Global Policy for Expanded Access Programs

1. PURPOSE

This policy outlines BeOne's approach to providing BeOne's investigational medicines (or medicines approved but not yet available) to patients with serious or life-threatening conditions who have exhausted available treatment options or are unable to participate in one of BeOne's clinical trials.

2. SCOPE

This policy applies to Expanded Access Programs globally. It does not include clinical trials, Investigator-Initiated Trials, BeOne corporate endowment, charity programs, or patient support/assistance programs for already launched medicines.

In cases where an investigational medicine is developed in partnership with another company, BeOne may not control decisions regarding Expanded Access.

3. ABBREVIATIONS AND DEFINITIONS

3.1 **Expanded Access Program** (EAP)

3.1.1 An internal BeOne umbrella term encompassing the Compassionate Use Program, Pre-Reimbursement Access Program, and Post-Trial Supply, as defined by the internal BeOne Standard Operating Procedures. Such access implies either in-country or cross-border shipments.

3.1.2 To note, various naming conventions may apply for such programs under different country regulations, such as Managed Access, Medical Need Program, Compassionate Access, Early Access, Single Patient Import, Patient Familiarization, Pre-Approval Access, Special Access, etc.

3.2 **Investigational Medicine** (IMP)

3.2.1 A medicine, combination product, or integrated device that is under investigation and has not yet been approved by local regulatory authorities for commercial use. The terms "unauthorized medicines" or "investigational drugs" may also refer to any medication (whether in commercial packs or clinical material) intended to treat a yet unauthorized indication, even after the medicine has become approved or commercially available for another indication, either locally or in another jurisdiction.

3.2.2 An investigational product is also such if it is a product with a marketing authorization when used in a way that is different from the approved use(s). For clarity, the Expanded Access program does not apply to the spontaneous use of an approved medicine for an indication beyond the authorized prescribing information ("off-label use").

3.3 **Unmet Medical Need**: refers to a situation where there is a lack of effective medical treatments or therapies for a specific condition, disease, or patient population. This can occur due to a range of factors, including:

3.3.1 Emerging Diseases: New or rare diseases for which no treatments have been developed yet.

3.3.2 Absence of Approved Treatments: Regulatory authorities have not approved any treatment for the intended patient population.

3.3.3 Inadequate Efficacy: Existing treatments are not sufficiently effective in managing or curing the condition.

3.3.4 Suboptimal Safety: Existing treatments may have significant side effects or safety concerns that limit their use.

3.3.5 Limited Accessibility: Approved treatments are not accessible to all patients due to geographic or logistical barriers.

3.4 **Treating Physician**: The healthcare professional (**HCP**) responsible for the care of patients and for the request to receive BeOne medicine through Expanded Access.

4. RESPONSIBILITIES

4.1 **BeOne** approves the program strategy and is responsible for reviewing and approving patient eligibility criteria, reviewing potential risks and benefits, providing medical oversight over the physician's request for Expanded Access, confirming that the HCP and institution are qualified, and ensuring compliance with local requirements.

4.2 **The treating physician** is responsible for assessing the benefit-risk ratio on behalf of the patient and initiating the access request. They are also responsible for obtaining the patient's informed consent, securing any required administrative authorizations, monitoring the patient during treatment, and reporting adverse events. In addition, the physician must:

4.2.1 Use the investigational product solely for the individual patient for whom access was requested.

4.2.2 Agree to comply with BeOne's requirements, including those related to patient confidentiality, data privacy, medical eligibility criteria, safety monitoring, and adverse event reporting, as well as all applicable laws and regulations.

4.3 **Medical Reviews** and **Processes** for an active Expanded Access Program.

4.3.1 The initiation of an Access Program is governed by the decision of the BeOne internal Expanded Access Program Committee (EAPC). A program is not considered active until the EAPC endorses a formal decision; in such cases, healthcare professionals will be informed that the program is not active.

4.3.2 New Patient Request: Requests must be submitted by the treating physician. The request should include information such as the patient's medical history and condition, justification for the request, evidence of no available comparable or satisfactory alternative treatments, and confirmation that the patient is not eligible for ongoing clinical trials involving the investigational medicine. The treating physician must make requests without including the patient's name or specific identifying information.

4.3.3 Review and Decision: BeOne will review each request per standard internal procedure. This review will consider the scientific evidence supporting the use of investigational medicine, the patient's medical condition, and the potential risks and benefits. We will endeavor to respond to each request expeditiously. Our response may be positive, negative, or conditional, depending on our assessment of the request.

4.3.4 Monitoring and Reporting: The physician must agree in writing to comply with several terms (e.g., patient confidentiality and data privacy, medical criteria, adverse event/safety reporting, treatment monitoring, drug supply handling and use, and protection of BeOne's confidential information) and obtain the patient's informed consent before treating the patient with the BeOne product.

4.3.5 Program Termination: Programs will be closed upon reaching their predetermined endpoint, such as when the investigational medicine receives regulatory approval, becomes commercially available, or when new safety concerns arise. Expanded Access may also be discontinued for other valid reasons, including those specific to an individual patient.

5. POLICY AND GUIDING PRINCIPLES FOR CONSIDERING EXPANDED ACCESS

BeOne is committed to finding pathways to help patients with serious or life-threatening conditions who have exhausted all available treatment options request access to our investigational medicine(s), and to do so in a manner that in consistent with all applicable legal and regulatory requirements.

The following guiding principles apply to requests for BeOne's investigational medicines through Expanded Access (Post-Trial Supply programs may be exempt from certain country scoping, unmet need, and other guiding principles due to their distinct purpose and framework):

5.1 **Covering Unmet Need**: Expanded Access programs are designed to allow patients to access medicines when an unmet medical need exists in a specific country.

5.2 **Fair and Just Consideration**: All requests will be considered fairly and equitably.

5.3 **Risk-Benefit Analysis**: Sufficient clinical evidence of safety and effectiveness in the given indication has been established, and the potential benefit justifies the potential risks, or the potential risks are acceptable in the context of the disease.

5.4 **Physician's Responsibility**: The treating physician is responsible for managing all aspects of the patient's treatment. BeOne does not accept direct requests from patients - all requests must be submitted by the treating physician.

5.5 **Regulatory Compliance**: Fulfillment of any Access Program must comply with applicable local laws and regulations.

5.6 **Controlled Medical Reviews:** BeOne retains the right to define the patient access criteria and collects data required explicitly for medical review and medicine distribution. Only pseudonymized data can be collected in accordance with patient privacy laws. Data extraction follows local compliance rules and requires specific patient informed consent.

5.7 **Non-Interference**: Providing IMP must not jeopardize the conduct of clinical trials, the regulatory approval process, or other types of access or distribution to medicines.

5.8 **Clinical Trial Precedency:** Participation in clinical trials remains the primary route by which patients access investigational medicines and contribute to collecting safety and efficacy data needed to support regulatory approval worldwide. Any Expanded Access program may be an option only for patients who are proven ineligible or unable to participate in a clinical trial.

5.9 **Free-of-Charge Access** (FOC): BeOne conducts Expanded Access without the intent to sell for commercial benefit. The medicine will be provided FOC or, in some cases, assigned a nominal value to facilitate necessary cross-border transportation processes. Expanded Access may be offered through a payment model only in specific local cases and subject to local regulations, as applicable laws permit.

5.10 **Reactive Nature** of Information Sharing: Information about future programs can be delivered to HCPs only as a reactive response to their request, without any promotional element. Beyond reactive responses to public requests, the number of patients treated and general information about active programs can be shared publicly through standard peer-reviewed channels, invited conferences, patient advocacy events, or specific websites.

5.11 **Right to Decline**: BeOne cannot guarantee that Access will be granted, even if the other program criteria are met.

5.12 **Right to Terminate**: BeOne reserves the right to revise or terminate our Access program based on new data, regulatory guidance, product availability, or other considerations.

5.13 **Limited Scope**: The Expanded Access Programs are limited to countries where BeOne is reasonably likely to submit a regulatory application, receive approval, and establish standard medical distribution in the future. Each medicine access program is designed to be specific to the country and medical indication.

5.14 **Active Development** requirement: The investigational medicine must be part of an active clinical development program. BeOne will not support access to products for which development has not been initiated or has been discontinued. An exception - Post-Trial Supply programs may still be considered for patients who participated in a clinical trial that was terminated due to the company’s decision to discontinue development of the investigational medicine.

5.15 **Resource constraints**: Expanded Access Programs are subject to operational and regulatory limitations. Requests will be considered only if adequate resources, such as sufficient drug supply and appropriate logistical mechanisms, are available to support individual patient access or the implementation of broader programs.

6. REFERENCES

6.1 Regulatory References

6.1.1 Article 4 Paragraph 2 of Commission Regulation (EC) No. 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council.

6.2 Other References

6.2.1 Expanded Access Navigator (http://navigator.reaganudall.org/), a unique partnership between the Reagan-Udall Foundation for the FDA, patient advocacy organizations, the pharmaceutical industry, and the federal government.

7. APPENDICES

7.1 Appendix 1 - Contact Information

7.2 Appendix 2 - BeOne Expanded Access Activities

7.3 Appendix 3 - Review and Updates

Appendix 1: Contact Information

Treating physicians can contact BeOne's Medical Affairs department at https://www.beonemedinfo.com for more information or to submit a request for Expanded Access at https://beonemedicines.com/patients/expanded-access-program/

Patients interested in accessing a BeOne investigational medicine for treatment are advised to discuss it with their respective doctors first.

Appendix 2: BeOne Expanded Access Activities

BeOne has a record of providing Expanded Access to BeOne investigational medicines for qualifying patients via single-patient or multi-patient pathways. Please refer to BeOne's Annual Responsible Business and Sustainability Report (https://beonemedicines.com/responsibility/responsible-business-sustainability/)

Appendix 3: Review and Updates

This policy will be reviewed periodically and updated as necessary to ensure compliance with regulatory requirements and alignment with BeOne's mission and values.