Practical aspects of developing, implementing and using facilitated regulatory pathways in the emerging markets

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Background

To expedites the review of new therapies, national regulatory authorities (NRAs) around the world have implemented expedited review pathways for products that address unmet serious public health needs.

These facilitated regulatory pathways (FRPs) are designed to accelerate development, submission, regulatory review and patient access to medicines, by providing, alternatives to standard development and regulatory routes.

New regulations in many emerging markets, countries, where an expanding portfolio of neglected diseases has resulted in the development of new country-specific pathways to expedite the regulatory review of new treatments for urgent medical needs.

While the characteristics of NRAs vary widely, a number of emerging NRAs have been well-characterized. No systematic assessment has been conducted of these characteristics for emerging NRAs. This study aimed to identify emerging NRAs to understand their diversity and similarities.

Objectives

• Assess FRP characteristics used by NRAs in emerging markets
• Aid the assessment and development of NRAs, and provide evidence to focus strategies for increasing regulatory capacity in emerging NRAs
• Inform the development of novel, globally, accelerated development and regulatory pathways through the identification of common processes

Methods

We identified NRAs with FRPs through Corbiscil-RIM and web searches. The reviewed NRAs had implemented an expedited approval pathway.

Characteristics were identified in a functional or substantive basis and on sequential regulatory activities.

Results

• We assessed 50 FRPs from 29 countries (Fig 1)
• We noted how often FRPs addressed a characteristic and the most common assessment for each characteristic (Table 1), the number and distribution of characteristics (Table 2) and provide a summary of the most relevant observed characteristics (Fig 2).
• The Middle East/North Africa (17) and Eastern Europe (17) addressed the most median characteristics. The South African (19) FRP addressed the most features.
• All FRPs addressed at least twice as many procedural characteristics.
• A majority of FRPs provided opportunities for frequent interactions between sponsor and agency review team.
• Of the 38 NRAs for which a review target time was defined, all but one had a target of 180 days or less and 54% had a target of 90 days or less.
• Post-approval commitment requirements in the form of post-authorization studies (53%) and risk management plans (67%) were often required.

Table 1. Most common response values for each facilitated regulatory pathway characteristic.

Table 2. Analysis of distribution of FRP characteristics by country.

Results (continued)

Figure 1. FRPs assessed from 29 countries.

Discussion

None of the authors of this presentation have anything to disclose concerning potential conflicts of interest that may have a direct or indirect interest in the subject matter of this presentation.

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Conclusions

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