MHRA
151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom

mhra.gov.uk

1 August 2014

Dear Sir/Madam,

MHRA IS SEEKING VIEWS ON (MLX387): THE LISTING OF PRESCRIPTION MEDICINES THAT SHALL NOT BEAR THE SAFETY FEATURE AND NON-PRESCRIPTION MEDICINES THAT SHALL BEAR THE SAFETY FEATURE (FALSIFIED MEDICINES DIRECTIVE)

On 1 July 2011, Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products was published. This Directive amends Directive 2001/83/EC on the Community Code relating to medicinal products for human use.

Directive 2011/62/EU introduces obligatory 'safety features' to allow verification of the authenticity of medicinal products and stipulates that:

1. medicinal products subject to prescription shall bear the safety features, including the unique identifier, unless they have been listed by the Commission in a delegated act;
2. medicinal products not subject to prescription shall not bear the safety features, unless they have been listed by the Commission in a delegated act.

In accordance with Article 54a(2) of Directive 2001/83/EC, the Commission shall adopt a delegated act which will set out the practicalities of the safety features including two lists:

- The ‘white’ list: prescription medicines that shall not bear the safety features
- The ‘black’ list: non-prescription medicines that shall bear the safety features

Directive 2011/62/EU stipulates that when drawing- up the 'black' list and the 'white' list, both the risk of the medicine being falsified and the risk arising from falsified medicines (i.e. the potential hazard) should be taken into account. The Directive also sets out the criteria that will need to be applied to evaluate these risks:

1. The reimbursement price and the sales volume of the medicinal product;
2. The number and frequency of previous incidents of falsified medicines reported in the Union and in third countries;
3. The specific characteristic of the product;
4. The seriousness of the conditions intended to be treated;
5. Other potential risks to public health.

The Commission has now asked Member States to submit proposals for medicinal products to be placed on the 'white' or 'black' list, taking into account the assessment criteria set by Directive 2011/62/EU and the criteria set by the Commission in Annex 1.

To include a prescription only medicines on the ‘white’ list all criteria in Annex 1 will need to be met. To include a non-prescription medicine on the ‘black’ list only criteria 2 (history of falsification) is relevant.

Member States have until 3 October to submit their proposals for the lists to the Commission. The delegated act will provide for a procedure for amending the lists after the lists have been published.

The UK Government is seeking your input for the listing and would like to receive your suggestions for the 'black' list and the 'white' list. We expect to list only a limited number of products.

Please note that any inclusions on the list must meet the criteria and a justification or supporting evidence of how this meets the criteria must be submitted. The template for submission of proposed medicines for inclusion on the ‘white’ and ‘black’ lists can be found in Annex II and is also available as an excel format for your convenience.

If you think that no product should be listed we would also like to hear this from you.

We would be grateful to receive your contributions to the list by **Monday 15 September 2014**.

Please send your contributions to Saira Madden (saira.madden@mhra.gsi.gov.uk).

Yours sincerely,

Jan MacDonald
B.Sc. M.Sc. M.R.Pharm.S.
Group Manager
VRMM

Annex I

The criteria for a prescription only medicine to be included on the 'white' list

A medicine must meet all five criteria to be included on the list.

Criterion 1: Price/Volume	1a. The pharmacy retail price (in the UK: reimbursement price), taxes/fees excluded, is lower than £4. OR 1b. The wholesale price, taxes excluded, is lower than £2.40 OR 1c. The ex-factory price, taxes excluded, is lower than £2.20 OR 1d. The volume of sales is lower than 0.6 pack/1000 inhabitants/year The price to be considered for this criterion is the retail/wholesale/ex-factory price of the medicinal product at the moment the Member State performs the assessment. The pharmacy retail price is the price at which a medicine is sold by a pharmacy, before taxes/fees and before any reimbursement or co-payment is deducted. This is not necessarily the price paid by the patient/customer. **An entry fulfils criterion 1 when at least 67% of the packs that match the INN/pharmaceutical form/strength of the entry fulfil either 1a, 1b, 1c or 1d.**
Criterion 2: Incidents in the EU or third country	The prescription medicinal product should have no documented incident of falsification in the legal supply chain in the EU or in collaborating third countries. **An entry fulfils criterion 2 when 100% of the packs that match the INN/pharmaceutical form/strength of the entry fulfil this criterion.**
Criterion 3: Characteristics of the product	3a. The prescription medicinal product should not belong to any of the below categories at high risk of falsification: • erectile dysfunction (e.g. ATC: G04BE); • weight loss and eating disorders (e.g. ATC: A08); • inhibitors and stimulants of the central nervous system (e.g. ATC: N01A, N02A, N03A, N05, N06A, N06B, N07BC); • anabolic hormones (e.g. ATC: G03B, A14A, H01A) **An entry fulfils criterion 3 when 100% of the packs that match the INN/pharmaceutical form/strength of the entry fulfil this criterion.**
Criterion 4: Severity of the conditions intended to be treated	The prescription medicinal product cannot be a life-saving or life-sustaining medicine, i.e. a medicinal product used to treat or diagnose a life-threatening disease. A life-threatening disease is defined as a disease or condition where the likelihood of death in the short term is high if the patient is deprived of an effective treatment or misdiagnosed due the administration or use of a falsified medicinal product. The definition is intended to include those potentially fatal diseases where death itself may not be imminent, but where treatment is necessary to prevent death in the short term. **An entry fulfils criterion 4 is fulfilled when 100% of the packs that match**

	the INN/pharmaceutical form/strength of the entry fulfil this criterion.
Criterion 5: Other potential risk to public health	The falsification of the medicinal product should not pose any significant risks to public health. **An entry fulfils criterion 5 is fulfilled when 100% of the packs that match the INN/pharmaceutical form/strength of the entry fulfil this criterion.**

The criteria for a non-prescription medicine to be included on the 'black' list

Criterion 1: Incidents in the EU or third country	The non-prescription medicinal product has <u>one or more</u> documented incident of falsification in the legal supply chain in the EU or collaborating third countries.

Annex II

Prescription only medicines to be included on the 'white' list

Active substance (INN)	**Pharmaceutical form**	**Strength**	**ATC**	**Supporting Evidence**
Entry 1				
Entry 2				
Entry 3				
……..				

Non-prescription medicines to be included on the 'black' list

Active substance (INN)	**Pharmaceutical form**	**Strength**	**ATC**	**Supporting Evidence** (please provide evidence of one or more incidents of falsification in the legal supply chain and specify the source of the information).
Entry 1				
Entry 2				
Entry 3				
……..				