

Resubmission of medicines not recommended after PACE consideration

From May 1st 2015, resubmissions for medicines that have been not recommended after a [Patient and Clinician Engagement \(PACE\)](#) meeting will be expedited where the only change in the resubmission relates to the product's acquisition cost.

For medicines used at the end of life and for very rare conditions, companies have the option of requesting a Patient and Clinician Engagement (PACE) meeting should the New Drugs Committee (NDC) issue preliminary "not recommended" advice for these medicines. As well as the opportunity for a PACE meeting, submitting companies also have the option to submit a new or improved patient access scheme (PAS).

The arrangements for handling a resubmission for a medicine that has been "not recommended" after PACE consideration will depend on the changes since the initial submission and are set out here:

New / revised Patient Access Scheme

Where the sponsor company wishes to make a resubmission and the only change is to introduce a new or improved **simple** PAS, the resubmission will require only brief consideration at NDC where the following criteria apply:

- No new clinical data available.
- No change to standard of care in NHS Scotland.
- Any changes to the list price of the medicine under review and/or to comparator medicines are reflected in the revised documents submitted.
- There has been no change to any other aspect of the submission (including the proposed positioning for the medicine).

A resubmission meeting these criteria will be reviewed to assess the impact of the PAS on the medicine's cost-effectiveness. This will be done in parallel to the Patient Access Scheme Assessment Group (PASAG) review (minimum of 4 weeks) and the PASAG decision will inform NDC according to standard process. The submission will be considered briefly at NDC in order that the submitting company may comment on the draft Detailed Advice Document (DAD) that feeds into the SMC committee's deliberations. A further PACE meeting will not be convened.

These resubmissions will normally be considered at NDC within 8 weeks of receipt and assessed at the subsequent SMC meeting where possible. In addition, where ADTCs advise that there is considerable patient or service need, these resubmissions may be prioritised for assessment.

New clinical / health economic evidence

Where there is significant new clinical and/or economic information (including a new or revised complex PAS), new analysis of existing information, or a change in the company's proposed positioning for the medicine, the resubmission will be assessed according to standard SMC timelines.

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