

White Paper

# Funding Environment for Rare Diseases in Low and Middle Income Countries

*A global study of the health financing context, challenges and opportunities for rare diseases in LMICs*

COMMISSIONED BY ROCHE

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# Executive summary

Rare diseases (RD) have inherently small and dispersed patient pools, putting them at a low priority for governments. Historically, this has led to insufficient shares of national health budgets worldwide being allocated to treat rare diseases. Due to this, the associated funding challenges for rare diseases bring continuous and increasing financial impact for patients, health systems and economies and, without action, will only grow.

This initiative aims to collaborate across health systems to resolve the challenges that deter sustainable treatment access to rare disease patients. As a first step, IQVIA and Roche carried out a series of research studies focused on understanding the current funding environment for rare diseases in selected Low and Middle Income Countries (LMICs) and assessing the opportunities to bridge the funding gap.

**Ten countries from across all regions were selected to analyse their health systems and funding environments.** The chosen countries were: Argentina, Peru, Colombia, South Africa, Ghana, Morocco, Lebanon, Romania, Malaysia, and Thailand. Country selection was based on a multi-criteria analysis taking into account quantitative and qualitative variables. For this purpose, we analysed epidemiology data, reimbursement models, health systems factors, societal RD relevance and macroeconomic data, among other variables, for more than 60 countries. A combined approach of literature analysis and interviews with local health experts was conducted to collect and analyse relevant information on the status of rare disease funding in the selected countries.



## Results

The research indicates that most of the countries have an underdeveloped public funding rare disease environment. Identified gaps mainly focused on fund allocation and management strategy by the government:

-  Funds are either absent or insufficiently allocated for RD
-  Lack of rare disease strategy, governance and legislation
-  No plans to ensure continuous provision of funds for RD by the government
-  Public reimbursement for high-cost innovative rare disease drugs is uncommon (Spinraza, a Spinal Muscular Atrophy (SMA) drug, was used as a proxy for high-cost RD treatments).

An overview of each country's rare disease landscape maturity was established as a result of the gap identification exercise. Landscape maturity was evaluated based on the public presence of three key criteria: a ring-fenced fund for RD, a patient registry and an orphan drug registration pathway. This assessment showed that only three out of ten



countries (Romania, Thailand and Argentina) have a medium level of public sector rare disease maturity. The rest of the countries have shown low recognition of RD with the absence of RD funds allocation and policies. In the private sector, private insurance coverage for rare diseases is very low or virtually non-existent in all countries.

With respect to the out-of-pocket (OOP) sector, the analysis performed in all the participant countries showed that only 1% of the population could afford costly innovative drugs, with the rest of the population having a meagre ability to fund high-cost innovative drugs.

Consulted external experts identified several areas to prioritise moving forward to have an effective dialogue with governments and decision makers, including:

- 1 Development of robust evidence on current RD funding gaps that contributes to raising awareness and understanding of rare diseases needs
- 2 Capturing patients' and caregivers' perspectives
- 3 Adoption of specific multidisciplinary, evidence-based HTA framework for RD that does not focus on cost-effectiveness
- 4 Payer and policy maker engagement based on unified approach from RD Community
- 5 Alignment of stakeholders' incentives to ensure sustainability and continuity of funding solutions.

## The world post-COVID-19

On top of the known healthcare challenges, the COVID-19 pandemic is putting developing health systems under tremendous pressure to meet population health needs. At the time of writing, many developed countries are starting to emerge into a new normal post-pandemic, while many developing countries are still suffering debilitating economic and health impacts, further reducing their focus and capacity for rare diseases.

While the full impact of the COVID-19 pandemic is yet to be determined, significant resources are currently being diverted to meet COVID-19's intensive demands on hospitals, healthcare providers and vaccination campaigns. Although it is hard to accurately predict the effects of COVID-19, in the mid-term, health systems budgets are expected to tighten, making it harder to deploy additional funds to previously deprioritised areas. The focus will most likely be on 'health for the masses' and not on targeted or individual therapeutic options. Some of these situations are not new for rare diseases but to change it will demand a new approach and new partnership models that will help reimagine healthcare delivery, financing, and access to innovation.

In the backdrop of COVID-19, securing access to rare diseases and maintaining these objectives will demand more than ever for non-traditional collaborative approaches, increasing efficiency gains and funding solutions from public and private institutions to appear in a greater capacity.

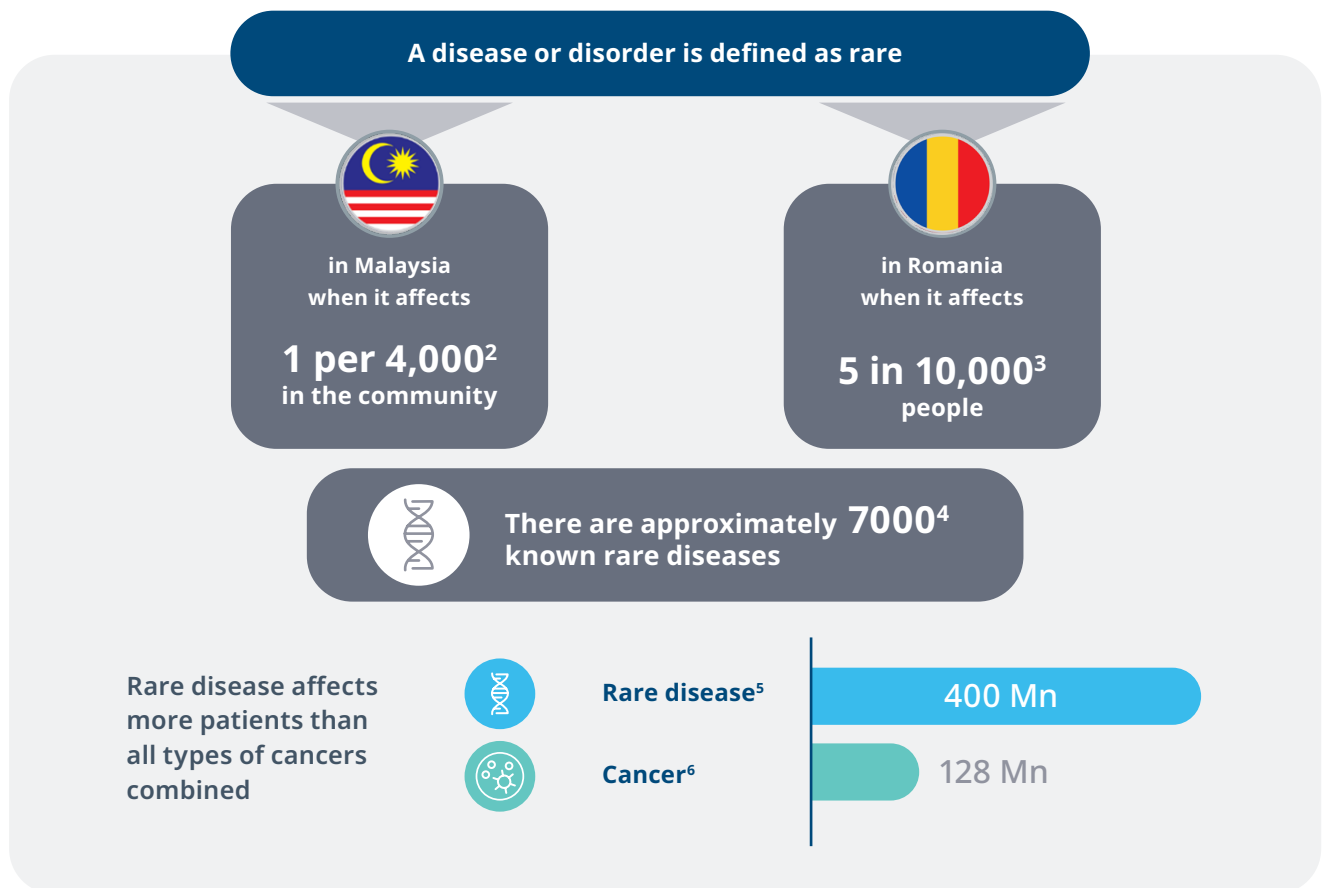
*“Securing access to rare diseases and maintaining these objectives will demand more than ever for non-traditional collaborative approaches.”*

# Introduction

## Rare diseases in LMICs - overview

A rare disease is a disease that affects a small percentage of the population. There is no global consensus on the definition, with definitions varying across different regions and countries. In LMICs, some countries (notably China<sup>1</sup>) have not yet established a formal definition, or others for instance, Malaysia or Romania, have established individual definitions as shown visually in Figure 1. While each rare disease may only affect a small number of people, collectively, they affect more people than all types of cancer combined, as shown visually in Figure 1.<sup>2,3</sup>

Figure 1. LMICs rare disease definition and prevalence



An inherent challenge for a disease affecting only a small percentage of the population is more complex funding and access barriers than common diseases. In LMICs, where even universal healthcare may still be lacking, these barriers are amplified further. The small and dispersed patient pools have caused rare diseases to be a low priority for the government and often pharmaceutical companies as well, leading to insufficient shares of national health budgets and research allocations. In many LMICs, there is currently no policy or funding in place for rare diseases. However, it is becoming a topic of interest, underlined by China's first national list of rare diseases in 2018<sup>7</sup>.

Many rare diseases also lack curative therapies, highlighting the need for improved coordination to ensure that patients have access to available treatments and services. Key stakeholders such as governments, public health agencies and medical research communities are faced with challenges at a policy level:

- 1 Lack of awareness and understanding of rare diseases**
  - Lack of awareness and understanding of rare diseases by policy makers and society in general
- 2 Lack of adequate information and inconsistent classification**
  - Inconsistent approach and insufficient information delaying entry to health systems e.g. misdiagnosis
- 3 Underprioritisation of rare disease at a national level**
  - Gaps in service provision as a result of fragmented health services
  - Limited treatment options, due to underinvestment in research and development (R&D)
- 4 Misalignment for orphan drug reimbursement criteria**
  - Cost-effectiveness usually overshadows other elements as a decision metric in the HTA process
  - Orphan drugs have low reimbursement opportunity using cost per quality-adjusted life-years (QALY)
- 5 Affordability**
  - Insufficient funds are allocated and secured for the treatments of RD

The combination of these challenges often leaves patients exposed to a choice between financial catastrophe or foregoing required treatment.

Collaboration across the healthcare system is required to deal with these systemic challenges. For example, the provision of training and awareness building among frontline healthcare workers to recognise rare diseases and direct patients to effective treatments. Failing to address rare diseases at a policy and systemic level will

lead to the neglect of society's most vulnerable people, leaving them to suffer chronic debilitation, often right from childhood, leaving a significant impact on families and carers.

In the past two decades, many countries have taken actions to tackle the problems mentioned above, but there is still room for improvement. National innovative funding must be sustained and expanded to address these complex funding gaps effectively.

# Study results

## Countries involved in the study

This study focuses on assessing the environmental challenges and opportunities related to the funding of rare diseases. For this purpose, ten countries were selected as a subset of LMICs: Argentina, Peru, Colombia, South Africa, Ghana, Morocco, Lebanon, Romania, Malaysia and Thailand. The country selection was based on a multi-criteria analysis with quantitative and qualitative variables.



The research study focused on the following strategic imperatives:



The ten countries were selected through a two-phase prioritisation exercise, considering the patient population sizes, epidemiology, RD policy focus, health financing systems and funding gaps.

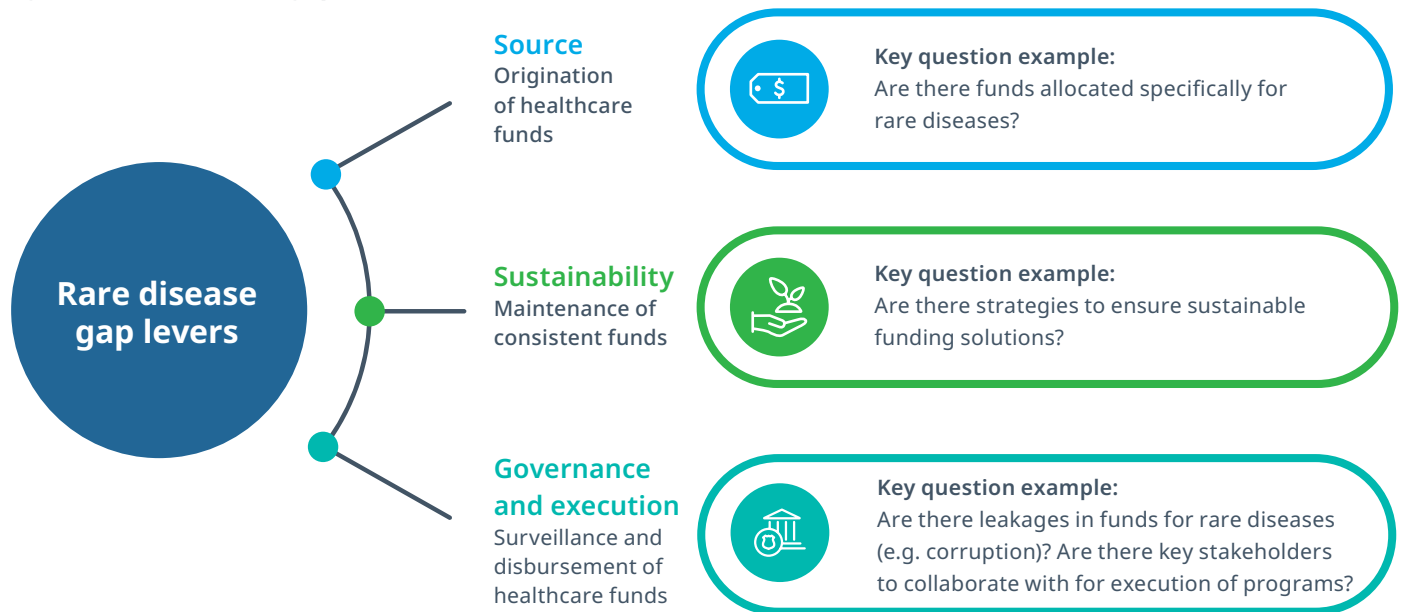
To get a better understanding of the funding mechanisms being explored for funding rare disease globally, you can read the [\*\*Innovative Funding Models for Treatment of Rare Diseases report\*\*](#).



# Identification of rare disease funding gaps




A comprehensive rare disease landscape analysis was developed with each country to better understand the rare disease funding landscape of their country. Three key levers were used to guide countries in identifying funding gaps across the three main payer types: government, private insurance and out-of-pocket. Key questions were also posed for each lever to further in the identification of existing funding gaps in their country. The three levers and key questions are shown below in Figure 2.

Figure 2. Rare disease gap levers



As a result of this exercise, it can be observed that most of the countries have an underdeveloped public rare disease environment, with the majority facing gaps in rare disease funding, management and policy. Public reimbursement and private insurance coverage for high-cost innovative rare disease drugs is also uncommon. Figure 3 shows the most common gaps identified.

Figure 3. Commonly identified gaps

Payer	Gaps identified locally
 <b>Government</b>	Insufficient <b>RD fund allocation</b> Lack of <b>RD strategy</b> (short or long-term) Absence of <b>national governing body</b> or <b>committee</b> for rare disease <b>Absence of legislation</b> for adoption of funding programs Poor <b>RD awareness</b>
 <b>Private insurance</b>	Absence of <b>RD coverage policy</b> or requires <b>high co-payments</b> No <b>coverage expansion incentive</b> for RD
 <b>Out-of-pocket</b>	Low ability to fund high-cost innovative drugs, often leading to financial catastrophe



An overview of each country's rare disease landscape maturity was evaluated as a result of the gap identification exercise. The maturity was evaluated based on the public presence of three key criteria; a ring-fenced fund, patient registry and an orphan drug registration pathway. Figure 4 shows the evaluation of the country's maturity, with most of the countries showing an underdeveloped public rare disease environment.

Figure 4. Countries' public sector rare disease maturity evaluation

Country	Rare disease maturity of the public sector			
	Ring-fenced funds	RD patient registry	Orphan drug registration pathway	Accelerated registration pathway
 Romania	✓ USD 100 Mn	✓		
 Thailand	✓ <USD 1 Mn		✓	✓
 Argentina		✓	✓	✓
 Colombia				
 Peru				
 South Africa				
 Lebanon				
 Malaysia	✓ USD 4 Mn		✓	✓
 Morocco				
 Ghana			✓	✓

 Present

 Partially present

 Absent

# Rare disease country snapshots

This section dives deeper into each of the country landscapes summarized above in Figure 4. These snapshot visuals showcase the different rare disease policies and initiatives that are in place in each country, and also the ongoing funding efforts for rare disease patients.

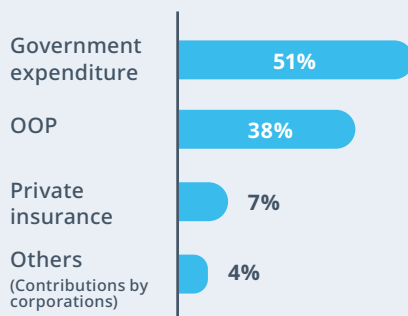


Malaysia

## There is progression in Malaysia's RD landscape with continuous development of the National Framework for Rare Diseases



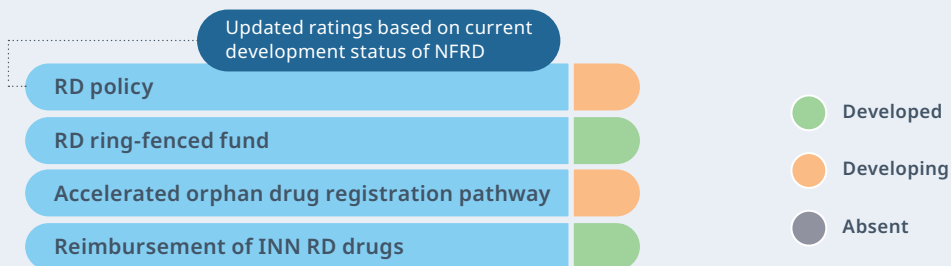
### Payer landscape - Overall healthcare expenditure



- Population covered by general reimbursement: ~100%
- Population covered by private insurance: ~41%



### RD policies and initiatives



### Treatment pathway unmet needs

- Delay in diagnosis confirmation
- Limited accessibility to diagnostic facilities and services
- Low disease awareness leading to delayed and misdiagnosis
- Low accessibility to innovative RD drugs



### Ongoing funding programs

The Ministry of Health (MOH) is developing a National Framework for Rare Diseases, with plans to:

- Create a governance committee for RDs
- Develop RD definition and patient registry
- Develop policies and strategies related to acquisition and access to orphan drugs

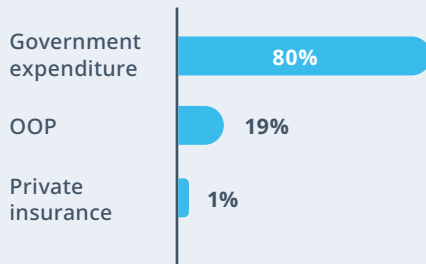
Source: IQVIA market prognosis, expert interviews and analysis



## There is a well-developed RD landscape in Romania, with the government driving healthcare expenditure



### Payer landscape - Overall healthcare expenditure



- Population covered by State Health Insurance and national health programs: ~100%
- Population covered by private insurance: ~2%



### RD policies and initiatives



### Treatment pathway unmet needs

- Lack of modern diagnostic devices and trained specialists
- Limited investment in public hospital facilities
- System for reimbursement assessment needs improvement
- Poor access in rural areas
- Treatment in public facilities face long waiting times



### Ongoing funding programs

Budget allocation for NRDP is updated with latest amount ~USD 100 Mn

#### Romania's National Rare Disease Program covers 25 RDs:

- ~USD 100 Mn was allocated for the 2019 National Rare Disease Program, with ~22% of the fund allocated for SMA
- Funds allocated for SMA is used to cover diagnosis and treatment (Spinraza)
- Spinraza is covered for all SMA patients in Romania. However only ~80 patients are currently covered due to limitations in budget

Source: IQVIA market prognosis, expert interviews and analysis

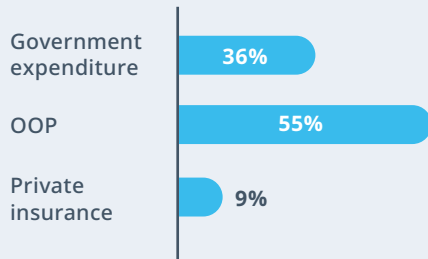


Ghana

## Ghana is an OOP-driven market whereby Patient Advocacy Groups (PAGs) are the main drivers for RD initiatives



### Payer landscape - Overall healthcare expenditure



- Population covered by National Health Insurance Scheme: ~40%
- Population covered by private insurance: ~1%



### RD policies and initiatives



- Developed
- Developing
- Absent



### Treatment pathway unmet needs

- Limited diagnostic facilities and costly services
- Shortage of trained specialists
- Low patient affordability
- Low accessibility to innovative therapies
- Low treatment accessibility in rural areas



### Ongoing funding programs

PAG – RDGI collaborates with local and international organisations in spearheading these RD initiatives:

- RD media campaigns
- Diagnostic program
- Therapeutics program
- Development of national registry

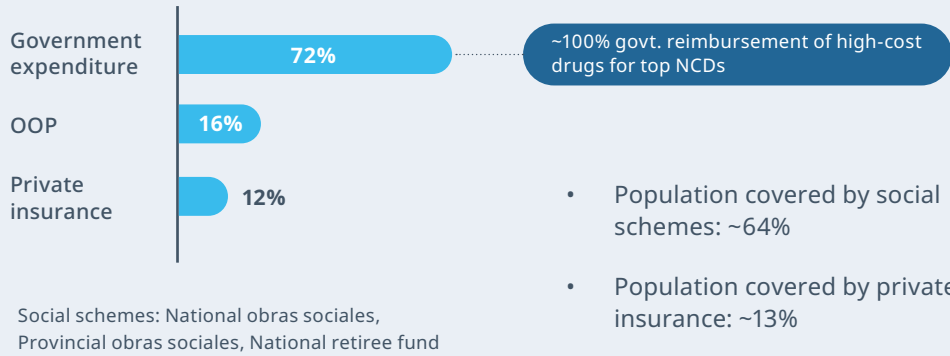
Source: IQVIA market prognosis, expert interviews and analysis



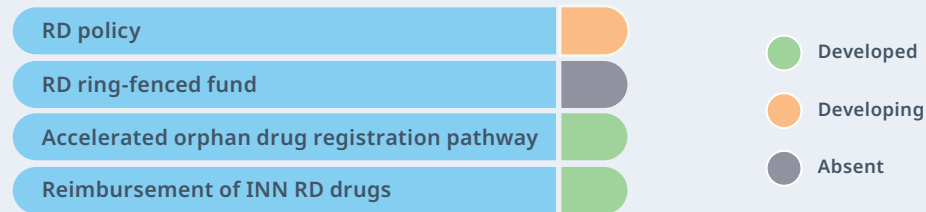
## The RD landscape in Argentina is evolving, with reimbursement of Spinraza and the development of RD-specific policies



### Payer landscape - Overall healthcare expenditure



### RD policies and initiatives



### Treatment pathway unmet needs

- Underdiagnosis especially for patients outside Buenos Aires
- Weak disease awareness among HCPs and patients
- Shortage of trained specialists
- Absence of official treatment guidelines



### Ongoing funding programs

- Government formed price agreement with Biogen in 2019 for Spinraza:
- SMA patient target of ~260
  - Price agreement of Spinraza was driven by PAGs' strong advocacy with the government

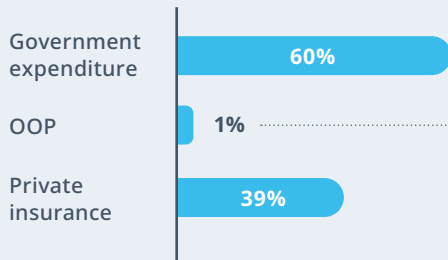
Source: IQVIA market prognosis, expert interviews and analysis



## Overall healthcare expenditure in SA is driven primarily by the government and private insurance with low priority for RD



### Payer landscape - Overall healthcare expenditure



OOP contribution to overall healthcare expenditure is updated

- Population covered by Uniformed Patient Fee Schedule (UPFS): ~84%
- Population covered by private insurance: ~16%



### RD policies and initiatives



- Developed
- Developing
- Absent



### Treatment pathway unmet needs

- Geographical barriers (i.e. lack of access in rural areas)
- Limited diagnosis facilities and services
- Shortage of specialists
- Limited reimbursement of innovative drugs
- Delayed registration of innovative drugs



### Ongoing funding programs

PAG – RDSA is developing a RD framework for the private sector that aims to:

- Develop a national definition for RDs
- Advocate for exclusion of RD drugs from the single exit price policy

Source: IQVIA market prognosis, expert interviews and analysis

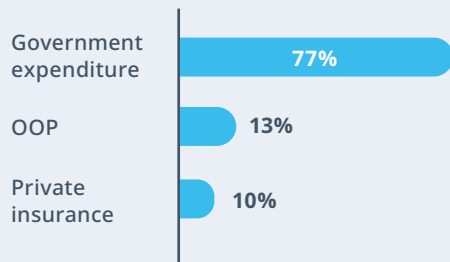


## Thailand

Thailand is a government-driven market with developments in the RD landscape recently, covering 24 RDs under the UCS



### Payer landscape - Overall healthcare expenditure



- Population covered by social coverage schemes: ~100%
- Population covered by private insurance: ~13%

Social coverage schemes: Civil Servant Medical Benefit scheme (CSMBS), Universal Coverage Scheme (UCS), Social Security Scheme (SSS)



### RD policies and initiatives



### Treatment pathway unmet needs

- Delayed and misdiagnosis due to low disease awareness of both patients and HCPs
- Shortage of trained specialists
- Limited reimbursement of innovative drugs
- Low treatment accessibility in rural areas



### Ongoing funding programs

In 2019, Thailand's National Health Security Office (NHSO) agreed to cover 24 rare diseases under the Universal Health Coverage Scheme (UCS):

- Ring-fenced fund for the 24 RDs: ~USD 415k
- However, the 24 RDs focused on rare metabolic disorders

Source: IQVIA market prognosis, expert interviews and analysis



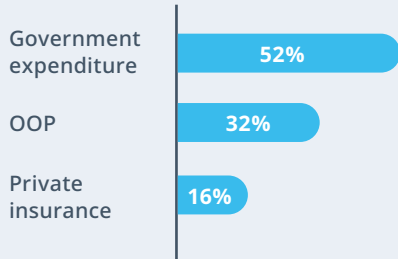


Lebanon

## Lebanon is a publicly-driven market with limited RD initiatives by the government



### Payer landscape - Overall healthcare expenditure

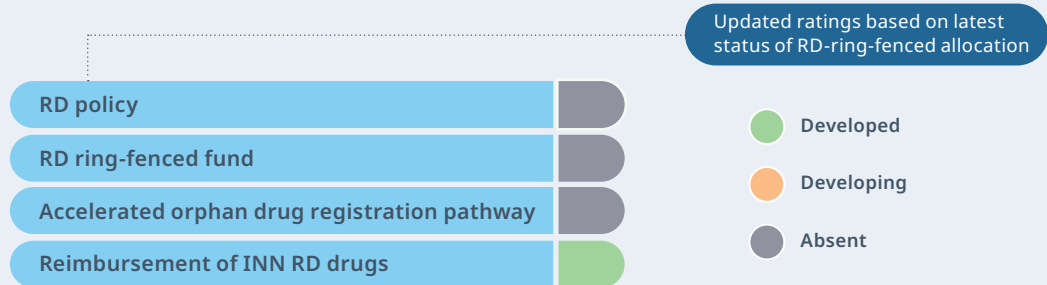


- Population covered by social schemes: ~92%
- Population covered by private insurance: ~5%

Social schemes: National security fund (NSSF), MoPH scheme and Military scheme



### RD policies and initiatives



### Treatment pathway unmet needs

- Limited access to diagnosis facility and services (especially in rural areas)
- Low RD awareness
- Shortage of trained specialists
- Limited access / reimbursement of high-cost innovative drugs



### Ongoing funding programs

- PAG – L.A.N.D:
- Provides supportive care (e.g. medical guidelines and supportive equipment) to patients with neuromuscular diseases
  - Funds diagnosis and symptomatic treatments

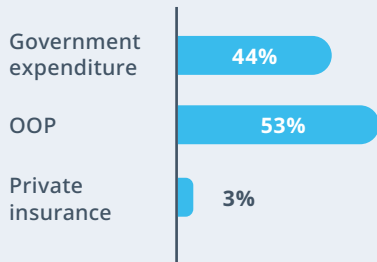
Source: IQVIA market prognosis, expert interviews and analysis



## Morocco's RD landscape is at an early developmental stage, with recent formation of a National Rare Disease Program in 2019



### Payer landscape - Overall healthcare expenditure

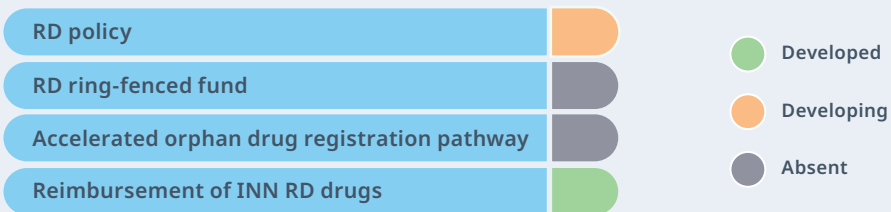


- Population covered by social schemes: ~53%
- Population covered by military scheme: ~3%
- Population covered by private insurance: ~4%

Social schemes: Mandatory Health Insurance Plan (AMO) and Medical Assistance Program (RAMED)



### RD policies and initiatives



### Treatment pathway unmet needs

- Limited RD specialists, diagnostic centres and CoE
- Delayed and misdiagnosis due to low disease awareness of HCPs and patients
- Low affordability of innovative RD drugs
- Weak reimbursement coverage of innovative RD drugs



### Ongoing funding programs

Public-private partnership (PPP) with Sanofi for the development of the National Rare Disease Program:

- Train HCPs to diagnose and treat RDs
- Launch RD CoEs at major university hospitals
- Develop RD national registry

Note: Current status of the PPP is still unclear due to the change of Morocco's health minister

Source: IQVIA market prognosis, expert interviews and analysis

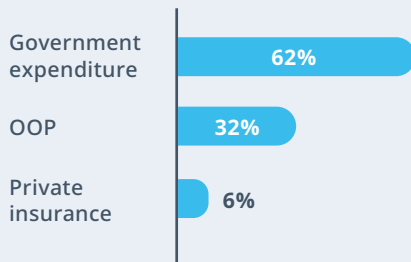


Peru

## Peru is a government-driven market with a developing RD landscape



### Payer landscape - Overall healthcare expenditure



- Population covered by social schemes: ~83%
- Population covered by private insurance: ~4%

Social schemes: Seguro Social de Salud (EsSalud) and Seguro Integral de Salud (SIS)



### RD policies and initiatives



### Treatment pathway unmet needs

- Geographical barriers (i.e. lack of access in rural areas)
- Limited diagnostic facilities and services
- Shortage of trained specialist and treatment centers
- Delayed accessibility to treatments
- Limited reimbursement of high-cost innovative drugs



### Ongoing funding programs

PAG – FEPER:

- Provides support and advice to patients
- Assists in fundraising for RD supportive care
- Disseminates medical, scientific and social information on RDs via media, events and awareness campaigns

Source: IQVIA market prognosis, expert interviews and analysis



# Colombia is a government-driven market that is still developing its RD landscape, with unmet needs in policies and disease management



## Payer landscape - Overall healthcare expenditure



Social schemes: Contributory scheme and subsidized scheme



## RD policies and initiatives



## Treatment pathway unmet needs

- Geographical barriers (i.e. lack of access in rural areas)
- Limited diagnostic facilities and services
- Shortage of trained specialists
- Delayed accessibility to treatments
- Limited reimbursement of innovative drugs



## Ongoing funding programs

- PAG – FUPER:
- Forms alliance between HCPs and university research centers
  - Assists RD diagnosis and clinical management
  - Educates public on RDs

Source: IQVIA market prognosis, expert interviews and analysis

# External experts' perspective

As part of this study, 2 external speakers were consulted to share their experiences and knowledge on RDs, R. Rajakanth (Executive Director of Rainbow Across Borders & Principal Consultant of Manifeste) and Dr. Camila Ignacia Quirland Lazo (Head of the Health Technology Assessment Unit, Oncology institute, Arturo Lopez Perez Foundation & Chilean representative in APEC Rare Disease Network).

Recommendations were taken for the implementation of innovative funding programs, and as part of this assessment proposed that five strategic areas need to be addressed in the implementation of an innovative funding program involving a multi-stakeholder ecosystem:

- 1 **Disease awareness:** Awareness should focus beyond the financial aspect of the disease (e.g. including the psychosocial part of the disease)
- 2 **Patient perspective:** Include patients' perspectives to develop an impactful message and to align key stakeholders (e.g. payers) on incentives or opportunities
- 3 Countries to modify reimbursement decisions to improve access to orphan drugs:
  - **Adopt a multidisciplinary HTA framework** that is evidence-based and not focused entirely on cost-effectiveness
  - **Adoption of specific payment mechanisms** to accommodate high uncertainty of orphan drug effectiveness and for data generation such as risk-sharing agreement
- 4 **Payer and policymaker engagement:** Communication of unified voice together with supportive data (e.g. rare disease financial and psychosocial impact study) to form an open conversation on sustainable funding solutions
- 5 **Sustainable solutions:** Ensure solutions formed are based on continuous and sustainable efforts (e.g. partnerships that meet collective and individual stakeholder interests)



# Conclusion



Across geographies, rare diseases present multiple access to care challenges for patients, one of them being lack of sustainable funding. This study presents a collection of many valuable insights on the status of RD coverage in LMICs that will further enable access to rare disease patients. Results show that currently the funding gap for rare diseases is significant and, without action, will only grow.

The research indicates that most of the LMICs that were part of the study have an underdeveloped public rare disease funding environment. Public reimbursement for high-cost innovative rare disease drugs is uncommon. Private insurance coverage for RD is very low in all of the evaluated countries. Additionally, patient registries and specific registration pathways for rare disease treatments are uncommon in most of LMICs.



The challenge for policymakers and rare disease stakeholders such as patient organisations and the private sector will be to identify funding solutions most appropriate for their health system and the population's needs and how to sustainably adopt them. It is also a priority to build adequate evidence for rare disease funding prioritisation and accompany it with strategic guidance on how to approach funding and financing solutions. In addition, it will be crucial to focus on identifying best practices and key learnings of similar international experiences and identifying external experts that can support discussions with key decision makers to create the required innovative solutions.

Moreover, in the case of HTA-led systems going forward, stakeholders in the space of rare diseases will have to work across health systems to advance multidisciplinary HTA frameworks that are evidence-based and not focused entirely on cost-effectiveness. Lastly, it will be essential to promote local/regional

collaboration for RD data sharing to address the lack of patient data (e.g. use of RWD in supplementing evidence-based reimbursement decisions).



All different parties involved with rare diseases need to begin a dialogue to develop sustainable funding solutions and jointly deliver a solid message to payers and policymakers about the urgency to reduce RD underfunding. Presentation of robust evidence on funding gaps, white papers and impact studies on the RD management and care of patients and families will play a critical role to catalyse strategic solutions.

*“It will be crucial to focus on identifying best practices and key learnings of similar international experiences and identifying external experts that can support discussions with key decision makers.”*

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Pablo is a Health Impact Lead at Roche's Global Access organization, based in Basel, Switzerland. In his role, Pablo collaborates with public and private stakeholders to rethink how finance can globally improve access to healthcare. He is currently exploring how new developments in fintech and impact investing can strengthen health system funding in low and middle-income countries. He brings strategy consulting as well as policy experience, having worked for market leading consulting firms in Latam and US and the Inter American Development Bank. His educational background is in Industrial Engineering and holds a master's in Health Economics from the University of Queensland, Australia.



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Fernando is a Health Impact Lead at Roche's Global Access organization, based in Basel, Switzerland. In his role, he is focused on shaping sustainable innovative funding and affordability solutions, collaborating with public and private stakeholders to forge strategic alliances and partnerships. As global health policy and market access leader, he brings more than 15 years of experience and has work experience in developing funding and financing solutions in more than 20 countries worldwide. He holds a degree in Administration, from the University of Buenos Aires (Argentina), as well as master's in Health Economics and Pharmacoeconomics and in Public Administration and Government in Latin America, both from the Universitat Pompeu Fabra (Spain).



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# About IQVIA Asia Pacific

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With regional headquarters in Singapore and offices in 15 countries, IQVIA Asia Pacific provides technology-enabled services and solutions to meet the growing and rapidly changing needs of clients, both local and multinational, operating in Asia Pacific. IQVIA is committed to advancing healthcare by offering evidence-based insights and deep domain expertise in thought leadership, with the aim of improving understanding and accelerating innovation within the healthcare ecosystem.

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# About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare.

Roche is working with partners across the healthcare sector to provide the best care for each person. The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2020 employed more than 100,000 people worldwide.

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