

Nagoya and ABS compliance

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Nagoya Protocol and other ABS legislations

The **Nagoya Protocol** effective since 2014 is a global agreement under the Convention on Biological Diversity. It establishes a legal framework to ensure the **fair and equitable sharing of benefits** arising from the use of genetic resources (GRs), supporting sustainable development.

The Nagoya Protocol applies to physical genetic resources of **non-human origin**.

Countries ratifying the protocol must implement it domestically by setting up clear **Access and Benefit-Sharing (ABS) regulations**.

Regardless of ratification, any country may adopt its own regulations.

Boehringer is committed to complying with the Nagoya Protocol and all relevant national ABS regulations.

Compliance can be challenging, as some countries do not clearly ratify local ABS regulations, and/or appoint local point of contact. In addition, these regulations can be subject to interpretation.



143

countries ratified the Nagoya Protocol

68

countries implemented domestic subsequent legislations

8

non-party countries implemented ABS regulations

Nagoya and ABS process at Boehringer in a nutshell

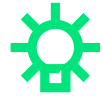
Scientists

- request for access to a GR and
- act according to the evaluation



GR Coordinators
conduct GR request
assessment

- Before any Genetic Resource (GR) can be used, a thorough evaluation of access and utilization conditions is required.
- Researchers must submit access requests, which are then reviewed by the site's Genetic Resource Coordinator (GRC).
- The majority of evaluations, approximately 75%, are straightforward and easily approved, while about 1% require in-depth evaluation.
- Complex cases are coordinated and managed by a dedicated team



Since 2019

2300+

access requests evaluated
for GRs originating from

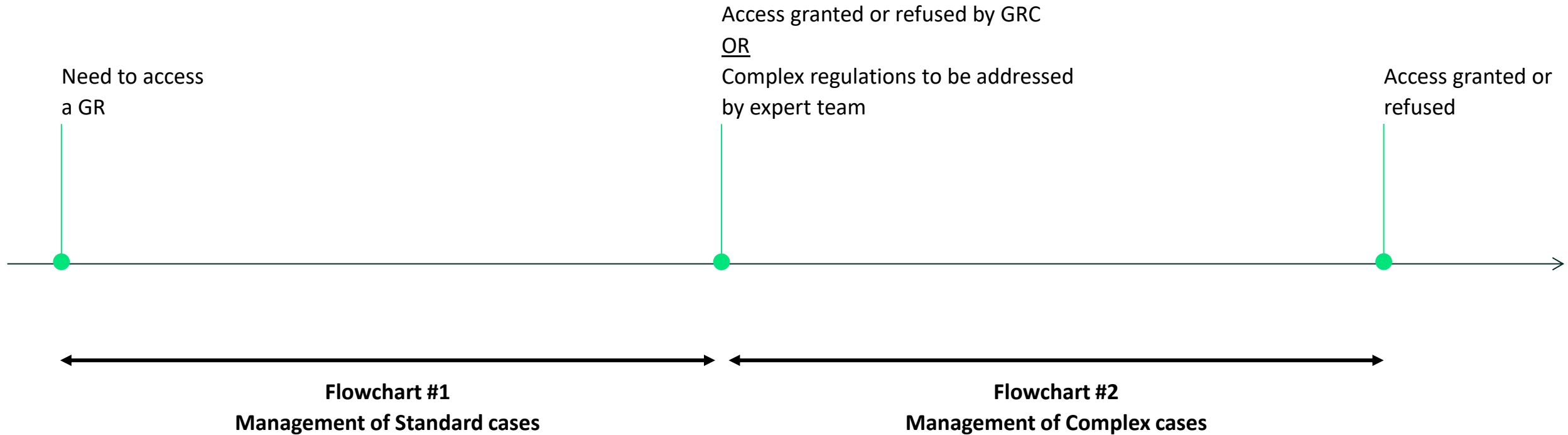
90+

countries

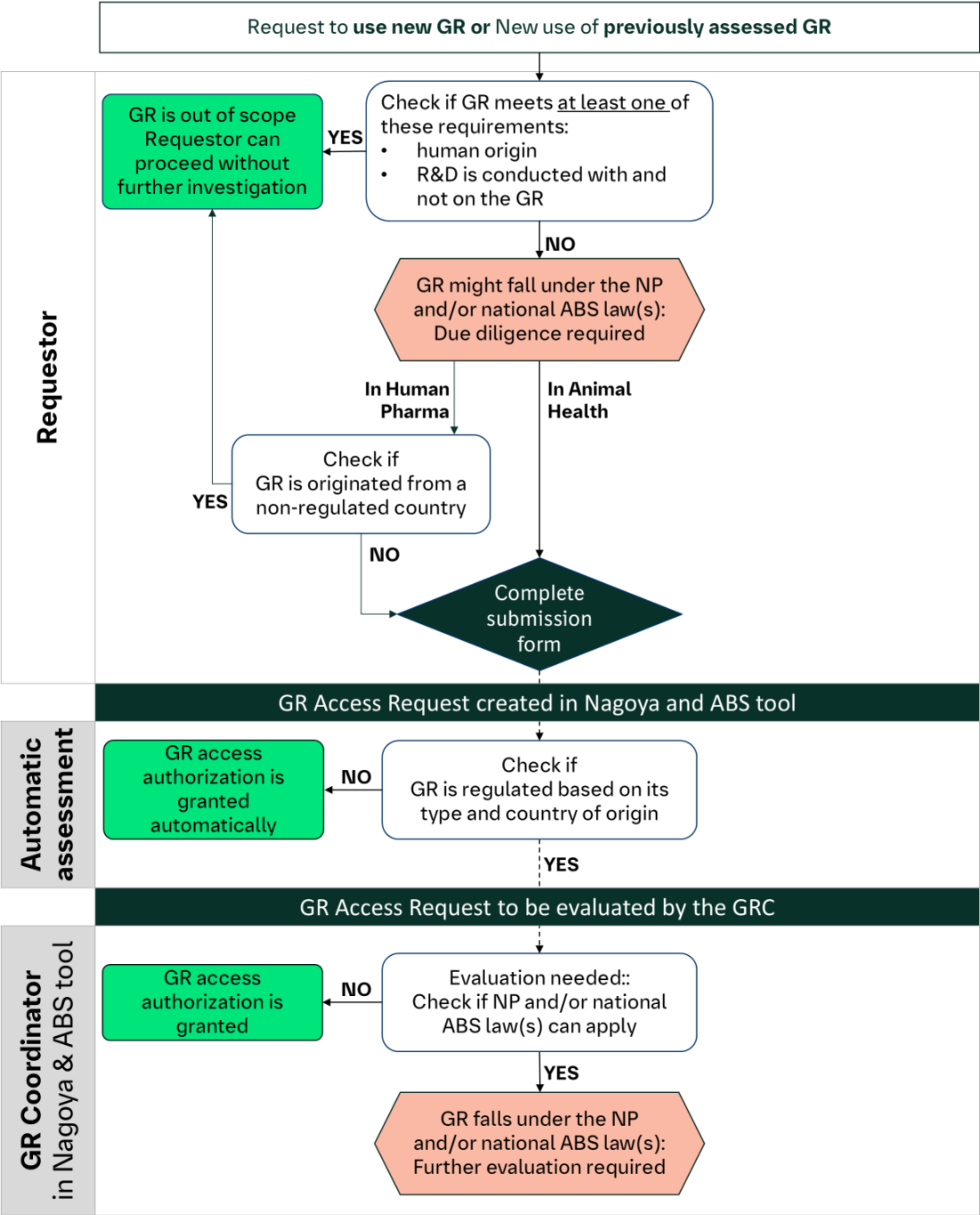
1%

are complex cases

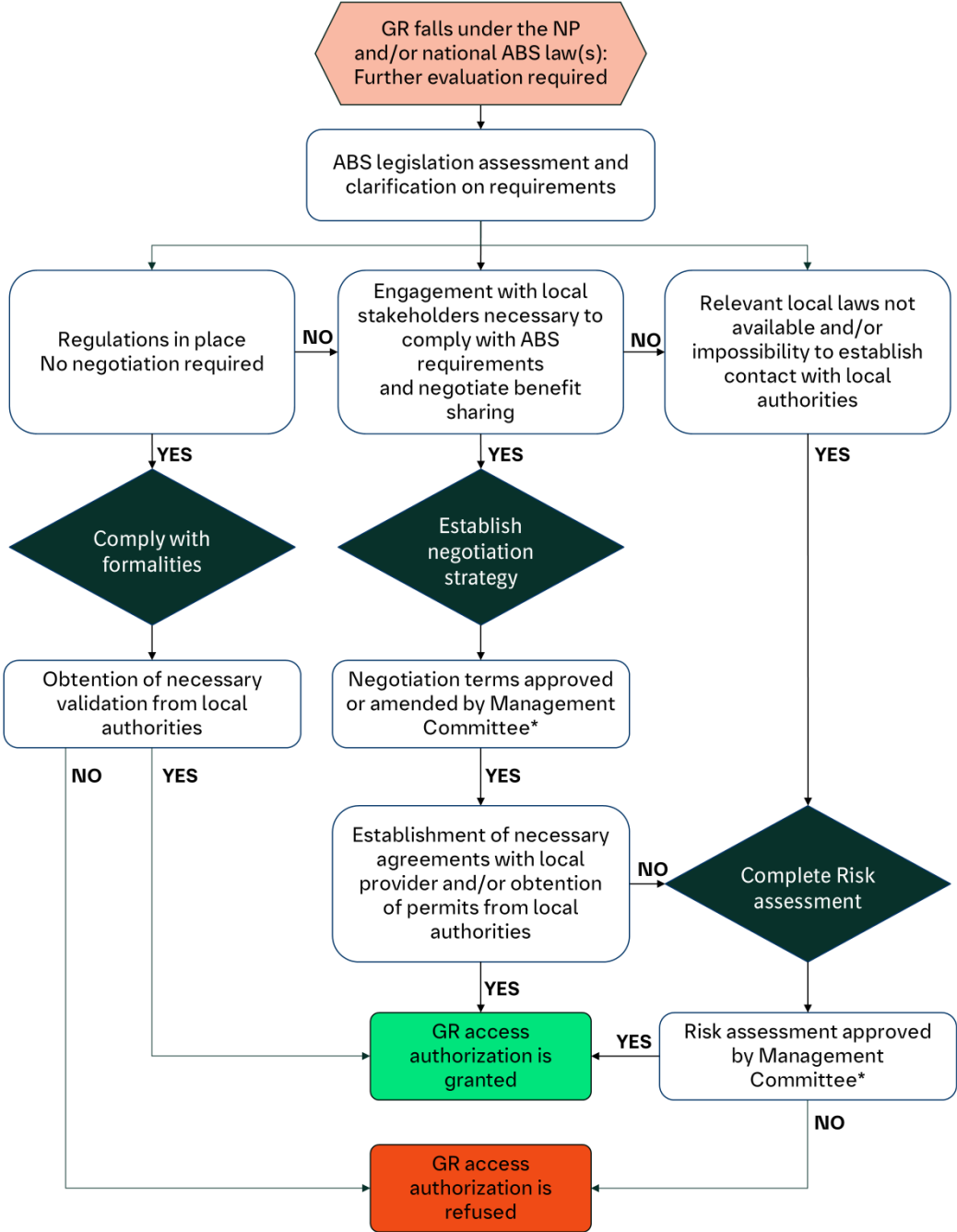
Evaluation process - Flowcharts



Flowchart #1



Flowchart #2



Management of complex cases – Check list

ABS requirements:	
In place in the country of origin?	● ● ●
Clear ABS compliance requirements?	● ● ●
Prior Informed Consent and/or permit required?	● ● ●
Benefit Sharing Agreement required?	● ● ●
Local provider:	
Local GR provider identified?	● ● ●
Engagement with local provider established?	● ● ●
Country of origin:	
National authorities identified and appointed?	● ● ●
Engagement established?	● ● ●
Alternative countries identified?	● ● ●

To **ensure compliance** with ABS requirements and **avoid delays** in project timelines,

The Nagoya team brings together **key internal stakeholders**, from Research, Legal, Global Strategic Marketing, Commercial Operations, to collaboratively define and implement a clear **strategy** and **action plan**.

Focus

FMD vaccine development and the Nagoya protocol

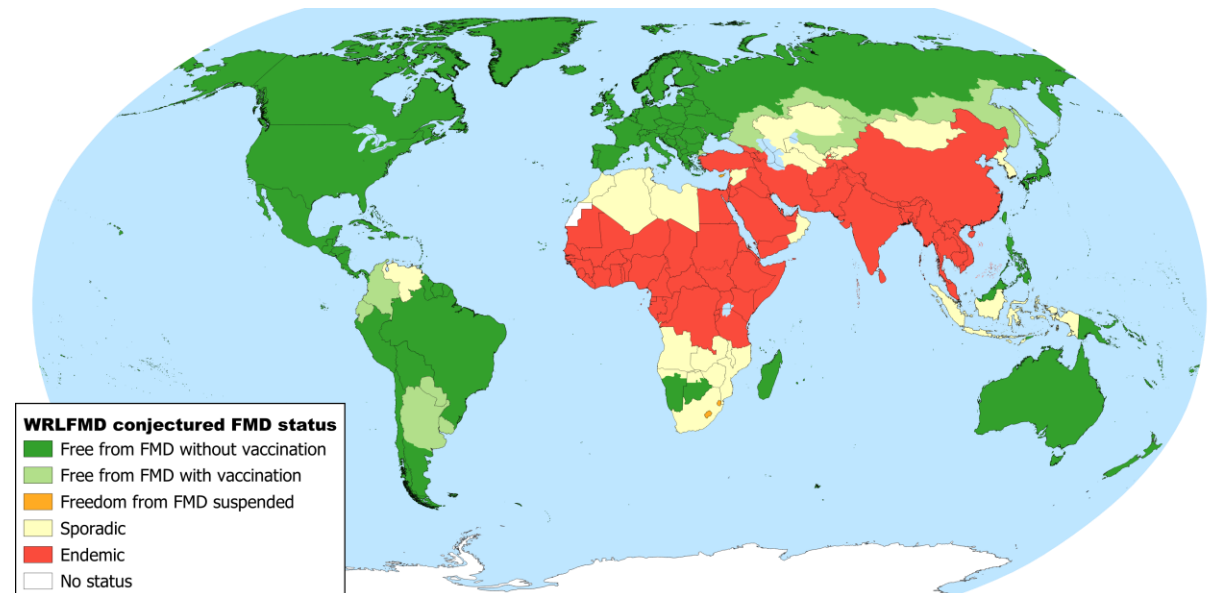
Foot and Mouth Disease vaccine development and the Nagoya protocol

Types of studies in vaccine development:

- Boehringer carries out diagnostics for vaccine matching using GR
- Boehringer requires access to GR for vaccine development
- Define which process is 'in scope' / 'out of scope' of utilization

Nagoya protocol and ABS are integrated throughout the development process:

- Contracts/Procedures/Training
- GR database
- Import/Export
- Study tracking
- Reporting
- Transfer



Focus

AHSV in South Africa

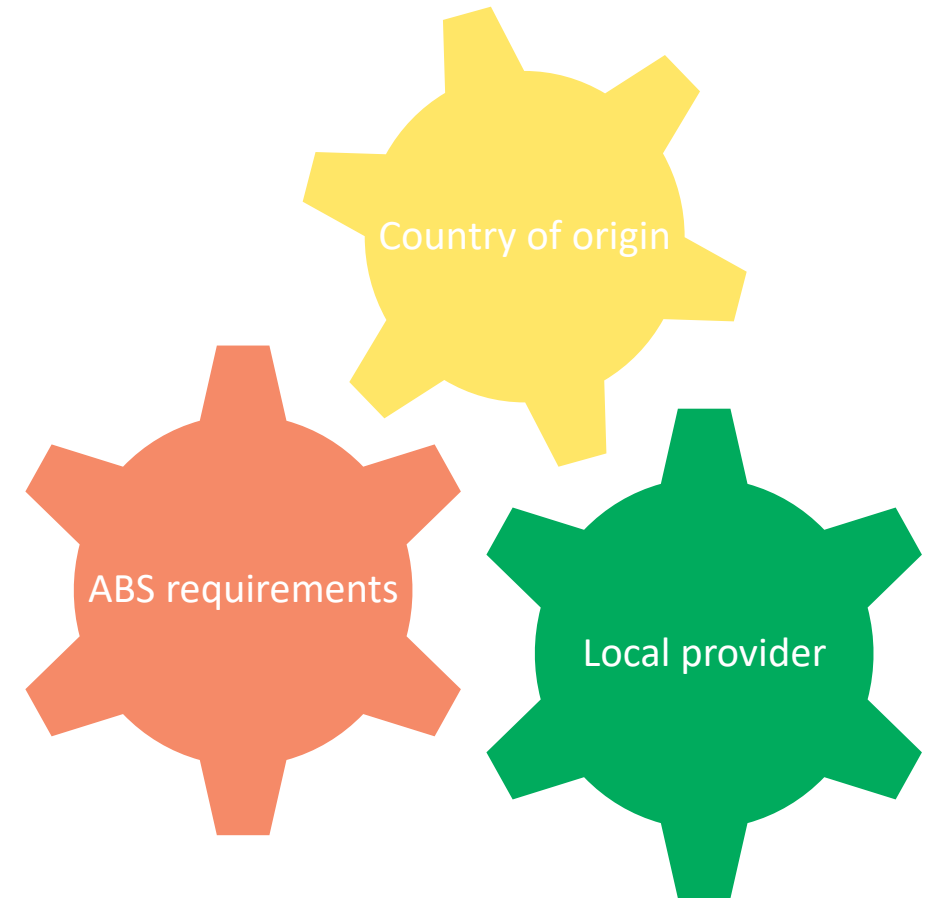
AHS virus DSI from South Africa

Business case:

- Boehringer is collaborating with the University of Pretoria (UP) in South Africa to develop vaccines against African Horse Sickness Virus (AHSV).
- Boehringer requires access to full genome sequences of AHSV originating from South Africa.
- These sequences are considered Digital Sequence Information (DSI).

To be addressed:

- Clarify the regulations governing DSI in South Africa and the associated access requirements
- Obtain and/or execute the necessary permits and agreements.



AHS South Africa case – Assessment and action plan

- Although South Africa has not ratified the Nagoya Protocol, access to genetic resources has been regulated, and digital sequence information (DSI) is treated as a genetic resource.
- In addition to signing an MTA and a Benefit Sharing Agreement (BSA) with the local provider, two permits are required

Purpose	Research phase: Design and evaluate vaccine candidates against AHS		Commercial phase: Clinical studies, and potentially IP filing	
ABS Requirements	Discovery Phase export permit	Material Transfer Agreement	Benefit Sharing Agreement	Bioprospecting permit
Status	Issued by South African authorities in May 2025	Executed in June 2025	Executed in February 2026	Application submitted in February 2026
Details	• Engagement with local authorities via University of Pretoria • Access to DSI is authorized → transfer can be initiated		• Approval of non-monetary benefit sharing terms by Nagoya and ABS Management Team • Alignment on BSA terms with UP	• Permit application includes MTA and BSA • South African authorities will evaluate the benefit sharing terms of the BSA and may request amendment

Backup

Focus on Digital Sequence Information (DSI)

- Digital Sequence Information (DSI) refers to the digital representation of genetic material.
- DSI is not included in the Nagoya Protocol definition of Genetic Resources. However, some countries have already introduced DSI access regulations
- A multilateral mechanism (MLM) that compensates countries for the use of DSI is currently under discussion at the UN Convention on Biological Diversity with conclusions expected in 2028

At Boehringer:

- Circular on MLM implications shared with Sustainability Executive Committee in collaboration with PGA in July 2025
- Active participation in DSI MLM forum via IFPMA*
- Access and utilization of DSI included in revised Nagoya & ABS SOP and tool

*International Federation of Pharmaceutical Manufacturers and Associations – in relations with UNs



27

countries regulate access
to digital GRs

196

countries currently
negotiating MLM on DSI