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Strategy Paper

Pre-Approval Access Policy

Considerations for
a Fit-for-Purpose
Pre-approval Access Policy

Considerations for a Fit-for-Purpose Pre-approval Access Policy

Policies on pre-approval access ('early access', 'expanded access' etc.) have come into focus since the enactment of the US 21st Century Cures Act. Driven by the requirements of the Act, pharmaceutical companies have been quick to develop public policies on pre-approval access for their websites. Whilst these policies generally reflect the requirements of the Act, they frequently fall short in taking into account the complexity of pre-approval access, especially in terms of applicability to all assets in a company's pipeline.

Ideally, a public policy on pre-approval access should be based upon a more detailed internal policy, which in turn should be the product of a comprehensive global strategy on pre-approval access.

Beyond the considerations of whether you will grant access to an asset prior to approval, who your point of contact will be and your response time, what other aspects of pre-approval access have been considered as part of your pre-approval access policy?

A brief checklist of essential topics includes:

- Is your policy fit for all assets in your pipeline?
- At what stage in development will you consider pre-approval access?
- What are the criteria upon which you will decide to proceed with a pre-approval access program?
- Will you manage pre-approval supply internally, or outsource?
- Will you charge for access?
- In which countries will you allow pre-approval access?
- Will you consider supplementary activities like data capture?
- What are other companies in your peer group doing with regard to pre-approval access?

These considerations are vital in order to put in place a robust pre-approval access policy. A workable policy needs to reflect your company's corporate ethos and needs to be flexible enough to work across all your affiliates, taking into account country-specific nuances around pre-approval access.

The Inceptua Medicines Access management team pioneered the development of global corporate strategies and policies on pre-approval access and has delivered strategies for Top 10 Pharma companies through to niche biotechs.

Contact us today to find out how we can help you ensure your pre-approval access strategy and policy is fit for purpose and provides you with a competitive advantage.

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