Expanded Access

General Requirement

- Expanded Access Programs (“EAPs”) are treatment options that allow the use of unlicensed product (irrespective of stage of development and authorization worldwide), which under defined conditions may be made available to patients who have exhausted all standards of care and are not eligible for a clinical trial for a life-threatening or serious illness and in which there is no alternative option in the respective market.
- Depending on the country/region, this kind of product supply is known by different terms, each with its own criteria and regulatory requirements for access (e.g., Expanded Access, Named Patient Supply, Compassionate Use Program, Managed Access Program, Special Access Program, Cohort Program, and Special Access Scheme).
- These general requirements provide an overview on the general criteria Viatris uses to evaluate expanded access requests. Local procedures and/or job aids may address implementation of this global procedure and any specific local requirements for making information about the EAP process publicly available.

EAP Principles

- Expanded access to an unlicensed product for an individual or a group of patients by a treating physician must comply with local laws and regulations governing such programs. Availability of such product to local healthcare system via special permit must be managed in accordance with company policies.
- In general, where permitted by local regulation, the unlicensed product supplied via global and local expanded access may no longer be provided by Viatris when it becomes available via the local healthcare system (i.e., authorized and available in the local market).
- The personal data of patients and physicians must be protected in accordance with company policies and applicable local laws and regulations.
- To be eligible for access to an unlicensed product, patients must meet the following criteria:
  - Suffer from a serious or life-threatening disease or condition;
  - Have undergone appropriate standard treatments without success or could not tolerate (or were ineligible to receive) drugs that are part of standard of care, and no comparable or satisfactory alternative treatment is available or exists to diagnose, monitor, or treat the disease or condition.
  - Ineligible for participation in any ongoing clinical study of this unlicensed product, which includes lack of access due to geographic limitations; or
  - Meet any other pertinent medical criteria for access to the unlicensed product as assessed by the Viatris clinical or medically responsible colleague.
- In addition to the patient eligibility requirements, the unlicensed product must meet the following criteria:
  - The unlicensed product is under investigation in one or more clinical studies anywhere globally.

- There is clinical data to suggest a favorable benefit-risk profile for the proposed use in the identified individual patient(s) for whom treatment with an unlicensed product is sought.
- The unlicensed product must have completed at least one phase I trial with an established dose.
- Adequate supply of the unlicensed product exists to perform necessary clinical studies in addition to providing global and local expanded access to patients, and the provisions of the unlicensed product via global and local expanded access will not interfere with or compromise the clinical development or authorization of the product in any other way.

- Safety reporting is an important component of EAPs, and the treating physician must report any adverse events ("AEs") to Viatris using the routine country mechanisms. There may also be additional local regulatory standards that apply.
- Viatris must ensure by means of Pharmacovigilance safety reporting requirements placed within the EAP Physician Agreement Letter Job Aid or via a Pharmacovigilance Agreement ("PVA") to collect pharmacovigilance-relevant information from such EAPs.

Submission of a request:

Information about Viatris' active clinical trials is available on **www.clinicaltrials.gov**.

Requests for access to a Viatris' investigational drug via its Expanded Access Program must be submitted by sending the **EAP Request Form** by e-mail to **ExpandedAccess@Viatris.com:**

- This form must be completed and submitted to Viatris by a qualified Healthcare Provider (HCP) through email to ExpandedAccess@Viatris.com.
- Please do not include identifiable patient information when completing this form
- If you are a patient, please consult with your HCP and request that your HCP complete the form.

Receipt of the request will be acknowledged within 5 business days.