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Novartis Public Affairs

Novartis Position on Access to Unauthorized Novartis Products through Managed Access Programs (MAPs)

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The purpose of Novartis is to reimagine medicine to improve and extend people's lives. Using science-based innovation, Novartis aims to deliver better outcomes for patients and to address society's evolving healthcare needs.

Clinical trials are an essential part of the development and registration of innovative products. They enable the collection of robust safety and efficacy data on investigational products to support regulatory approval and subsequent commercial availability, thus allowing broader patient access.

However, there are instances where a patient has a serious or life-threatening disease or condition for which there are no available treatment options, or all available treatment options have been exhausted, and enrollment into a clinical trial is not possible.

Additionally, investigational products are typically unavailable during the period between the end of clinical trials and the achievement of regulatory approval and commercial availability. This gap can be especially difficult for patients who urgently need treatment and have no alternative or satisfactory options available.

For patients who have no treatment options, there exist a variety of local regulations and mechanisms to provide unauthorized products before regulatory approval and subsequent commercial availability. Different terms exist locally for these access provisions including "Compassionate Use", "Expanded Access", "Named Patient Supply", "Special Access Schemes/Programs".

At Novartis, "Managed Access Programs" (MAPs) refer to all these local mechanisms where we provide access to any of our unauthorized products outside of clinical trials and before local approval or commercial availability.

Novartis Position

- Novartis is committed to exploring options to provide patients with access to our unauthorized products, prior to local regulatory approval and subject to local regulations.[1]
- Novartis considers granting access to our unauthorized products when all the following criteria are met:
  - ✓ An independent request has been received from the treating physician.
  - ✓ The patient to be treated has a serious[2] or life threatening[3] disease or condition, and no comparable or satisfactory alternative therapy is available to monitor or treat the disease or condition.
  - ✓ The patient is ineligible for enrollment into or unable to access ongoing clinical trials.
  - ✓ The patient meets the medical criteria established by the medical experts working on the product development program.
  - ✓ Sufficient data is available to expect a potential benefit of treatment which outweighs the potential risk(s) in the context of the disease or condition to be treated.
  - ✓ Novartis has an adequate supply of the product[4] and providing the product will not interfere with ongoing clinical trial(s) or with the overall development program[5].
  - ✓ The requested access mechanism is allowed as per local laws and regulations.
- Each request will be acknowledged within 24 hours upon receipt.

[1] Novartis commitment to patients and caregivers | Novartis
[2] A disease or condition associated with morbidity that has substantial impact on day-to-day functioning. CFR - Code of Federal Regulations Title 21
[3] A stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment CFR - Code of Federal Regulations Title 21
[4] In instances where there are supply constraints, access for patients in countries where regulatory approval has been obtained for the product will be prioritized over managed access provision to new patients in countries without regulatory approval.
[5] There may be situations when we are faced with a limited supply of products e.g., during the early phases of development. In such cases, clinical trial patients will always be given priority to ensure full assessment of the safety and efficacy of the product within the development program.

- Each request will be reviewed fairly and promptly by Novartis medical experts.
- Novartis commits to making every effort to provide a response within a maximum of five working days once all required information has been received from the treating physician.
- Novartis commits to the timely provision of the product once all required approvals e.g. health authority, import license are in place. This timeline may be impacted by factors such as local requirements or government health authority feedback.
- Novartis will provide the product free of charge to patients prior to obtaining the first major health authority approval for the product.
- Once the product is locally approved and commercially available, a MAP can no longer be used as a mechanism to provide access.

To address the unmet medical needs of patients as quickly as possible, Novartis has a process in place to support prompt and fair decision-making and ensure a consistent approach across the world in compliance with applicable local laws and regulations.

Further information and contact:

- For more information on Managed Access Programs (MAPs), please refer to our webpage or contact the medical team in your Novartis local country office.
- A Managed Access request must be submitted by the treating physician on behalf of the patient. Requests can be submitted via the Novartis MAP portal.

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