

Monthly briefings are produced in order to help members of the media and other interested groups understand the work and advice of the Scottish Medicines Consortium. The full advice for each drug that we have assessed can be found at [www.scottishmedicines.org](http://www.scottishmedicines.org)

SMC has this month accepted the following drug for use within NHSScotland.

## Saxagliptin (Onglyza<sup>®</sup>)

SMC accepted saxagliptin for the treatment of type 2 diabetes mellitus in adult patients as add-on combination therapy with metformin, when metformin together with diet and exercise does not provide adequate glycaemic (blood sugar) control.

Saxagliptin is restricted for use in patients only when the addition of sulphonylureas is not appropriate, and represents an alternative to other agents such as thiazolidinediones.

- Diabetes mellitus is a condition in which there is too much sugar present in the blood. Type 2 diabetes develops when the body does not make enough insulin (a hormone which helps sugar to be used by the body) or the insulin that is produced does not work properly. Keeping blood sugar levels as near to normal as possible reduces the risk of long-term diabetes complications such as heart disease, blindness, stroke and kidney failure.
- Saxagliptin is one of a new class of oral antidiabetic agents known as dipeptidyl peptidase-4 inhibitors or incretin enhancers. Incretin hormones, such as glucagon-like peptide 1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), stimulate the release of the hormone insulin. In type 2 diabetes, incretin function is damaged and patients are unable to properly regulate their blood sugar levels. Medicines in this new class are expected to produce a more sustained effect on glucose control. Saxagliptin is taken as a tablet once daily.

## About SMC

The purpose of the Scottish Medicines Consortium (SMC) is to accept for use those newly licensed drugs that clearly represent good value for money to NHSScotland.

SMC analyses information supplied by the drug manufacturer on the health benefits of the drug and justification of its price.

Because the NHS has limited resources, SMC works to make sure that those drugs which represent good value for money are accepted for routine use as quickly as possible so that they can benefit patients.

The Consortium is made up of lead clinicians, pharmacists and health economists together with representatives of health boards, the pharmaceutical industry, the public and the Scottish Government.

### ■ Contact Details

If you are interested in the work of SMC you can visit our website at:

[www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk)

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- In two randomised controlled studies, saxagliptin was as effective as another dipeptidyl peptidase-4 inhibitor in reducing glycated haemoglobin (average blood glucose level over the past 2–3 months). In addition, saxagliptin had little effect on mean body weight.
- Saxagliptin was generally well tolerated, with side effects of infection and hypoglycaemia reported in both treatment groups. No cardiovascular side effects were reported in the saxagliptin group.
- SMC accepted saxagliptin for restricted use because it was considered to offer value for money.

SMC decided that the following drugs are not value for money for NHSScotland.

## Extended release epidural morphine (Depodur<sup>®</sup>)

SMC did not accept extended release epidural morphine (EREM) for the relief of postoperative pain following major orthopaedic, abdominal or pelvic surgery.

- Major surgery can result in the patient experiencing significant pain and therefore requiring pain relief medication.
- The epidural space is the area outside the spinal cord but inside the vertebral canal of the spinal column. The epidural space is used for drug administration as it allows the drug to be injected near to the spinal cord and the nerves surrounding it and therefore helps to relieve the pain caused by surgery. This particular product is described as an extended-release injection as the pain relief lasts for about 48 hours after one dose has been given.
- In some studies, EREM was shown to give better pain relief than a single dose of a short-acting form of an epidural opioid drug (strong pain killer). However, evidence for efficacy was obtained from studies that do not reflect current practice for epidural analgesia in NHSScotland.
- EREM was generally well tolerated with side effects similar to short-acting epidural morphine, though itch and difficulties with urine production occurred more often with the higher doses of EREM.
- SMC did not accept EREM for use within NHSScotland because a number of weaknesses in the case submitted by the manufacturer meant that value for money was not demonstrated. The key weakness was the inclusion of savings from reduced time in a high dependency unit and reduced length of hospital stay associated with EREM. These savings were estimated from studies conducted in other countries, but are unlikely to be realised in Scottish practice.

## Ketoprofen/omeprazole (Axorid<sup>®</sup>)

SMC did not recommend ketoprofen/omeprazole for the symptomatic treatment of rheumatoid arthritis, ankylosing spondylitis and osteoarthritis in patients with a previous history or who are at risk of developing nonsteroidal anti-inflammatory drug (NSAID)-associated gastric ulcers, duodenal ulcers and gastroduodenal erosions in whom continued treatment with ketoprofen is essential.

- Rheumatoid arthritis, ankylosing spondylitis and osteoarthritis are conditions affecting joints and the surrounding soft tissues. Rheumatoid arthritis is a chronic condition in which the immune system attacks the lining of the joints, causing them to become inflamed and stop working properly. Ankylosing spondylitis is the persistent inflammation of the spine and sacroiliac joints (joints that lie at the junction of the spine and the pelvis) in the pelvis eventually causing fusion of the spine. Osteoarthritis is a condition characterised by the breakdown of the cartilage (the smooth surface that lines the bones and allows joints to move easily) of the joint. Symptoms for these rheumatic disorders vary, ranging from mild discomfort to progressively debilitating which interferes with movement and daily activities.
- Treatment for these rheumatic conditions include NSAIDs (such as aspirin and ibuprofen) to reduce symptoms of inflammation, relieve pain and swelling. A serious unwanted effect of NSAIDs is the increased risk of ulcers developing in the gastrointestinal tract due to length of their use and high doses. Axorid<sup>®</sup> is a new product containing a prolonged-release form of the NSAID ketoprofen in combination with a proton pump inhibitor omeprazole, which reduces the amount of acid produced in the stomach. This new formulation reduces the risk of NSAID side effects of NSAIDs on the stomach and duodenum in patients already suffering from ulcers that need continuous anti-inflammatory treatment. Ketoprofen/omeprazole is taken as a tablet once daily depending on symptoms.
- No clinical efficacy and safety studies were deemed necessary as ketoprofen and omeprazole are already approved for their respective indications. Several studies in healthy volunteers showed the bioequivalence of this combination product to the reference products.
- SMC did not accept ketoprofen/omeprazole for use because a number of weaknesses in the economic case submitted by the manufacturer meant that value for money was not demonstrated. The key weakness was the manufacturer's use of an inappropriate comparator.

For drugs that have not been accepted by SMC, all NHS boards have procedures in place to consider individual requests when a doctor feels the drug would be right for a particular patient. SMC has told the manufacturers why the drug was not accepted and would be pleased to receive any resubmission.

For further information and to view the complete advice for the drugs listed above, visit our website at:

[www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk)