

Access Consortium Promise Pilot Pathway

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New Access Work-Sharing Pathway for Priority Procedures.

The Access Consortium working group for new active substances has established an aligned process for priority review, which includes the decision on priority status. In order to facilitate the process for applicants, common timelines for the priority review request have been established, and the request is evaluated in a collaborative way, seeking a consensus decision.

In creating the Promise Pilot Pathway, the Access partners sought commonality in their respective criteria for priority review. Applications for new active substances fulfilling the following criteria are eligible for the Promise Pilot Pathway:

- diagnoses, treats or prevents a condition that is serious, life-threatening or severely debilitating and
- for which no other treatment is currently registered and marketed in participating jurisdictions for the proposed indication

The scope of the Promise Pathway will be further reviewed after the pilot.

Please find more details in the newly published Operational Procedures.

<https://www.gov.uk/government/news/access-consortium-promise-pilot-pathway>