### SUMMARY OF ASSESSMENT AND ITS FINDINGS

#### BACKGROUND

Relvar® Ellipta® (fluticasone furoate/vilanterol trifenate) manufactured by GSK is a dry powder for inhalation which was launched in the UK in January 2014. UKMi have assessed this new product using the product safety tool.

The product has marketing authorisation for both asthma and COPD, although the specifics vary according to the product’s strength. The 92/22 mcg strength is for use in asthma and COPD; the higher strength, 184/22 mcg product is for use in asthma only. There are currently a number of licensed preparations on the market containing fluticasone in various formulations; our understanding is that a vilanterol-only inhaler is also in the pipeline.

#### DETAILS OF PRODUCTS ASSESSED

The product was assessed in the form available to patients. I.e. the actual physical product was assessed as the 92/22 mcg strength. In addition a dummy demonstration and training device was available, as was an image of the 184/22 mcg strength. Images of the device (but not the outer packaging) for both strengths are reproduced below.

#### CONCLUSIONS FOLLOWING APPLICATION OF VALIDATED ASSESSMENT TOOL

Our main concern is that it is unclear that the inhaler is of a preventer rather than a reliever type, and this may cause confusion for patients and introduce potential for inappropriate use. Our concerns relate firstly to the name of the inhaler: “Relvar® Ellipta®”, which looks and sounds too much like “reliever”. These concerns are compounded by the extensive use of the colour BLUE on the low strength inhaler (which has blue outer packaging, inner label, and lid); similarly the higher strength inhaler has a BLUE lid (although with a pink label).

We have a number of additional concerns:

- Once the foil pack is opened and the desiccant removed, the product has a relatively short in-use shelf life of 6 weeks. Whilst the shelf life does allow for complete use of the inhaler at the licensed dose, it may not facilitate efficient use should patients wish to keep more than one device in different locations (which would be relatively common for patients with asthma or COPD). In practice, the risk of patients using an out-of-date device may therefore be greater than with other devices. In addition, since the product is moisture sensitive, patients and prescribers may have concerns if patients take their device to more humid countries.
- Relvar® Ellipta® is the name of the product, whilst the device is called Ellipta®. However, in our view, the brand name of the product is not suitably differentiated from the name of the device on much of the packaging. This has the potential to cause confusion, particularly as and when further Ellipta® products become available.
- Similarly, the generic constituent names and other details are written in 3 languages on both the device and outer labelling. Again, this introduces a potential for confusion.
- Micrograms are stated using both the conventional “mcg” and the outside convention “µg”. It is unclear why such labelling is in place, but it introduces a potential for confusion.

In summary, there are, in our view, potential safety issues related to the presentation of this new inhaler device. NHS organisations and individual prescribers and patients need to decide whether the level of potential risk is acceptable.

#### POTENTIAL NEXT STEPS AND MITIGATION ACTIONS

In our view, the manufacturer of the device should consider:

- The potential medication safety implications of using the colour BLUE quite extensively on an inhaler of this type and whether this can be changed. In addition, it remains to be seen whether Relvar® Ellipta® is a suitable name for such an inhaler.
- Removing the “µ” abbreviation and replacing this with the word “micrograms”.
- Including fewer languages (ideally one per market) on the product’s packaging and labelling.
- Support that helps patients use the device within the limited expiry window. For example, a box for patients...
to write on the label the date opened would be useful.

- Improving the clarity of the generic drug names, brand name, and device name to make product selection easier and safer.

Recommendations for local users

- We suggest that decision making groups for health economies and individual prescribers consider in detail whether introduction of the risks identified above are offset by any clinical or other gains offered by the product.
- If the inhaler is used, we recommend careful counselling and advice is provided to patients. In particular, this should ensure that they are aware of the presentational issues above, the name of the inhaler and the device, and that this is NOT (despite its colour) a reliever inhaler. In addition, patients should also be informed that the device has a relatively limited expiry once opened.

This report was produced in March 2014 using the physical product of the low strength inhaler and photographic images of both strengths of Relvar® Ellipta®. Images were obtained from GSK.

This report summarises product assessments undertaken by:
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**IMAGES OF PRODUCTS**