IN USE PRODUCT SAFETY ASSESSMENT REPORT FOR Anoro® Ellipta®
(umeclidinium/vilanterol inhalation powder)

SUMMARY OF ASSESSMENT AND ITS FINDINGS, September 2015

BACKGROUND
Anoro® Ellipta® 55/22 micrograms (umeclidinium/vilanterol trifenatate) manufactured by GSK is a dry powder for inhalation which was launched in the UK in July 2014. UKMI has assessed this new product using the UKMI product safety tool.

The product is indicated for maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). It one of three Ellipta® inhalers available the UK.

Other Ellipta® products are:
- Relvar® containing vilanterol trifenatate and fluticasone (note: two strengths are available; the 99/22 microgram strength is licensed for COPD and asthma and the 184/22 microgram strength is licensed for asthma only) and
- Incruse® containing umeclidinium bromide

DETAILS OF PRODUCTS ASSESSED

Images of the Anoro® Ellipta® product and associated labels were assessed. In addition a dummy demonstration and training device was available. Images of the outer packaging and device are re-produced below. Minor packaging and PIL changes have been approved and images will updated when available.

CONCLUSIONS FOLLOWING APPLICATION OF VALIDATED ASSESSMENT TOOL

The following points were raised after independent consideration of the product by two pharmacists.

- As with the other currently available Ellipta® inhalers, once the foil pack is opened and the desiccant removed, Anoro® Ellipta® 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 licenced dose, it may not facilitate efficient use should patients wish to keep more than one device in different locations. In practice, the risk of patients using an out-of-date device may be greater than with other devices, although the additional information advising patients not to open the tray until they are ready to inhale a dose and for the patient to write the discard date on the Ellipta® label mitigates this risk.

- Two other Ellipta® devices are available which contain components of the Anoro® product; Relvar® (contains vilanterol) and Incruse® (contains umeclidinium only) and therefore there is potential for confusion with each other when prescribing and dispensing, particularly if selecting from generic names on prescribing systems. This issue may of course apply to other inhaler devices which are available with similar variations of constituents.

- The generic constituent names and other details are written in 3 languages on both the device and outer labelling. This introduces a potential for confusion.

- Micrograms are stated in full and using the conventional “mcg” and the outside convention “µg”. This was stipulated in the EU labelling requirements but could introduce a potential for confusion.

POTENTIAL NEXT STEPS AND MITIGATION ACTIONS

The manufacturer of the device has recently changed the packaging to help patients use the device within the limited expiry window. The new packaging will be available from October 2015. Both versions of the packaging will be available whilst old stock is used up.

Recommendations for local users
- We recommend careful counselling and advice is provided to patients. In particular, this should ensure that they are aware that there are currently two other Ellipta® inhalers on the market, containing components of Anoro®. There are also more Ellipta® devices in the pipeline. In addition, patients should also be informed that the device has a relatively limited expiry once opened which should be marked on the label.

- Prescribing and dispensing systems (both electronic and paper-based) should be reviewed to minimise the likelihood of prescribing or selecting the wrong Ellipta® product. Particularly as new Ellipta® products are launched to the UK market.
This report was produced in September 2015 using actual and photographic images of Anoro® Ellipta®. Images were obtained from GSK. The images will be updated when available.

This report summarises product assessments undertaken by: East Anglia Medicines Information Service (Ipswich) and Northern and Yorkshire Regional Drug and Therapeutics Centre (Newcastle). Contact email eastanglia.mis@ipswichhospital.nhs.uk

IMAGES OF PRODUCTS