EARLY ACCESS AND TARGETED SUPPLY CONSIDERATIONS IN EMERGING MARKETS

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BACKGROUND/INTRODUCTION

- Innovative biological agents with the potential to cure serious illness are increasingly used in a variety early access programs.
- These agents are not used in the wider population as they still require regulatory approval.
- However, these managed entry agreements (MEAs) can be used and are targeted mainly for the benefit of a subsection of patients who often do no meet clinical study criteria and have very few options left.
- These early access programs Compassionate use (CUP) and Expanded use programs (EUP) are mostly initiated by physician and can still be used from an early stages of clinical development.
- MEAs at least for rare and ultra rare diseases may also be used as an adjunct to clinical trails to get data to support clinical development.
- However, it is not widely discussed if these programs can also be a useful mechanism which could allow the manufacturers to mange targeted supply of drugs within the existing access framework in various regions.

OBJECTIVE(S)

- To evaluate the existing frameworks in place for managed access agreements in emerging markets and identify factors that influence access to innovative therapies.

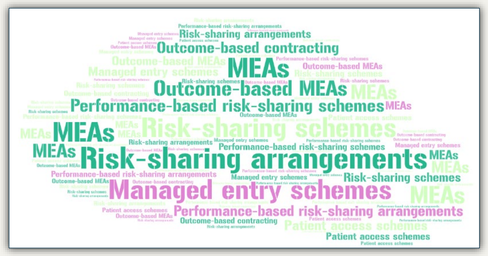
METHODS

- In-depth secondary research to identify provisions of managed access within a selection of emerging market countries including, Argentina, Brazil, Colombia, Turkey, Russia, China, South Korea.
- The likely pathway for managed access was assessed to summarize temporary access mechanisms, stakeholders, budget impact barriers, and access timelines for launching innovative therapies.
- Consideration was also given to impact of local infrastructure, regulatory framework, and political climate.

RESULTS

- The environment for access programs is continually evolving; Provisions of access mechanisms manifest differently in each of selected markets and are known by different names (**Figure 1**).
- The infrastructure and political environment within geographical region are not equivalent.

Figure 1 Manged access programs are known under various names



- Most countries have an early access program (EAP) but there is variation in the acceptance level and the capacity of the country to implement (**Table 1&2**).
- Some countries also have post approval entry agreements (**Table 1**). The mechanism of managed access (post approval) programs range from being contingent on disease severity and unmet need (Brazil, Colombia), to being managed by different stakeholders (Turkey) or is in its infancy (China).
- Time to achieve an early access or managed access agreement is not quick and can take 12-18 months depending on country.

Table 1 Provisions for early market access and manged entry agreements in emerging markets

COUNTRY	EARLY ACCESS AGREEMENT POTENTIAL	POST APPROVAL OR REIMBURSEMENT AGREEMENTS (MEA)	CURRENT STATUS
Argentina	Potentially	Yes	• MEAs are just starting • One value-based agreement since 2017 (bevacizumab)
Brazil	Yes	Plan announced in 2019	• CONITEC performance evaluations- eculizumab and nusinersen
Colombia	Yes	Yes	• MEAs possible with insurers to get competitive advantage (confidential) • No MEAs with Govt of Colombia until 2019 • Negotiation underway for 2 MEAs (confidential)
Turkey	Yes (cap on patient numbers)	Yes	• MEAs have been adopted on a pilot basis
China	Yes, very early & limited to Hainan province	No	• A new pharmaceutical product can only be reimbursed if it is selected by NHSA (National Catalogue) or by the provincial level healthcare safety administration (Provincial Catalogue)
Russia	Yes (NPP)	No	• MEAs is not possible due to Federal Law #44 which limits all public purchases to be tender based
S. Korea	Yes	Yes (Financial and performance based)	• Financial and performance based

Abbreviation: NPP-Named patient program

Table 2 Framework for early access programs in emerging markets

COUNTRY	PROGRAMS IN USE
Argentina	• Provisions of ANMAT facilitate right to access • Expanded Access Program (PAE) (provision 828/17 of ANMAT • Exceptional Access Regime (provision 10 401/16 of ANMAT)
Brazil	• ANVISA regulates the right of access programs • Compassionate use and Expanded access since year 2013
Colombia	• Compassionate: Vital Unavailable Medicine (Medicamento Vital No Disponible) • Expanded: Vital Unavailable Medicine (Medicamento Vital No Disponible)
Turkey	• Compassionate: Compassionate Use program (CUP) • Expanded: Continued Access (Erken Erişim)
China	• Compassionate: Unapproved Drug Use: (The Drug Administration Law of the People's Republic of China, 2015-04-24)
Russia	• Compassionate: "Named patient supply under vital indications" • Expanded: Not defined in regulation
S. Korea	• Compassionate: Named Patient Use (Self Treatment) • Expanded: Treatment use of an investigational new drug or Emergency use of an investigational new drug

DISCUSSION

- Managed access agreements are a useful tool in introducing innovative therapies in emerging markets, and it is important to plan ahead at an early stage, as well as understand the differences between country frameworks.
- There are opportunities and challenges in utilizing managed entry patient access programs in the emerging markets, it is not applicable to all innovations and the decision to include in the planning will depend on local context.

CONCLUSIONS

- Managed access agreements are a useful tool in introducing innovative therapies in emerging markets, and it is important to plan ahead at an early stage, as well as understand the differences between country frameworks.
- There are opportunities and challenges in utilizing managed entry patient access programs in the emerging markets, it is not applicable to all innovations and the decision to include in the planning will depend on local context.
- Emerging markets are overhauling regulatory frameworks to facilitate access for innovative and expensive new drugs
- What type of MEAs?
  - Financial-based agreements are easier to perform
- Thing will ease rolling of MEAs
  - Existing infrastructure for data collection rather than setting up new registry

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