



Interface Prescribing & New Therapies Subgroup



26th July 2011

Roflumilast (Daxas®▼) for the maintenance treatment of Chronic Obstructive Pulmonary Disease (COPD)

The Interface Prescribing & New Therapies Subgroup of the GMMMG discussed the above drug for the above indication. The recommendation of this subgroup is as follows*:

The New Therapies Subgroup of the GMMMG considered the use of Roflumilast (Daxas®▼) for the maintenance treatment of patients with COPD.

The group does not recommend the use of roflumilast.

On a re-review of clinical data roflumilast could not be recommended as all clinical efficacy data currently available was against placebo and for a maximum duration of 52 weeks. Therefore longer term benefits and safety of roflumilast and its place in therapy are currently unknown.

In addition the results of the clinical studies do not provide any indication as to which combinations of therapies may be most appropriate – in particular whether the use of roflumilast as an alternative to or as an addition to inhaled corticosteroids.

According to set criteria roflumilast was deemed to be a low priority for funding

Review date: July 2013

* Unless superseded by NICE guidance or substantial and significant new evidence becomes available.

▼ Newly marketed drugs and vaccines are intensively monitored for a minimum of two years, in order to confirm the risk / benefit profile of the product. Healthcare professionals are encouraged to report all suspected adverse drug reactions regardless of the severity of the reaction.