# Business Engagement Assessment

| | |
|---|---|
| ***Title of Proposal*** | ***Introduction of Tell-and-Do Variations for a Specific Subset of Parallel Import Licenses*** |
| Lead Regulator | *Medicines and Healthcare Products Regulatory Agency (MHRA)* |
| Contact for enquiries | *Dr David Guest, Parallel Import Unit Manager* |

| | | | |
|---|---|---|---|
| Date of assessment | *21 August 2013* | Commencement date | |
| Net Cost to Business in England: | *TBC* | Stage of assessment | *Draft* |
| Price base year | *2013* | Is this directly applicable EU or other international legislation? | *No* |
| Does this include implementation of Red Tape Challenge commitments? | *No* | | |

***Brief outline of proposed change in regulatory action***

**The current regulatory position requires** companies that import medicinal products from within the European Union (known as 'Parallel Importers') into the UK to notify MHRA if they observe certain changes to the imported products (such as changed appearance of dosage forms). MHRA is notified of these changes to ensure that they do not impact the product's therapeutic effects. While MHRA is investigating the changes, there is a '*stop-processing*' requirement on the importing companies which prohibits them from processing, repackaging, or releasing the product onto the market until given approval. This waiting period can be an unexpected disruption of several months and affects the importer's business negatively.

**The new proposal will abolish the 'stop-processing' requirement for Parallel Importers (PIs) if** imported products are part of European Mutual Recognition (MR) or De-Centralised (DC) procedures. Changes of these products will have already been considered by all relevant member states in the procedures, including the UK. In these circumstances, the UK will already know of the changes to the product when it arrives in the UK and therefore the requirement to "stop processing" is not necessary. The proposal instead requires PIs to notify the Agency of the changes but allows PIs to release the products onto the UK market. **This notification principle is known as 'Tell-and-Do'.**

**One of the risks** identified with the proposal, namely that the Tell-and-Do process may be applied by PIs to inappropriate cases has necessitated the development of a risk management and mitigation plan containing the following elements:

- A list of those imported products to which the 'tell-and-do' regime applies will be shared with PIs and will be updated frequently;
- Workshops to explain the new regime to regulatory staff of PIs have been and will continue to be conducted;
- 10 'test notifications' from each PI are required prior to being permitted to use the new regime;

***Why is the change proposed? Evidence of the current problem?***

**Informal consultation with PIs has revealed that the current regulatory requirements have a negative effect on their business.** PIs incur unexpected costs and losses, forgo revenue and or may see their ability to operate reduced because of the inability to process or sell the imported goods while waiting for MHRA approval:

- First, unplanned storage costs may be triggered.
- Second, PIs may lose all potential sales revenue if products go out of date while waiting for approval from the MHRA.
- Third, PIs may not have access to credit and are therefore dependent on sales revenues to turn over their limited working capital quickly
- Fourth, as PIs may not be able to honour their delivery commitments with buyers, PIs may lose supply contracts and future sales (although one PI's loss may be another's gain).

***Which types of business will be affected? How many are affected?***

**There are currently 63 licensed Parallel Importing companies.** All of them are likely to benefit from the proposal and these benefits will be on-going rather than one-off. **Between 55 and 70% of all PIs are expected to be small and micro size enterprises.** The proposal is not expected to impose any costs on any sector.

*NB: As part of our engagement exercise, we ask firms to comment particularly on this section. We seek confirmation from industry on our relative firm-size estimates. Please comment on the accuracy of our estimates and propose – if applicable – a different estimate, along with an explanation for them.*

***How will the change impact these businesses?***

The proposal directly affects Parallel Importers. The proposal seeks to **reduce the burden of regulation on business** while keeping risks to public health to a minimum. In particular the 'stop-processing' requirements for PIs would be replaced by a 'tell-and-do' regime which removes unforeseeable delays for PIs and simplifies their sales planning.

**MHRA expects the proposal to have a positive effect on the UK economy.** The proposal affects Parallel Importers who will benefit from being able to continue business operations as planned and thereby avoid unexpected waiting times, costs and lost profits. No impacts on Civil Society Organisations (CSOs) are expected.

**Scale of impact**

**The expected amount of savings to the Parallel Import industry from the proposal is currently estimated to be £4 million per year.**

Following informal consultation with PIs, we have estimated the **cost of one month waiting time to be £1,000.** We will seek confirmation of this estimate in further informal consultation with Parallel Importers. The **average waiting time for Agency approval is currently 4 months**. MHRA data indicates that the proposal eliminates the waiting time for **circa 1,000 notifications per year**.

*NB: As part of our engagement exercise, we ask firms to comment particularly on this section. Please help us by sharing your average cost of one month waiting time due to the stop-processing requirement. Please also comment if you have identified any other benefits or costs and provide a clear description and quantification of them where possible.*

**Business Engagement**

MHRA has introduced the Tell-and-Do approach in a number of workshops in April 2013 with almost all PIs attending, an indication of how positively the industry viewed the change. Moreover the Parallel Import Unit has informally contacted some affected companies who helped generate the preliminary estimates above.

The Agency is currently conducting another engagement exercise and is asking manufacturers and distributors of pharmaceutical products to **comment on any aspect of this Business Engagement Assessment, particularly with a view to quantify costs and benefits of the proposal. The deadline for comments is 1 November 2013 and a final Business Engagement Assessment will be published shortly thereafter.**

***Impact on small businesses***

**No disproportionate impact on small and micro businesses has been identified.**
Given that this measure is of permissive nature, we expect that businesses will only take advantage of the opportunities offered by the new proposal if the associated benefits outweigh costs. Small businesses are therefore expected to switch to the 'Tell-and-Do' regime only if they find the net benefit of doing so to be positive.