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Expanded Access Programs: Opportunities and Challenges for Pharma

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Abstracts

Expanded access programmes make available investigational drugs to chronically sick or dying patients who have no other licenced product or clinical trial alternative. Driven by clinicians and patients, this highly-emotive area has both benefits and risks for pharma. What are the advantages? Where are the dangers? Does pharma have a moral imperative to engage?

Expanded Access Programs: Opportunities and Challenges for Pharma is a detailed report for industry management who must assess, approve or manage expanded access requests and programmes. Enriched with case studies, the report reveals the “real-world” experience and opinions of 17 senior industry, regulatory and stakeholder experts in the US and Europe and presents critical insights on the current operating environment for expanded access programmes.

Key Benefits

Understand clinician and patient drivers for expanded access

Formulate strategies to respond to requests that meet the needs of the wide variety of stakeholders involved

Understand the complex and varying regulatory requirements in leading markets

Balance the risks and “real-world” research benefits of engaging in expanded access programmes

Assess whether running your own expanded access programmes or engaging a

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service company is the route to go

Review the therapeutic areas currently attracting interest for expanded access programmes

Be aware of the PR benefits and dangers of engaging in expanded access programmes

Understand how “Right to Try” and CURE legislation may impact this area in the US

Answers to Critical Questions

Expanded Access: how best to manage clinician/patient requests?

Regulation of expanded access programmes varies widely in the US and EU – what are the essentials you need to know?

Companies are often expected to foot the bill for expanded access programmes – so what are the research and communication upsides that would support your participation?

What role can service companies play in smoothing access and management between pharma and clinicians/patients?

Avoiding unintentional consequences: how could expanded access impact the main drive to get the compound to market for all patients?

Media can be valuable partners in getting awareness of expanded access programme availability, but can also backfire if things don’t go to plan. How can you manage communications and avoid falling into a PR black hole?

Top Takeaways

Understand the factors that drive patients and clinicians to submit requests for early access to investigational drugs Be aware of the positive – if complicated - regulatory environment in the US and EU governing early access programmes

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Examine the financial implications: you may get paid, but more often you'll be footing the bill

Learn from "real world" experience on how industry is engaging with expanded access programmes and meeting the challenges they present

Identify the key benefits that accrue in terms of early exposure of your investigational drug in a real world setting

Appreciate how an early access programme can help support and speed your product application, and also how they can slow progress to regulatory approval.

Expert Contributors

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