**Concept Note:**

**Requirements for provision of a ‘bridging’ report for SRA-approved medicines for consideration of registration in non-SRA settings**

It is expected and general practice that medicines authorized for use by SRAs are approved for the conditions of use relevant for the respective SRA territory. When a SRA-approved product is submitted for the regulatory approval in a country where conditions of use or benefit-risk profile of the medicine can differ, it is assumed that the applicant for registration (marketing authorization) is able to support the application by providing evidence justifying positive benefit-risk profile for proposed conditions of use also for this country. Since SRA assessments do not always confirm availability of data and questions relevant for use in other environments, the SRA assessment reports can be considered in this respect to be incomplete. Currently it is only EMA’s scientific opinion according to EU Regulation (EC) No 726/2004 EU Art 58, which may be considered to significantly address these questions.

Differences in target population, epidemiology and other features of the disease, concomitantly used drugs and hence the interaction potential, local treatment and diagnostic modalities and other factors can substantially affect benefit-risk of a medicinal product. There can be also issues related to certain quality parameters, especially in relation to the stability under different climatic conditions. Therefore, in order to provide regulators in target countries with information relevant for use of the product in their countries it is proposed to develop a bridging report supplementing the SRA assessment report (quality, safety) and the quality and clinical overviews provided in Module 2 of the CTD.

Such a bridging report should especially provide the applicant’s with the justification of the:

* relevance of studied population for the target population (ethnicity, gender representation, age groups, …) as regards demonstration safety and efficacy,
* relevance of SRA-approved conditions of use as regards epidemiology and disease pattern in the target countries as well as other implications for efficacy and safety, e.g. feasibility of monitoring and precautionary measures (e.g. resistance testing or therapeutic drug monitoring),
* food and drug-drug interactions relevant for target countries that are not discussed in the SRA assessment report,
* therapeutic role of a product and its recommended use according to relevant national and international treatment guidelines,
* proposed post-registration risk management plan and pharmacovigilance follow-up,
* other related quality issues, including but not limited to, storage conditions and conditions of administration and use.

Such report is justified in the case that SRA assessment report does not cover these elements of assessment to sufficient extent. Provision of a bridging report should not be mandatory, but can substantially facilitate conduct of the regulatory assessment, reduce extent of potential regulatory questions and shorten duration of regulatory approval process. Such report can be valid for more than one country, where conditions of use of the medicine are seen in principle similar. Similarly like in the case of overviews submitted in Module 2, the bridging report should be prepared by expert(s) contracted by an applicant, who will attach the professional CV(s).