeit medicines.

3.1 With regard to manufacture, placing on the market and inspections connected with medicinal products:

3.1.1. Ensure all participants in the supply chain are covered by pharmaceutical legislation

3.1.2. Improve product integrity and traceability

3.1.3. Improve the technical requirements of Good Manufacturing Practice and Good Distribution Practice

3.1.4. Tighten inspections by the Regulatory Authorities

3.1.5. Increase transparency

3.2 With regard to the requirements for import / export / transshipment of medicinal products:

Ensure all products coming into the EU are covered by pharmaceutical legislation, regardless of whether such products are intended to be placed on the market within the EU or are intended for onward export.

3.3 With regard to manufacture, placing on the market and inspections connected with active pharmaceutical ingredients:

3.3.1. Mandate that all manufacturers or importers of active pharmaceutical ingredients notify the regulatory authorities, who maintain a database of them

3.3.2. Ensure that manufacturers /importers audit API suppliers on a regular basis and insist on minimum professional qualifications for auditors, similar to those for Qualified Persons

3.3.3. Require enhanced control of APIs by manufacturers, utilising, for example, Near Infrared Spectroscopy or fingerprint technologies

3.3.4. Make the requirements of Good Manufacturing Practice legally binding

3.3.5. Regulatory authorities able to perform GMP inspections of API suppliers at will rather than just in relation to cases of suspected non-compliance to GMP

Each of these distinct areas is dealt with in greater detail in section 4, the Reckitt Benckiser position.

4. The Reckitt Benckiser Position

The European Commission have stated that counterfeit medicinal products have become an increasing threat to public health, through the provision of sub-standard or dangerous counterfeit products, primarily due to their high cost and thus high potential return for the criminally-minded.

Whilst this may be true of mainstream prescription medicines, there is little evidence that this is the case of over-the-counter (OTC) medicines, which are produced for retail sale to patients rather than provided via any reimbursement process.

Because OTC medicinal products tend to be relatively inexpensive, mass produced and often bear intricate branding, there is little incentive for counterfeiters to enter this 'market' as the returns tend not to outweigh the costs or risks inherent in so doing.

In relation to the individual proposals made by the European Commission, Reckitt Benckiser have adopted the following stance:

3.1. With regard to manufacture, placing on the market and inspections connected with medicinal products:

3.1.1. Ensure all participants in the supply chain are covered by pharmaceutical legislation (as covered by Section 4.1.1. of the European Commission proposal)

As a manufacturer and wholesaler, Reckitt Benckiser are already covered by pharmaceutical legislation and as such are not directly effected by this element but agree in principal with the proposals. Regarding the requirement for regular audits by manufacturers of contract manufacturers to ensure GMP/GDP compliance (and, should it prove necessary, suppliers and wholesalers suspected of non-compliance), using suitably qualified auditors, such audits are already performed by Reckitt Benckiser.

3.1.2. Improve product integrity and traceability (as covered by Sections 4.1.3., 4.1.4. and 4.1.5. of the European Commission proposal)

Section 4.1.3. states that a unique seal be used by the manufacturer, along with a ban on repackaging. Whilst this may be a suitable solution for 'life'syle' or life-saving medicines, due to their relatively high cost, it is agreed that such a measure need only be applied to certain categories of product and has to be proportional to the risk involved – for OTC products this risk is low both in terms of the potential outcome for the patient and also the likelihood of these products being targeted for counterfeiting by the criminal fraternity.

Section 4.1.4. states that a central database be maintained to enhance batch traceability throughout the distribution chain, accessible to all participants within the supply chain. A few questions need to be asked: 'Accessible to whom?' because wholesalers and large multiple retailers already have in place systems for batch traceability. 'Would such a system combat counterfeiting in OTC products?' because as envisaged, such a system may be beneficial for

expensive or abuseable products or for certain prescription only medicines but is unlikely to have any impact, other than cost, on the OTC industry. The system currently in use by the vast majority of the pharmaceutical industry is fit for purpose and need not be tightened, unless by exception.

Section 4.1.5. calls for mass-serialisation of down to individual pack traceability. Again, would such a system combat counterfeiting in OTC products? Similarly, it may be beneficial for certain prescription only medicines but is unlikely to have anything other than a negative impact on the OTC industry.

3.1.3. Improve the technical requirements of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) (as covered by Section 4.1.6. of the European Commission proposal)

As an authorised wholesaler, Reckitt Benckiser would be affected by the suggested measure but would welcome the proposed issuing of a GDP certificate after each inspection and the creation of a community-wide accessible database of GDP-compliant wholesalers.

3.1.4. Tighten inspections by the Regulatory Authorities (as covered by Section 4.1.2. of the European Commission proposal)

As already subject to inspections by the regulatory authorities, Reckitt Benckiser are not directly effected by this element but agree in principal with the proposals.

3.1.5. Increase transparency

Reckitt Benckiser welcomes efforts to improve transparency within the pharmaceutical industry and agree in principal with the proposals.

3.2. With regard to the requirements for import / export / transshipment of medicinal products (as covered by Section 4.2. of the European Commission proposal):

Reckitt Benckiser agree with the proposal that all products coming into the EU are covered by pharmaceutical legislation, regardless of whether such products are intended to be placed on the market within the EU or are intended for onward export. Whilst Reckitt Benckiser do perform such importation, it is believed that the impact of this measure would be minimal.

3.3. With regard to manufacture, placing on the market and inspections connected with active pharmaceutical ingredients:

3.3.1. Mandate that all manufacturers or importers of active pharmaceutical ingredients notify the regulatory authorities, who then maintain a database of them (as covered by Section 4.3.1. of the European Commission proposal)

Reckitt Benckiser are not directly effected by this element but agree in principal with the proposals.

3.3.2. Ensure that manufacturers / importers audit API suppliers on a regular basis and insist on minimum professional qualifications for auditors, similar to those for Qualified Persons (as covered by Section 4.3.2. of the European Commission proposal)

Reckitt Benckiser already perform audits of suppliers of APIs to a high level of confidence and on a regular basis, and whilst we agree in principal with the proposals, mandating such a requirement would be unreasonable where, for example, the supplier is an affiliate of a large, third-party pharmaceutical company, with a DMF and approved by a competent authority.

3.3.3. Require enhanced control of APIs by manufacturers, utilising, for example, Near Infrared Spectroscopy or fingerprint technologies (as covered by Section 4.3.2. of the European Commission proposal)

Reckitt Benckiser already use NIR for the identification of certain APIs but it should be noted that this is not applicable to all APIs. Additionally, caution should be exercised when recommending unproven technologies

3.3.4. Make the requirements of Good Manufacturing Practice legally binding (as covered by Section 4.3.2. of the European Commission proposal)

Reckitt Benckiser are not directly effected by this element but agree in principal with the proposals.

3.3.5. Regulatory authorities able to perform GMP inspections of API suppliers at will rather than just in relation to cases of suspected non-compliance to GMP (as covered by Section 4.3.3. of the European Commission proposal)

Reckitt Benckiser are not directly effected by this element but agree in principal with the proposals.