SMC2876

levodopa 20mg/mL + carbidopa monohydrate 5mg/mL + entacapone 20mg/mL intestinal gel (Lecigon®)

Britannia Pharmaceuticals Ltd

10 July 2026

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutics Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following a resubmission

levodopa 20mg/mL + carbidopa monohydrate 5mg/mL + entacapone 20mg/mL intestinal gel (Lecigon®) is accepted for restricted use within NHSScotland.

Indication under review: treatment of advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available oral combinations of Parkinson medicinal products have not given satisfactory results.

SMC restriction: for use in patients not eligible for deep brain stimulation (DBS).

Evidence from a phase I pharmacokinetic study showed that the dose-adjusted levodopa exposure was significantly higher with Lecigon® treatment, when compared with levodopa + carbidopa monohydrate intestinal gel (Duodopa®); the relevant comparator for this submission. Supportive evidence from a real-world study and an indirect comparison provided by the company suggest comparable efficacy and safety between these two treatments.

This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.

Chair
Scottish Medicines Consortium

1. Clinical Context

1.1. Medicine background

Lecigon® is a combination of levodopa, carbidopa and entacapone (ratio 4:1:4) in the form of an intestinal gel and is available in cartridges for administration using a portable pump (Crono LECIG). Lecigon® is administered as a continuous intestinal infusion directly into the duodenum or upper jejunum via percutaneous endoscopic gastrostomy with jejunal tube (PEG-J).[1]

The total daily dose comprises of three individually adjusted doses: the morning bolus dose, the continuous maintenance dose and extra bolus doses. Treatment is usually limited to the patient's awake period but can be administered up to 24 hours per day, if medically justified. The maximum recommended daily dose is 100 mL (which corresponds to 2,000 mg levodopa, 500 mg carbidopa monohydrate and 2,000 mg entacapone). See the Summary of Product Characteristics (SPC) for more details. SMC has previously issued not recommended advice for Lecigon® for this indication and positioning (SMC2507).

1.2. Disease background

Parkinson's disease (PD) is a progressive, neurodegenerative movement disorder characterised by the core motor symptoms of rigidity, postural instability, resting tremors and bradykinesia. The condition is also associated with non-motor symptoms such as sleep disturbance, brain fog, and constipation.[2, 3] It is primarily a condition of older adults, with prevalence rising from 50 years of age; patients typically progress to the advanced stages of PD within 10 to 20 years of the early onset of symptoms .[4, 5] Advanced PD is typically associated with motor fluctuations which include 'on' periods (with normal function and control of symptoms) and 'off' periods (with weakness and restricted mobility).[2] People with advanced PD may also experience complications such as anxiety, depression, swallowing difficulties and dementia.[6] Oral levodopa is the first-line treatment for patients in the early stages of PD who have motor symptoms. In advanced PD, the effectiveness of levodopa treatment is reduced, which can lead to periods of both hyperkinesia (increased movements) and dyskinesia (abnormal and involuntary movements) and can be difficult to treat.

1.3. Company proposed position

The submitting company has requested that Lecigon® is restricted for use as per the licensed indication in patients who are not eligible for deep brain stimulation (DBS).

1.4. Treatment pathway and relevant comparators

At present, PD is incurable and the goal of treatment is to provide symptom control and improve quality of life. Oral levodopa is the first-line treatment for patients in the early stages of PD who have motor symptoms. To increase the levodopa availability in the brain, it can be administered with a dopa decarboxylase inhibitor, like carbidopa. As PD progresses, additional treatments can be added to manage motor symptoms, including catechol-O-methyl transferase (COMT) inhibitors like entacapone.[7]

For this indication and positioning, treatment options include continuous intrajejunal infusion of levodopa + carbidopa (Duodopa®) intestinal gel (SMC316/06), subcutaneous apomorphine, and continuous subcutaneous foslevodopa + foscarbidopa (Produodopa®) infusion (SMC2574). The

submitting company considered Produodopa® and apomorphine not to be relevant comparators due to the route of administration. Clinical experts consulted by SMC confirmed that Duodopa® is the most relevant comparator for this submission.

1.5. Category for decision-making process

Eligibility for a PACE meeting

Lecigon® meets SMC orphan equivalent criteria.

2. Summary of Clinical Evidence

2.1. Evidence for the licensed indication under review

The evidence to support the use of Lecigon® comes from the LSM-003 study. Details are summarised in Table 2.1.

Table 2.1. Overview of relevant study

Criteria	LSM-003[8-10]
Study design	Single-centre, 2-day, open-label, randomised, cross-over, phase I pharmacokinetic study.
Eligible patients	• Aged ≥ 30 years • Advanced levodopa-responsive Parkinson's disease (PD) • On stable Duodopa® treatment (<125 mL per day) for a minimum of 30 days prior to the study • No fluctuation in clinical PD symptoms within 7 days prior to screening • Body mass index (BMI) between 17.0 kg/m^2 and 31.0 kg/m^2 • No prior exposure to entacapone within 3 months prior to the study
Treatments and Randomisation	Patients were randomised equally to receive one of two treatment sequences over two consecutive days: Lecigon® followed by Duodopa® (n=6) or Duodopa® followed by Lecigon® (n=5). Both treatments were administered via the same gastrojejunostomy tube and consisted of three individually adjusted and predefined doses within a 14-hour period: a morning dose, a continuous 14-hour infusion (maintenance dose) and extra bolus doses (if required). The Lecigon® doses (morning, maintenance and bolus) corresponded to 80% of the pre-study Duodopa® doses, except in six patients who received morning doses corresponding to 90% of the pre-study Duodopa® doses. All maintenance Duodopa® doses corresponded to 100% of the pre-study individually optimised doses of Duodopa®. All patients completed the 14-hour infusion on day 1 and crossed over to receive the alternative study treatment on day 2. Oral immediate release levodopa + carbidopa tablets (Sinemet®)[11] were permitted as PD rescue medication after stopping the infusion and for up to 3 hours before the second infusion. Concomitant anti-PD medicines, such as dopamine agonists and monoamine oxidase-B inhibitors, were allowed if the doses had been stable for more than 30 days before the study.
Primary outcome	Systemic exposure of levodopa, measured by the dose-adjusted Area Under the Curve (AUC) between hours 0 to 14 (AUC_{0-14}/dose) for levodopa.
Selected exploratory outcomes	Change in mean Treatment Response Scale (TRS) scores. The TRS is a 7-point scale ranging from -3 (severe parkinsonism) to 0 ('on' state with no dyskinesia) to +3 ('on' state with severe choreatic dyskinesia). Trained study nurses assessed patient motor function according to the TRS at the same times as the pharmacokinetic blood sampling.
Statistical analysis	Efficacy analyses were performed in the full analysis set (FAS), which included all randomised patients who were diagnosed with PD, were exposed to both study drugs and had sufficient data to compute primary or secondary pharmacokinetic variables in both periods.

Results

In LSM-003, the mean total dose of levodopa administered was lower in the Lecigon® group (875 mg) compared with the Duodopa® group (1,142 mg).[10] The dose-adjusted AUC (AUC_{0-14}/dose) for levodopa was higher with Lecigon® compared with Duodopa®, with a ratio of 1.34 (95% confidence interval [CI] 1.19 to 1.45); this was statistically significant. Systemic exposure to levodopa (AUC_{0-14}) was similar for both formulations with an AUC ratio of 1.10 (95% CI 0.95 to 1.17).[8, 10] There was no difference in mean TRS scores between treatments.[8, 10]

2.2. Evidence to support the positioning proposed by the submitting company

To support the proposed positioning, that is those who are not eligible for DBS, the submitting company highlight that the mean age of patients recruited in the LSM-003 study and ELEGANCE study (see section 2.4) was 69.5 years and 68.2 years respectively. DBS is not recommended for patients over the age of 70 by the European Federation of Neurological Societies/Movement Disorders Society-European Section (EFNS/MDS-ES) guideline[7], and the higher risk and invasive nature of DBS precludes many patients with advanced disease.[12]

2.3. Health-related quality of life (HRQoL) outcomes

No HRQoL outcomes were assessed in LSM-003. However, HRQoL was assessed in the ELEGANCE study (see section 2.4) using the 8-item Parkinson's Disease Questionnaire (PDQ-8). Following treatment with Lecigon®, the mean PDQ-8 summary index scores improved from baseline at visits 2 and 3.[13]

2.4. Supportive studies

The submitting company also presented evidence from the real-world ELEGANCE study in their submission. ELEGANCE (NCT05043103) is an ongoing, observational study aimed at assessing the long-term effectiveness and safety of Lecigon®. Recruitment was carried out in 13 European countries from July 2021 and finished in September 2024. The study recruited patients who had advanced PD with motor fluctuations despite taking optimised oral or transdermal PD therapy and who were already on Lecigon® (for up to 3 months before giving informed consent) as part of routine clinical practice. Patients were observed at an initial assessment visit prior to starting Lecigon® treatment; follow-up visits took place after approximately 3 to 6 months of treatment (visit 2), 6 to 12 months of treatment (visit 3) and then every 6 months thereafter for up to 24 months of Lecigon® treatment. Results from the planned interim analysis (data cut December 2023) after up to 12 months of treatment are available (median follow-up of 182 days). At this analysis, 167 patients had at least one measure of effectiveness at visit 2 or visit 3. The majority (87%) of patients had prior oral dopamine replacement therapy before switching to Lecigon®, while 13% of patients switched from a device-aided infusion therapy comprising of either Duodopa® (8.4%) or apomorphine (4.8%) infusion therapy. Compared with baseline (visit 1), Lecigon® treatment reduced the daily hours of 'off' time (a state of poor symptom control) by approximately 3.5 hours at visit 2, and this was maintained at visit 3; this was observed in patients who had switched from oral medication or from an infusion therapy. Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) part II and part IV total scores were also improved at visits 2 and 3 compared with baseline, suggesting overall improvements in functional

ability and motor fluctuations. These improvements exceeded the minimal clinically important difference (MCID) thresholds.[13]

2.5. Indirect evidence to support clinical and cost-effectiveness comparisons

In the absence of long-term direct evidence comparing Lecigon® with Duodopa®, the submitting company provided a naïve indirect treatment comparison (ITC); a naïve ITC versus Produodopa® was also carried out for completeness but will not be discussed further as it is not a relevant comparator. The ITCs were used to support the use of a cost-minimisation analysis in the economic case. Further details are presented in Table 2.2.

Table 2.5: Summary of indirect treatment comparison

Criteria	Overview
Design	Naïve indirect treatment comparison (ITC)
Population	Patients with advanced Parkinson's disease (PD)
Comparators	Lecigon® compared with Duodopa®
Studies included	Real-world data from three international, observational studies were included in the ITC: ELEGANCE (for Lecigon®)[13], GLORIA (for Duodopa®)[14-16] and DUOGLOBE (for Duodopa®)[17, 18]
Outcomes	Outcomes were assessed descriptively in a side-by-side comparison of the study results (assessed at 12 months), including: • Change in daily 'off' time from baseline • Change in Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) part II score (UPDRS part II score in the comparator studies)[a] • Change from baseline in Parkinson's Disease Sleep Scale (PDSS-2) total scores • Parkinson's Disease Questionnaire 8-item (PDQ-8) or 39-item (PDQ-39) summary index change from baseline • Safety outcomes (including treatment-emergent adverse events [AEs], AEs associated with study medicine, AEs leading to treatment discontinuation, serious and severe AEs, deaths and specific AEs)
Results	Overall, the results suggest that the treatments had comparable efficacy. However, there was a notable difference in change in MDS-UPDRS (or UPDRS) part II score between the ELEGANCE and DUOGLOBE studies (-3.4 versus 0.7), which may reflect differences in baseline scores (20.7 versus 14.8) and outcome definitions between the studies

[a] A decrease in MDS-UPDRS part II indicates an improvement in the severity of symptoms relating to activities of daily living

3. Summary of Safety Evidence

Evidence from LSM-003 provides very limited safety information of Lecigon® compared with Duodopa®, which is the relevant comparator. Evidence from ELEGANCE supports the safety of Lecigon® for this indication; however, no comparative safety data are available. The expected safety profile for Lecigon® is based on available data from clinical trials and post-marketing experience of levodopa/carbidopa intestinal gel and oral levodopa/carbidopa/entacapone.[1] Safety outcomes were also assessed in the ITC and suggest that comparable safety between Lecigon® and Duodopa® appears reasonable.

In LSM-003, 16 adverse events (AEs) were reported in the study; 10 AEs were reported by 55% (6/11) of patients on Lecigon® and 6 AEs were reported by 18% (2/11) of patients on Duodopa®. AEs considered to be associated with Lecigon® were headache, nausea and dizziness. No serious or

severe AEs were reported during this 2-day study, and no AE led to study discontinuation or change in therapy. No clinically important changes in vital signs, electrocardiograms or physical examinations occurred. No adverse reactions were considered to be associated with the pump during administration of Lecigon®.[8, 10]

In ELEGANCE, the median Lecigon® treatment duration was 182 days (range: 76 to 592 days) at the interim analysis (data cut December 2023). In the safety analysis set (n=167), 50% of patients reported an AE before or at visit 3; the most common AEs were either procedure (16%) or device-related (17%), which is expected given the known safety profile of Lecigon®. Three patients (1.8%) discontinued the study before or at visit 3.[13]

4. Summary of Clinical Effectiveness Considerations

4.1. Key strengths

- Lecigon® is the first intestinal gel preparation containing entacapone approved for the treatment of advanced PD.[19] Entacapone has been shown to increase the bioavailability of levodopa, thereby providing the same effective levodopa dose at a lower dose of administered levodopa. This was observed in the 2-day, randomised, phase I pharmacokinetic study, LSM-003 where the dose-adjusted $AUC_{0\text{-}14h}$ for levodopa was higher with Lecigon® compared with Duodopa®, despite giving a reduced mean levodopa dose with Lecigon®. However, a larger study would be needed to confirm that a reduction in levodopa dose would result in clinically meaningful benefits for patients.
- In ELEGANCE, Lecigon® treatment for up to 12 months provided sustained control of motor symptoms and was well tolerated. HRQoL also improved as measured by PDQ-8 summary index score from baseline[13]; these improvements exceeded the MCID thresholds.[20]

4.2. Key uncertainties

- Clinical evidence came from a phase I pharmacokinetic study (LSM-003). While this study may provide useful information on bioavailability, it was not designed to compare treatments in terms of clinical response. The study also had very limited patient numbers (n=11) and short observation period (17 hours repeated over two consecutive days); therefore, it is unclear whether these results translate into meaningful clinical outcomes.
- Aside from LSM-003, there are no direct data comparing Lecigon® with the most relevant comparator (Duodopa®). The submitting company provided a naïve ITC which has inherent limitations and differences between studies (for example, in terms of baseline severity and outcome definitions) may bias the results. The eligibility criteria of the included studies (for example, in terms of DBS eligibility) may also affect the generalisability of the results. Feedback from a statistician consulted by SMC considered the naïve ITC to be inappropriate and advised that a sensitivity analysis adjusting for these population differences would be appropriate. However, despite the inherent limitations of naively comparing observational studies, the company's conclusion that Lecigon® has comparable efficacy with Duodopa® appears reasonable given the similarities of the active ingredients. Lecigon® will offer patients an alternative to Duodopa®.

- There were several limitations with the ELEGANCE study. The results are exploratory interim findings (up to 12 months) of an uncontrolled, observational study; there was no randomisation or control group. There was no sample size calculated and there was no adjustment for multiplicity. There are likely to be differences in clinical practice and data collection between the treatment centres which may influence treatment outcomes; none of the treatment centres were in the UK which also limits generalisability to Scottish practice. The study population only included 22 patients who switched from Duodopa® (n=14) or apomorphine (n=8) and none from Produodopa®; it is likely that some patients in clinical practice who are eligible for Lecigon® would switch from these treatments.[13]
- The submitting company highlighted that the Lecigon® pump with a full cartridge is less than half the weight of the Duodopa® pump with a full cassette and is smaller in size.[8] The submitting company provided evidence from ELEGANCE[13] and other observational studies[21, 22] which showed that most study participants found the Duodopa® pump was large, heavy and bulky; however, most participants would still recommend it to others. The evidence also suggested that switching to Lecigon® may improve user-friendliness; however, this is based on small numbers and it is unknown if this improves quality of life.[13]

4.3. Clinical expert input

Clinical experts consulted by SMC considered that there is no unmet need due to the pre-existing availability of Duodopa®. They were mixed in their views that Lecigon® is a therapeutic advancement; some felt that the number of patients who would benefit from its availability would be small while others noted the potential benefits of reduced levodopa doses and smaller pump. While Duodopa® is the most relevant comparator, it is underutilised in this patient group at present.

4.4. Service implications

Clinical experts consulted by SMC did not anticipate any additional service implications since the service is already set up to deliver Duodopa®, including the surgical procedure to insert a PEG-J.

5. Summary of Patient and Carer Involvement

The following information reflects the views of the specified Patient Group.

- We received a patient group submission from Parkinson's UK Scotland, which is a registered charity.
- Parkinson's UK Scotland has received 0.1% pharmaceutical company funding in the past two years, including from the submitting company.
- Advanced Parkinson's is extremely challenging to live with, both for the person with the condition and those closest to them. Many people can achieve a reasonable level of symptomatic control with conventional medication, but some experience extreme symptoms. These people have very poor quality of life, and need a lot of support from unpaid carers, health and social care professionals.
- There are very limited treatment options: Deep Brain Stimulation (DBS) surgery and continuous dopaminergic infusion (Duodopa). There are considerable contraindications

and barriers to accessing DBS surgery, which mean that it is not accessible to many people with advanced Parkinson's. Lecigon would provide an alternative for people who may do less well on Duodopa, or who have not been able to tolerate it.

- The smaller size and weight of the Lecigon pump and cassettes are likely to make this an attractive option for people needing continuous dopaminergic stimulation, especially for those who are older or frailer.
- Everyone with Parkinson's follows an individual medication regime, and individuals respond differently to different oral medications - it may be helpful to have more than one option for continuous dopaminergic infusion.

6. Summary of Comparative Health Economic Evidence

6.1. Economic case

An economic case was provided by the submitting company and is summarised in Table 6.1.

Table 6.1 Description of economic analysis

Criteria	Overview
Analysis type	Cost-minimisation analysis
Time horizon	7 years
Population	Patients with advanced Parkinson's disease not eligible for DBS
Comparators	Lecigon® was compared against Duodopa® and Produodopa®. Clinical expert feedback received by SMC suggested that Duodopa® was the main comparator used in Scottish practice, and so this was the focus of the appraisal. Details of the comparison with Produodopa® are not presented here.
Model description	A cost-minimisation analysis was conducted. Costs were calculated on a per-cycle basis of 28 days.
Clinical data	The LSM-003 study offered direct clinical comparison between Lecigon® and Duodopa®.[8] This formed the basis for a cost-minimisation model, as the treatment effect was assumed equivalent between these treatments. The assumption of equivalence was further supported by a naïve indirect treatment comparison (ITC) using data from the ELEGANCE and GLORIA studies. The ELEGANCE study informed the dosing for Lecigon®.[13] The GLORIA study informed the dosing for Duodopa®.[14-16]
Extrapolation	Equal treatment efficacy between Lecigon® and Duodopa® was assumed across the full time horizon of the model.
Quality of life	Not applicable.
Costs and resource use	Medicine acquisition costs were included for all treatments. Resource use costs were not included in the analysis, as these were assumed to be equivalent for Lecigon® and Duodopa®. Adverse event costs were also not included as the safety profile was assumed equivalent between all treatments.
PAS/contract price	A Patient Access Scheme (PAS) was submitted by the company and assessed by the Patient Access Scheme Assessment Group (PASAG) as acceptable for implementation in NHSScotland. Under the PAS, a discount was offered on the list price. A PAS discount is in place for Duodopa® and this was included in the results used for decision-making by using estimates of the comparator PAS price.

6.2. Results

SMC considered results for decision-making that took into account all relevant PAS. SMC is unable to present these results due to competition law issues. SMC would wish to present the with-PAS cost-effectiveness results that were used for decision-making. However, SMC is unable to publish these results due to commercial in confidence concerns regarding the PAS.

6.3. Sensitivity analyses

A range of sensitivity and scenario analyses were considered, and descriptions of these key scenarios are provided in Table 6.2.

Table 6.2: Scenario analysis versus Duodopa®

	Parameter	Base case	Scenario
1	Daily cartridge use for Lecigon® and Duodopa®	Mean daily cartridge use for Lecigon® and Duodopa® derived from mean daily dose data from ELEGANCE study (Lecigon®) and GLORIA study (Duodopa®) Lecigon: 1.03 Duodopa: 1	Mean daily cartridge use for Lecigon® and Duodopa® derived from mean daily dose data from the LSM-003 study Lecigon: 1 Duodopa: 1
2			Lecigon: 2 Duodopa: 1
3			Lecigon: 1 Duodopa: 2
4			Lecigon: 2 Duodopa: 2
5			Lecigon: 1.5 Duodopa: 1.13
6a	Time horizon	7 years	2 years
6b			5 years

6.4. Key strengths

- The choice of a cost-minimisation model was deemed appropriate for this analysis.
- Duodopa® was explored as the key comparator in the analysis; this aligns with responses from clinical experts contacted by SMC.

6.5. Key uncertainties

- Variation in daily cartridge use for Lecigon® and Duodopa® can shift the intervention from being cost-saving to cost-increasing. In Table 6.4. Scenarios 2 and 5, where patients in the Lecigon® arm use more cartridges than patients in the Duodopa® arm, this has upwards impact on results. However, when based on the ELEGANCE and GLORIA studies, Lecigon® is cost-minimising compared to Duodopa® when cartridges were used in accordance with their SPCs (with appropriate carry-over of unused cartridges while adhering to the 24-hour expiry period).

7. Conclusion

After considering all the available evidence, the Committee accepted Lecigon® for restricted use in NHSScotland.

8. Guidelines and Protocols

In July 2017, the National Institute for Health and Clinical Excellence (NICE) published clinical guidance for PD in adults (Guideline 71); last updated in May 2026.[23]

In 2013 the European Federation of Neurological Societies and Movement Disorder Society-European Section (EFNS/MDS-ED) produced a summary of recommendations for the therapeutic

management of PD.[7] In 2022, an updated guideline was published on the use of invasive therapies for PD.[24]

9. Additional Information

9.1. Product availability date

24 September 2024.

Table 9.1 List price of medicine under review

Medicine	Dose regimen	Cost per year (£)
levodopa 20mg/mL + carbidopa monohydrate 5mg/mL + entacapone 20mg/mL intestinal gel (Lecigon®)	**1 to 2 cartridges per day**	**27,667 to 55,334**

Note: one Lecigon® cartridge is 47 mL; the maximum recommended daily dose is 100 mL, however based on the ELEGANCE study more than two cartridges per day were rarely needed. Costs from BNF online on 30 April 2026. Costs calculated using the full cost of vials/ampoules assuming wastage. Costs do not take any patient access schemes into consideration.

10. Company Estimate of Eligible Population and Estimated Budget Impact

The submitting company estimated there would be 46 patients eligible for treatment with Lecigon® in year 1, increasing to 54 patients in year 3. The estimated uptake rate was 55% in year 1 and 75% in year 3. This resulted in 25 patients estimated to receive treatment in year 1 rising to 40 patients in year 3.

SMC is unable to publish the budget impact due to commercial in confidence issues. A budget impact template is provided in confidence to NHS health boards to enable them to estimate the predicted budget impact. This template does not incorporate any PAS discounts associated with comparator medicines.

*Other data were also assessed but remain confidential.**

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This assessment is based on data submitted by the applicant company up to and including 14 May 2026.

**Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal:*https://www.scottishmedicines.org.uk/about-us/policies-publications/

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC includes Scottish national contract prices in its decision-making. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document.

Patient Access Schemes (PAS): A PAS is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. The Patient Access Scheme Assessment Group (PASAG), established under the auspices of Public Services Delivery Scotland, reviews and advises NHS Scotland on the feasibility and acceptability on implementing proposed schemes. PASAG operates separately from SMC to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHS Scotland on the basis of a PAS that has been considered acceptable for implementation by PASAG, a set of guidance notes on the operation of the scheme will be circulated to health boards' Area Drugs and Therapeutics Committees prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after careful consideration and evaluation of the available evidence. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.