

‘Not Recommended’ advice following non-submission by a pharmaceutical company

Pharmaceutical companies are encouraged to keep the Scottish Medicines Consortium (SMC) secretariat informed of their proposed timelines for introducing a medicine to the UK market, as this will help ensure that the timing of SMC advice meets the needs of NHSScotland.

SMC aims to issue advice to NHSScotland on newly licensed medicines as soon as practical after medicine availability. To achieve this, taking into account the 18-22 week review process, pharmaceutical company submissions should be made before the medicine becomes available for use. Ideally the submission should be made as soon as practical after a positive opinion has been issued by the European Medicines Agency (EMA), Committee for Medicinal Products for Human use (CHMP) or before final approval by the Medicines and Healthcare products Regulatory Agency (MHRA).

If the pharmaceutical company is unable to make a submission for a medicine that is within remit in an acceptable timeframe, SMC will issue advice to NHSScotland indicating that the medicine is not recommended for use. The pharmaceutical company has the opportunity to engage with the SMC secretariat about what might be an acceptable submission timeline before the decision to issue ‘Not Recommended’ advice is taken.

If the pharmaceutical company indicates that it does not intend to make a submission, SMC will issue ‘Not Recommended’ advice to NHSScotland soon after the medicine has become available for use. The company will be provided with the draft ‘Not Recommended’ Statement of Advice before it is considered by SMC. If the pharmaceutical company has advised that they will make a submission in the future (but not within an acceptable timeframe) the SMC Statement of Advice will include the following sentence: *The holder of the marketing authorisation has indicated that they plan to make a submission to SMC in the future.*

When ‘Not Recommended’ advice has been issued because of non-submission, this does not prevent the pharmaceutical company from making a submission at any point in the future. SMC advice based on a subsequent submission will supersede the initial ‘Not Recommended’ advice.