



Final Appraisal Recommendation

Advice No: 4012 – December 2012

Sildenafil (Revatio[®]▼) 10 mg/ml powder for oral suspension

Limited submission by Pfizer Ltd

Recommendation of AWMSG

Sildenafil (Revatio[®]▼) 10 mg/ml powder for oral suspension is recommended as an option for use within NHS Wales for the treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease.

Additional notes:

- AWMSG noted the FDA safety alert and obtained further advice from the MHRA and clinical experts to inform their decision.
- AWMSG is of the opinion that sildenafil (Revatio[®]▼) powder for oral suspension is appropriate for specialist only prescribing within NHS Wales for the above recommendation.

In reaching the above recommendation AWMSG has taken account of the AWMSG Secretariat Assessment Report (ASAR), the preliminary appraisal recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue:	Pfizer Ltd
Date of first issue	December 2012
Last reviewed	September 2016



NICE has accredited the process used by the All Wales Medicines Strategy Group (AWMSG) to produce its final appraisal recommendation. Accreditation is valid for 5 years from October 2011. More information on accreditation can be viewed at www.evidence.nhs.uk.

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