SMC Scottish Medicines Consortium

Advising on new medicines for Scotland

NHS SCOTLAND

Process for issuing 'not recommended' advice due to non-submission by a pharmaceutical company

Pharmaceutical companies are encouraged to keep the SMC secretariat informed of their proposed timelines for introducing a product to the UK market, as this will help ensure that the timing of SMC advice meets the needs of NHS Scotland.

SMC aims to issue advice to NHS Scotland on all newly licensed medicines as soon as practical after product availability. To achieve this, taking into account the 18-22 week NDC/SMC review process, pharmaceutical company submissions should be made before the product 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, in the case of products submitted to the Medicines and Healthcare Products Regulatory Agency (MHRA), before the final approval is granted.

If the manufacturer is unable to make a submission for a product that is within remit in an acceptable timeframe, SMC will consider the need to issue advice to NHS Scotland indicating that the medicine is not recommended for use. The company has the opportunity, however, 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 NHS Scotland soon after the medicine has become available for use. The company will be provided with the draft 'not recommended' advice statement before it is considered by SMC.

When not recommended advice has been issued due to 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.

April 2017