Acesso equitativo a vacinas: passado, presente e possíveis futuros

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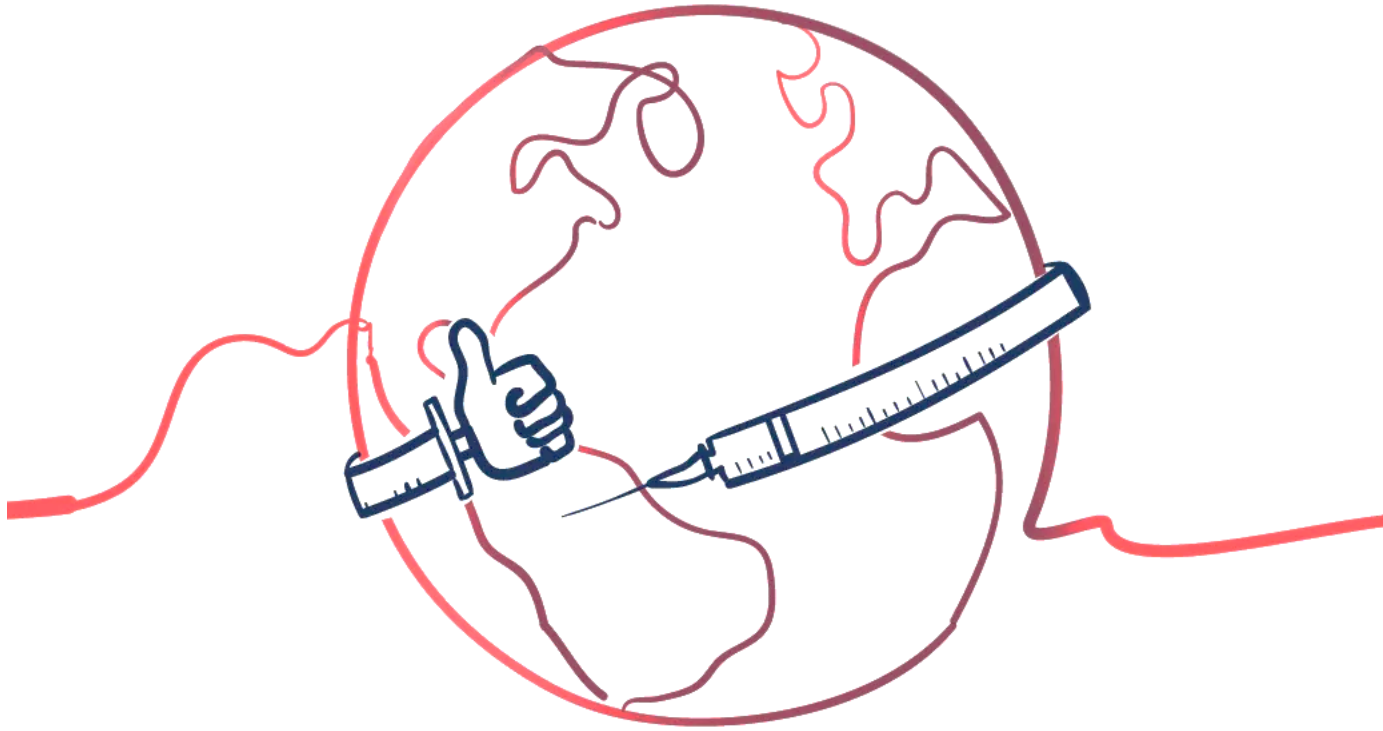
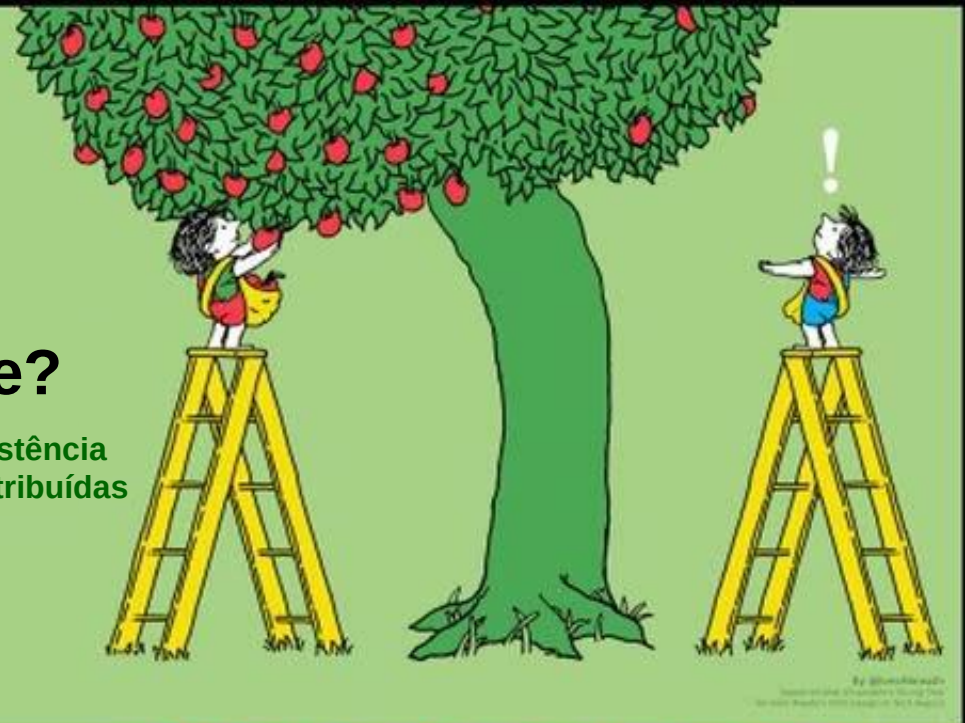


Desigualdade

Acesso desigual
a oportunidades

Igualdade?

Ferramentas e assistência
uniformemente distribuídas

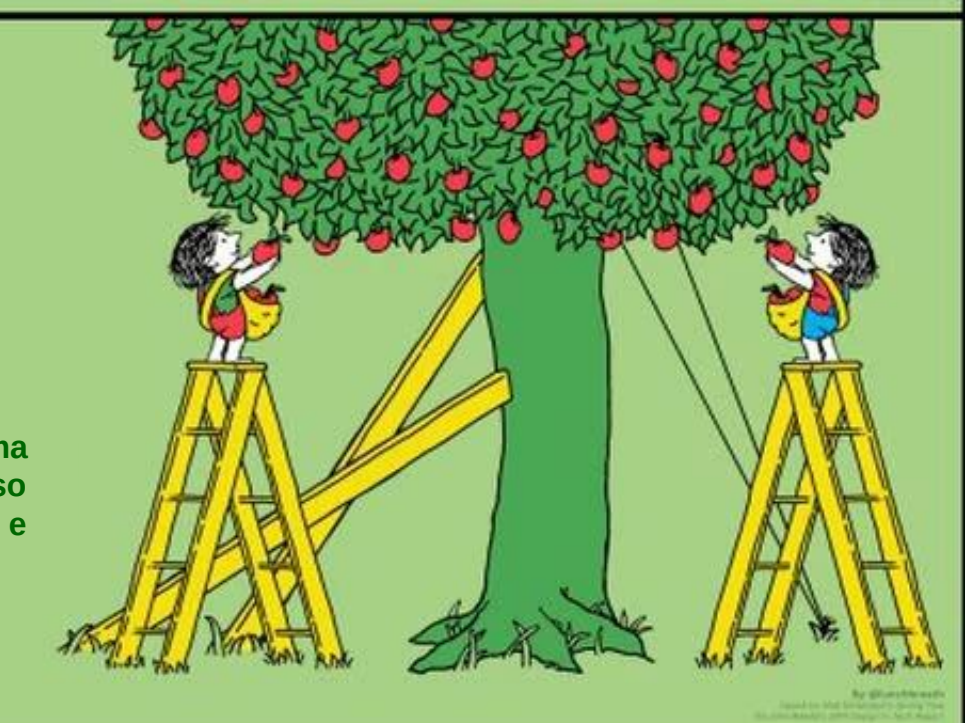


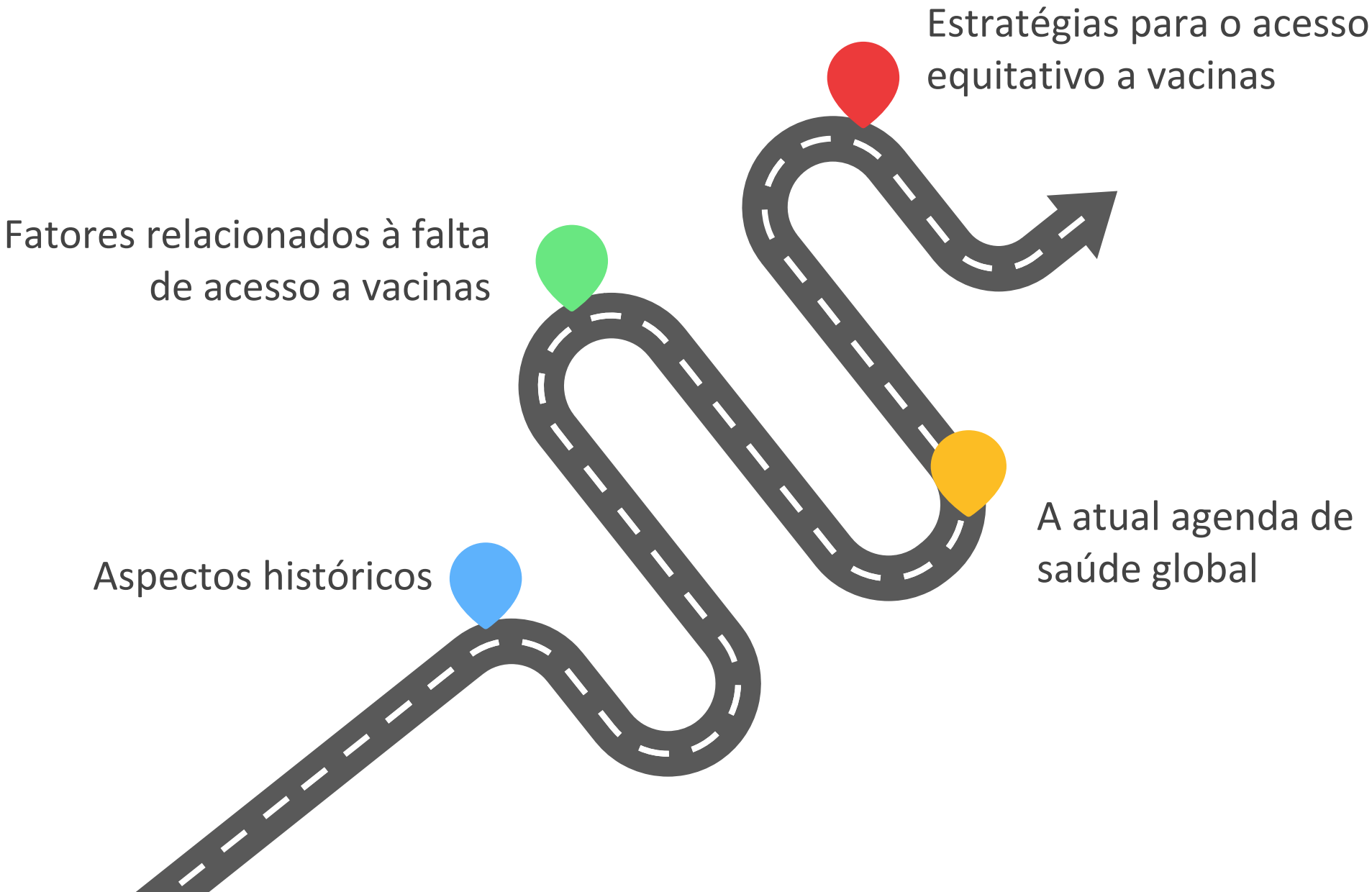
Equidade

Ferramentas
personalizadas que
identificam e abordam a
desigualdade

Justiça

Corrigindo o sistema
para oferecer acesso
igual a ferramentas e
oportunidades

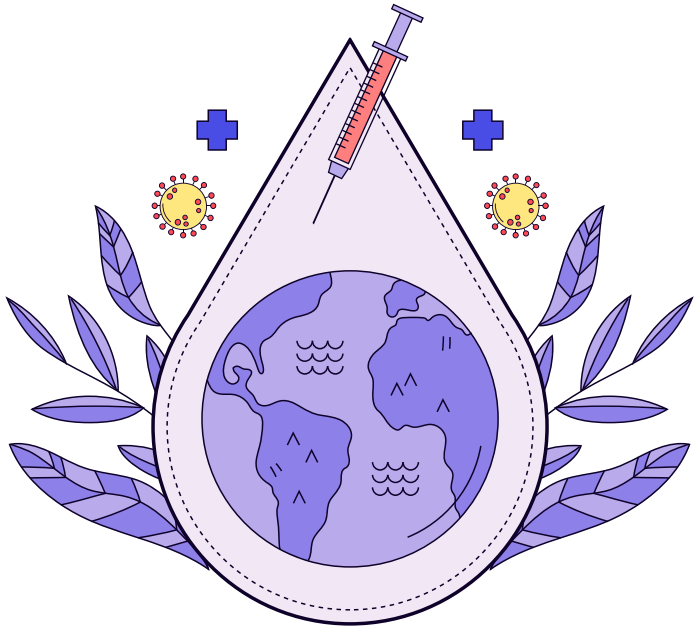



Estratégias para o acesso equitativo a vacinas
Fatores relacionados à falta de acesso a vacinas
A atual agenda de saúde global
Aspectos históricos

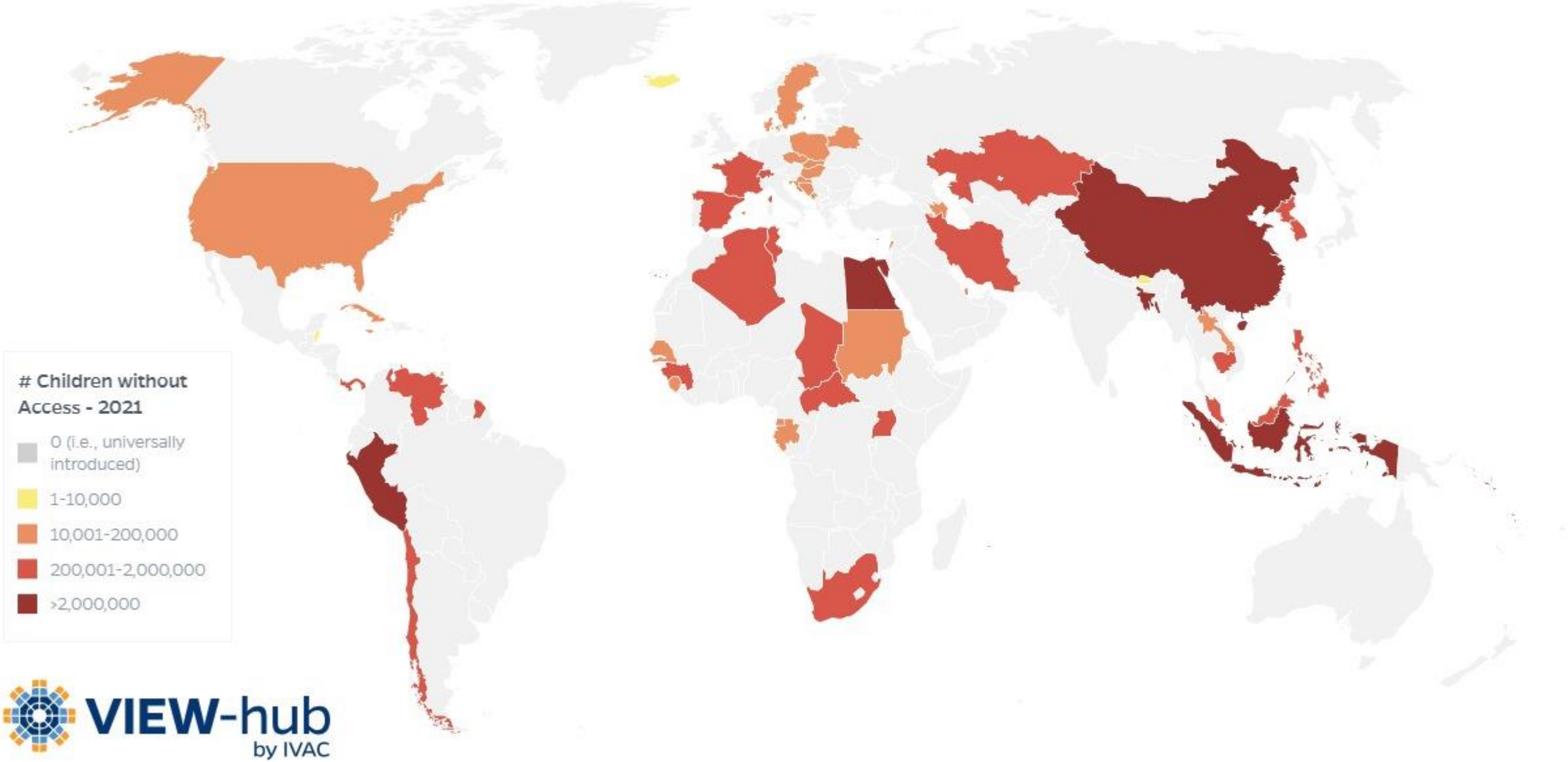
Aspectos históricos: entendendo criticamente o problema da equidade em vacinas

Vacinas sempre foram assunto de interesse...

- Descoberta, divulgação, revoluções tecnológicas: percepção, demanda e acesso;
- Programa Ampliado de Imunização (1974): esforços para eliminação da varíola
- Criação dos programas nacionais de Imunização
- Estabelecimento dos calendários de imunização básicos
- Estratégias de vacinação e acesso
- Global Vaccine Action Plan (2011 – 2020)



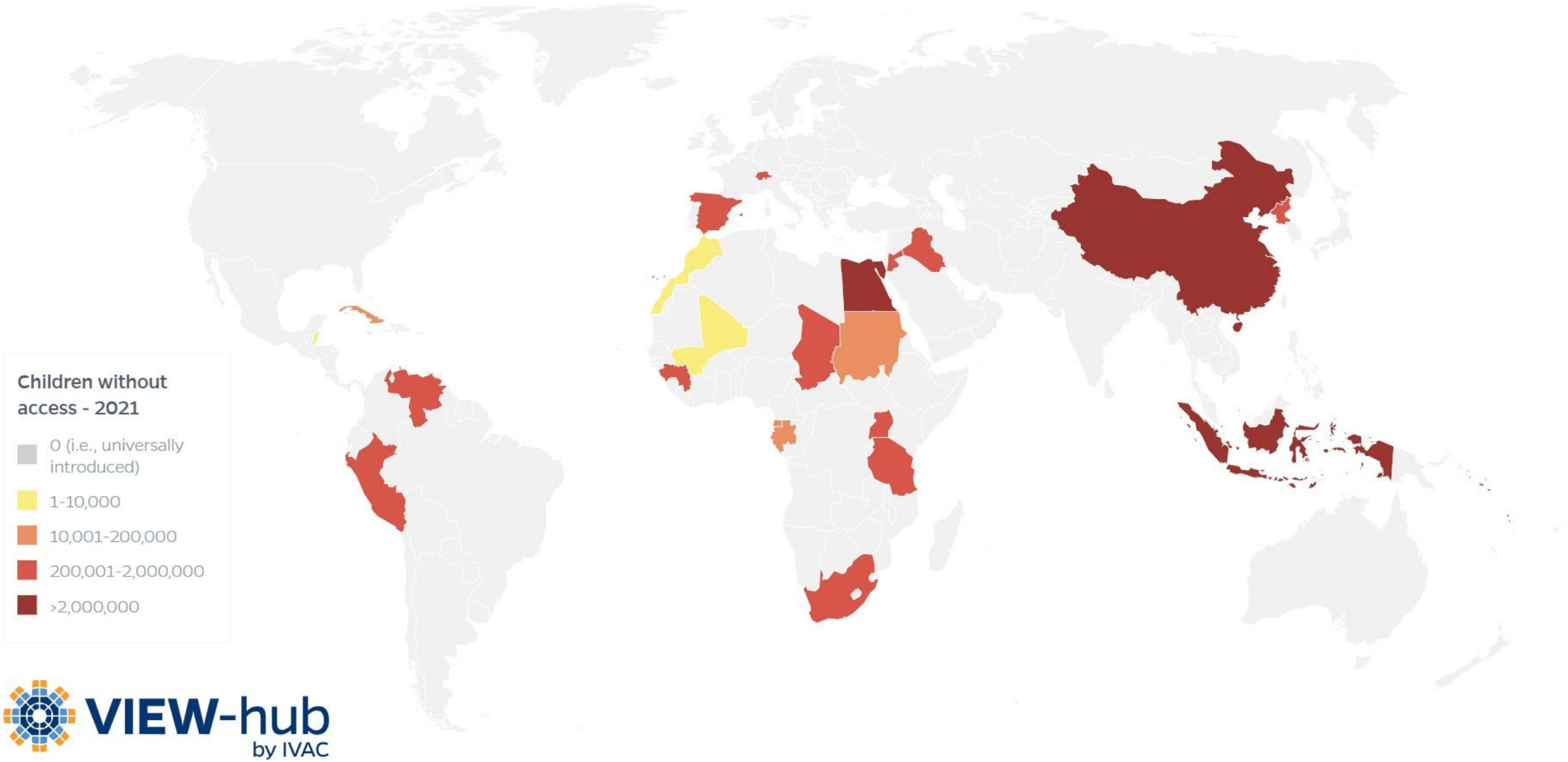
RV ▶ Vaccine Access ▶ # Children without Access



June 29, 2023 © The International Vaccine Access Center (IVAC)

Fonte:https://view-hub.org/vaccine/rota/access

PCV ▶ Vaccine Access ▶ Children without access



VIEW-hub by IVAC

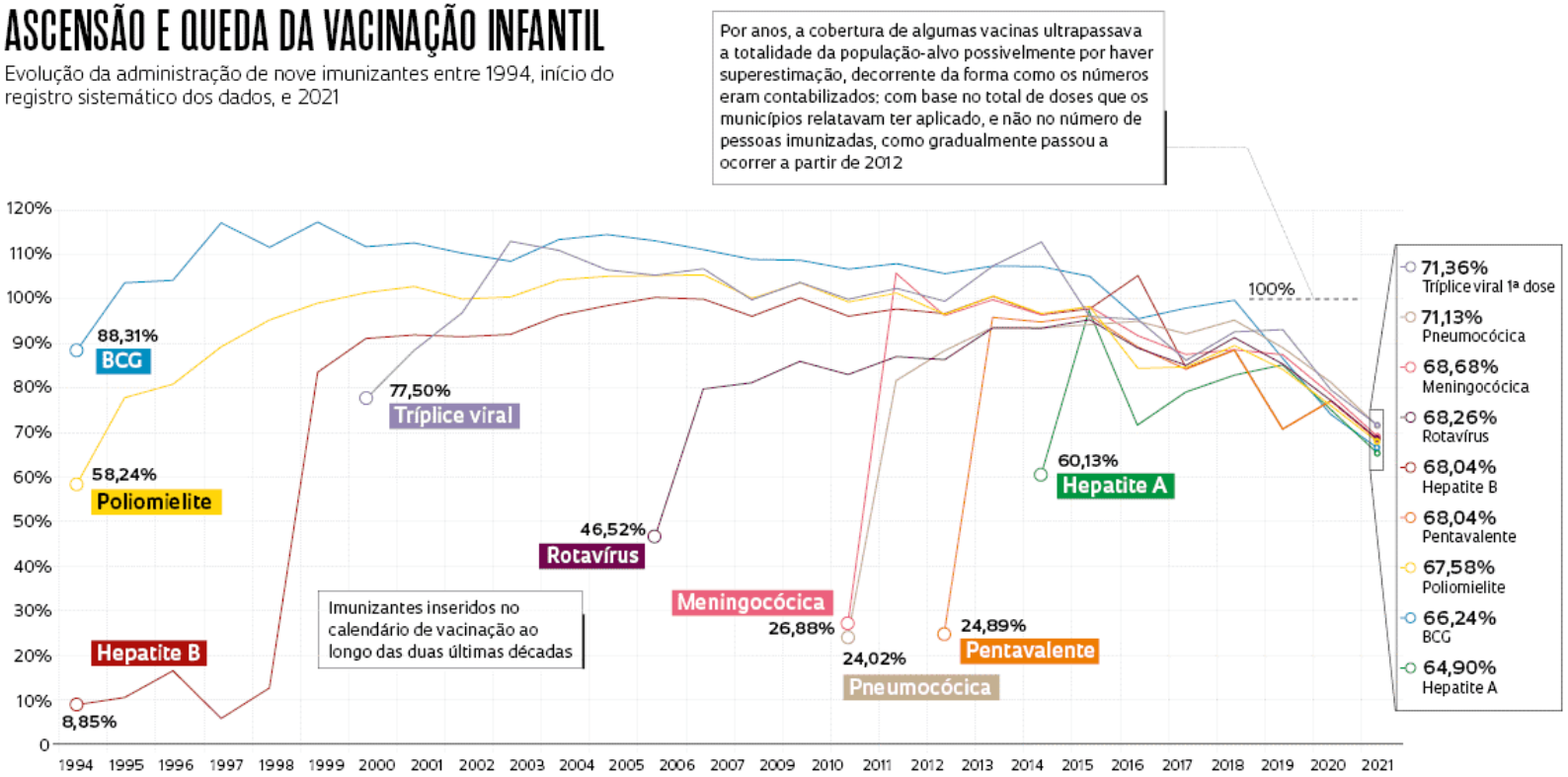
June 29, 2023 © The International Vaccine Access Center (IVAC)

Fonte:https://view-hub.org/vaccine/rota/access

Mas e no Brasil?

ASCENSÃO E QUEDA DA VACINAÇÃO INFANTIL

Evolução da administração de nove imunizantes entre 1994, início do registro sistemático dos dados, e 2021



FONTE SI-PNI / DATASUS

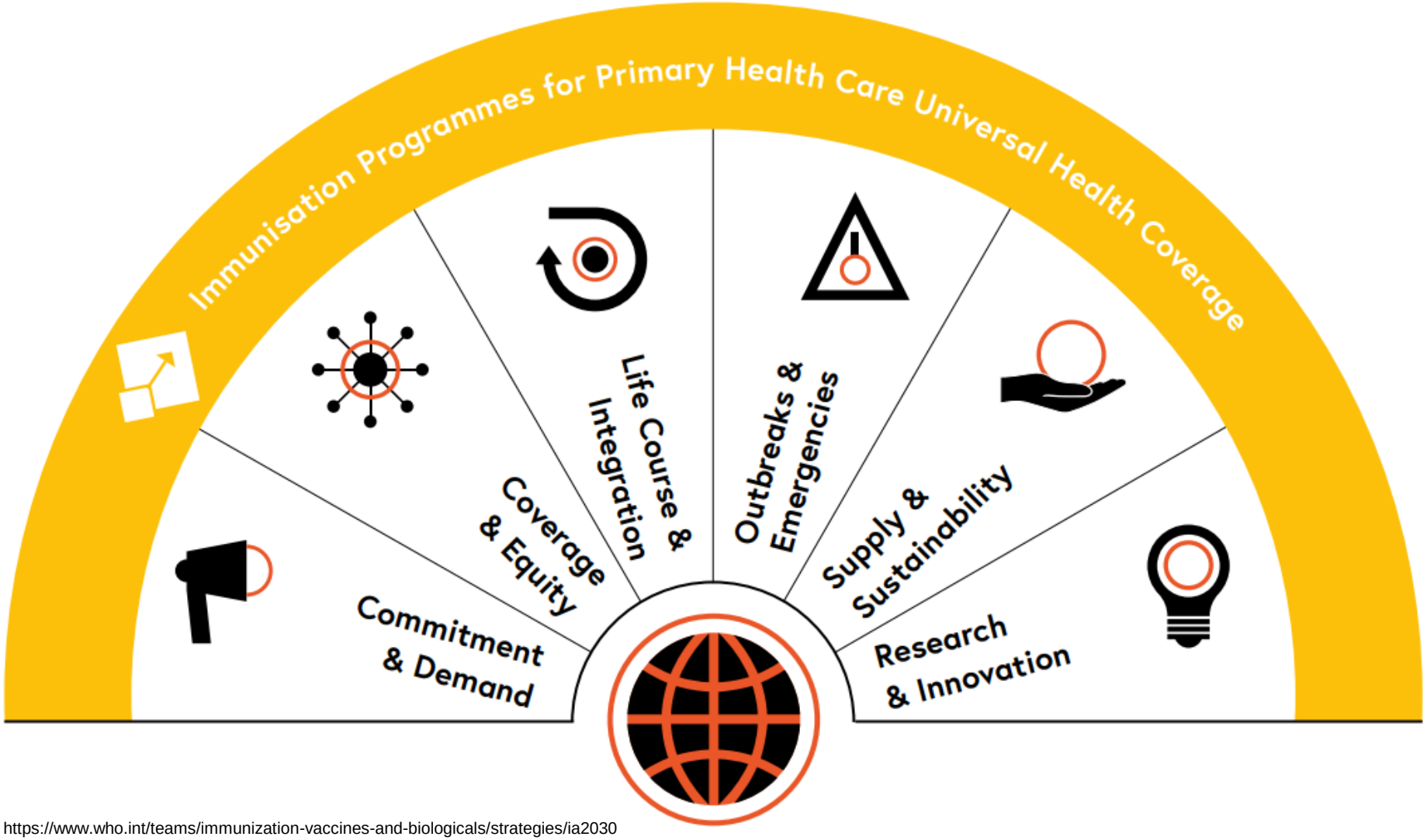
Tabela 4. Cobertura para o esquema completo (doses aplicadas) e diferença de cobertura entre o estrato socioeconômico A e o estrato D, em cada capital e no Distrito Federal, coortes de 2017 e 2018.

Cidade	Cobertura esquema completo*	Desigualdade: diferença entre estratos alto e muito baixo (%)
Curitiba	74,4 (66,3–81,1)	-3,2
Teresina	73,7 (63,0–82,1)	10,4
Brasília	73,1 (69,3–76,5)	-0,4
Palmas	67,5 (60,5–73,8)	-8,7
Aracaju	65,3 (58,7–71,4)	2,9
Porto Alegre	65,2 (59,7–70,3)	-6,1
Salvador	65,0 (60,6–69,1)	-15,3
Porto Velho	64,8 (58,0–71,1)	18,2
São Paulo	64,0 (60,1–67,7)	-5,3
Belo Horizonte	63,8 (59,5–67,9)	-9,2
Cuiabá	60,9 (53,2–68,0)	16,1
Rio Branco	60,8 (53,3–67,7)	3,1
Boa Vista	60,0 (48,8–70,2)	14,3
Maceió	58,3 (50,2–66,0)	-4,5
Belém	57,5 (47,4–67,0)	7,8
Vitória	57,1 (50,6–63,6)	-33,8
Recife	56,9 (49,6–63,9)	-14,7
Goiânia	56,6 (50,2–62,8)	-8,8
Campo Grande	54,2 (48,2–60,0)	-12,4
Manaus	54,1 (49,6–58,6)	-3,7
Fortaleza	54,0 (47,3–60,5)	-24,1
São Luís	51,6 (43,1–60,1)	17,4
Rio de Janeiro	51,6 (45,8–57,4)	5,1
Florianópolis	49,6 (40,8–58,4)	-8,2
João Pessoa	42,6 (36,3–49,2)	-12,2
Natal	36,6 (26,8–47,8)	-24,4
Macapá	35,8 (28,1–44,3)	7,7

*A febre amarela não foi incluída porque sua introdução no esquema básico variou entre os estados e nem todos tinham implementado a vacina em 2017.

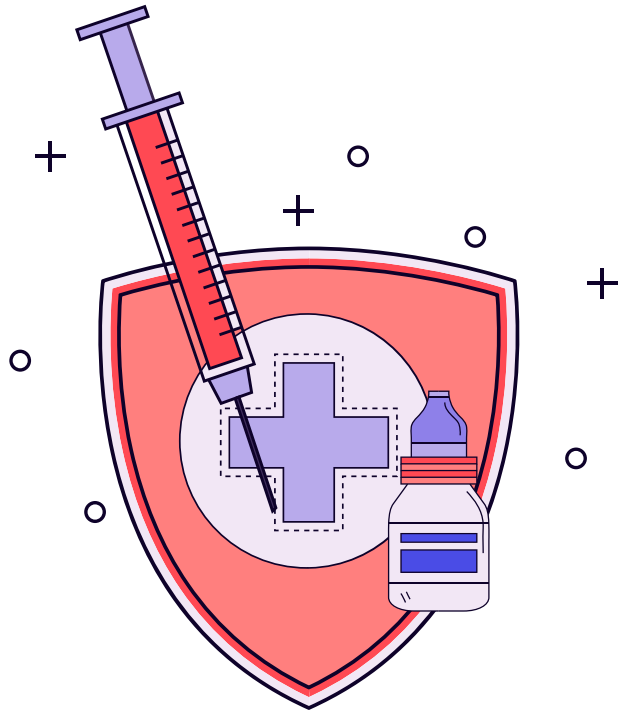
Fonte: http://sipni.datasus.gov.br/si-pni-web/faces/inicio.jsf e https://doi.org/10.1590/1980-549720230031

A Agenda de Imunização 2030



Fonte: Immunization agenda 2030. https://www.who.int/teams/immunization-vaccines-and-biologicals/strategies/ia2030

Cenários ainda mais complexos: emergências em saúde pública



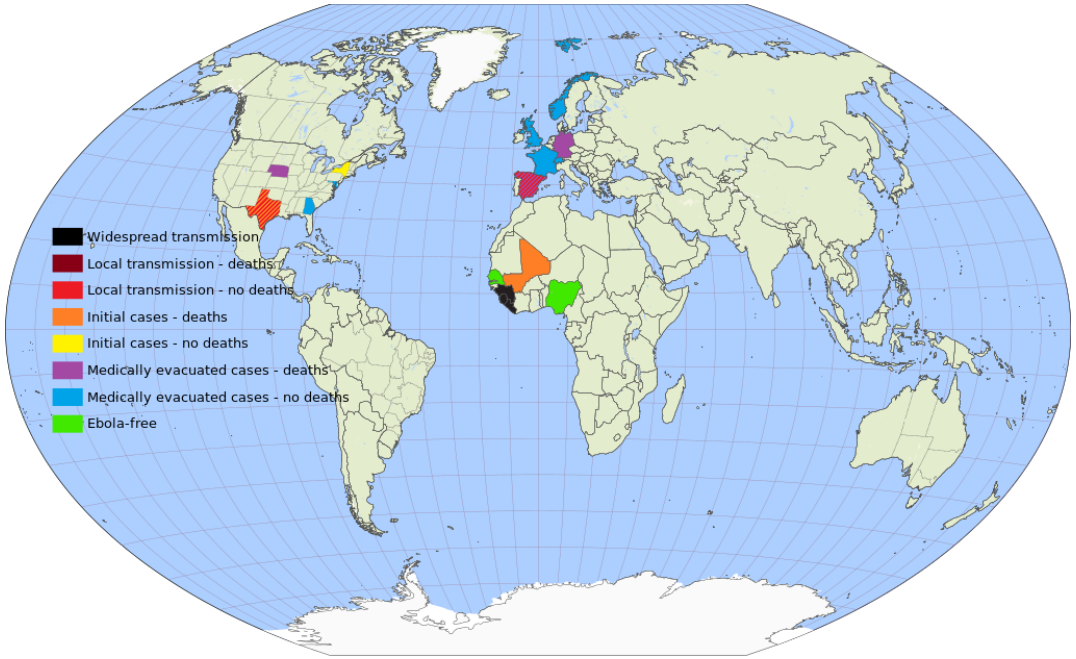
Ebola

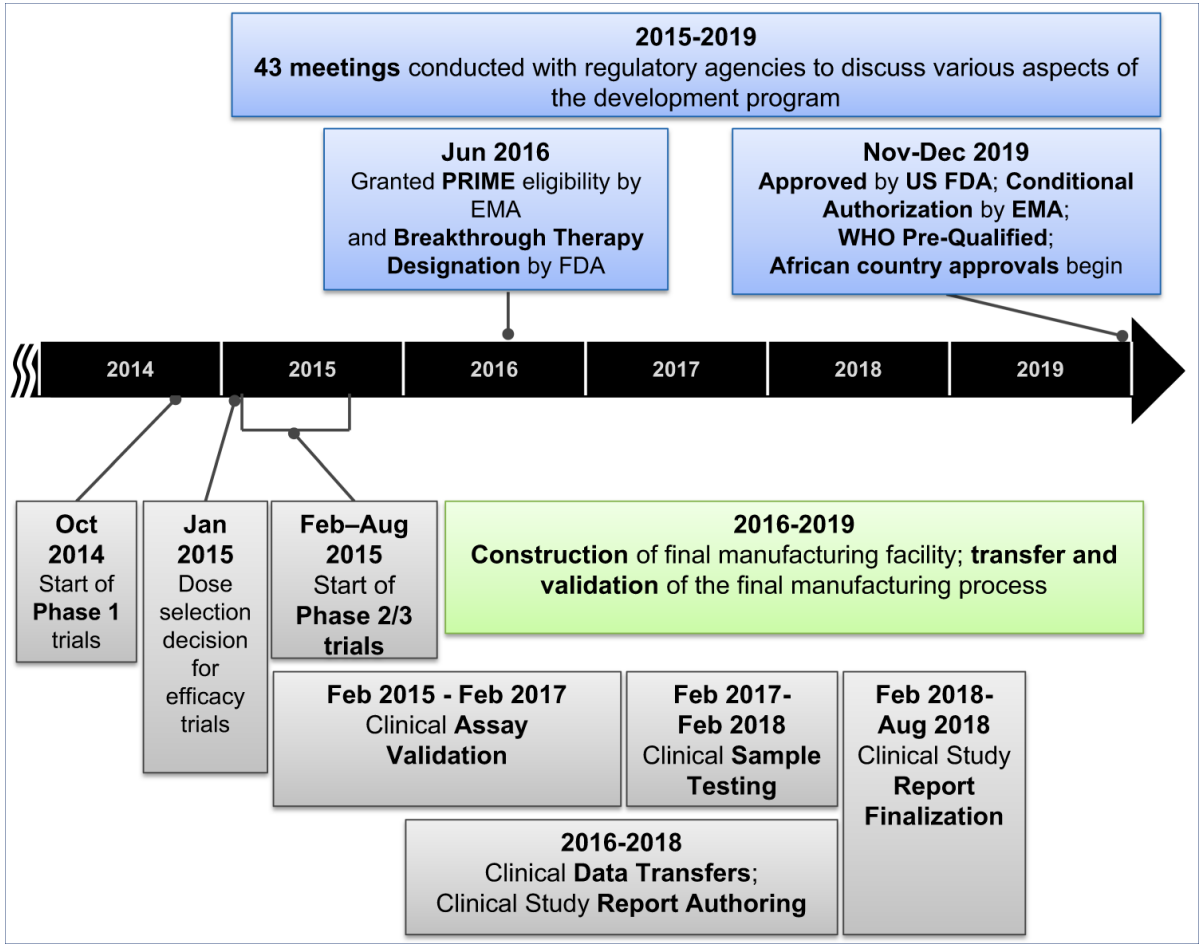
COVID-19

Monkeypox

Caso I: Ebola

ESPII declarada em 2014





<u>Vacinas disponíveis para o vírus do zaire:</u>

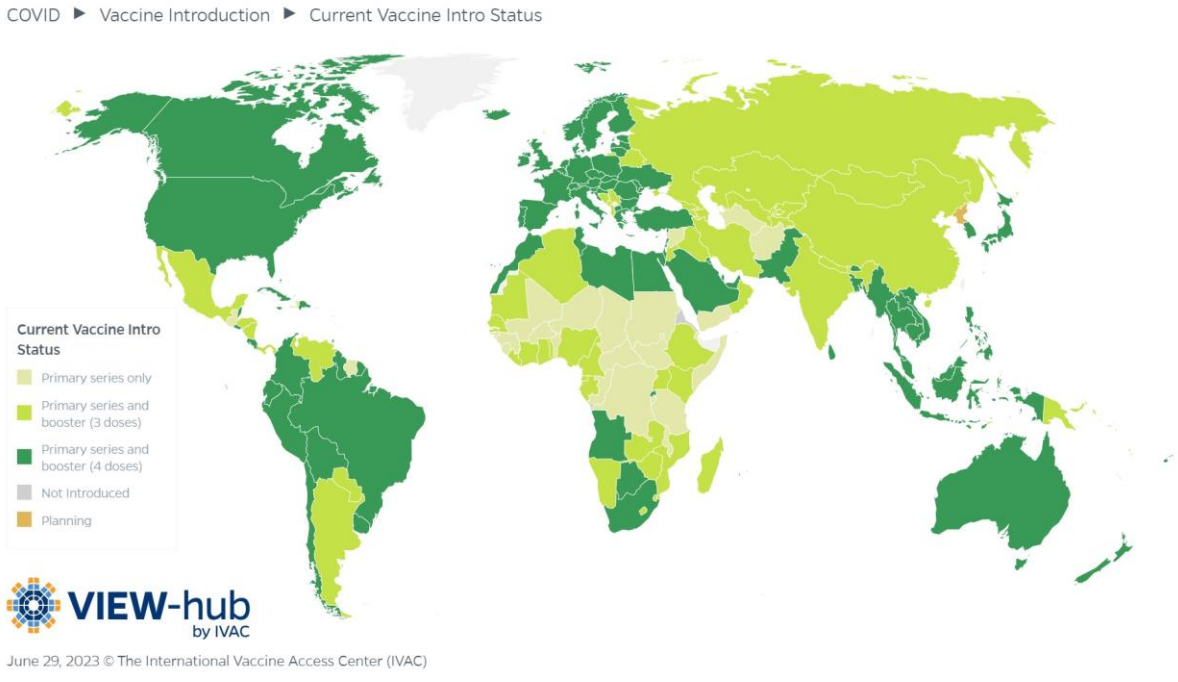
ERVEBO (adenovírus; 2 doses)– MSD/ FDA
Zabdeno e Mvabea (adenovírus; 2 doses) – J&J/ EMA

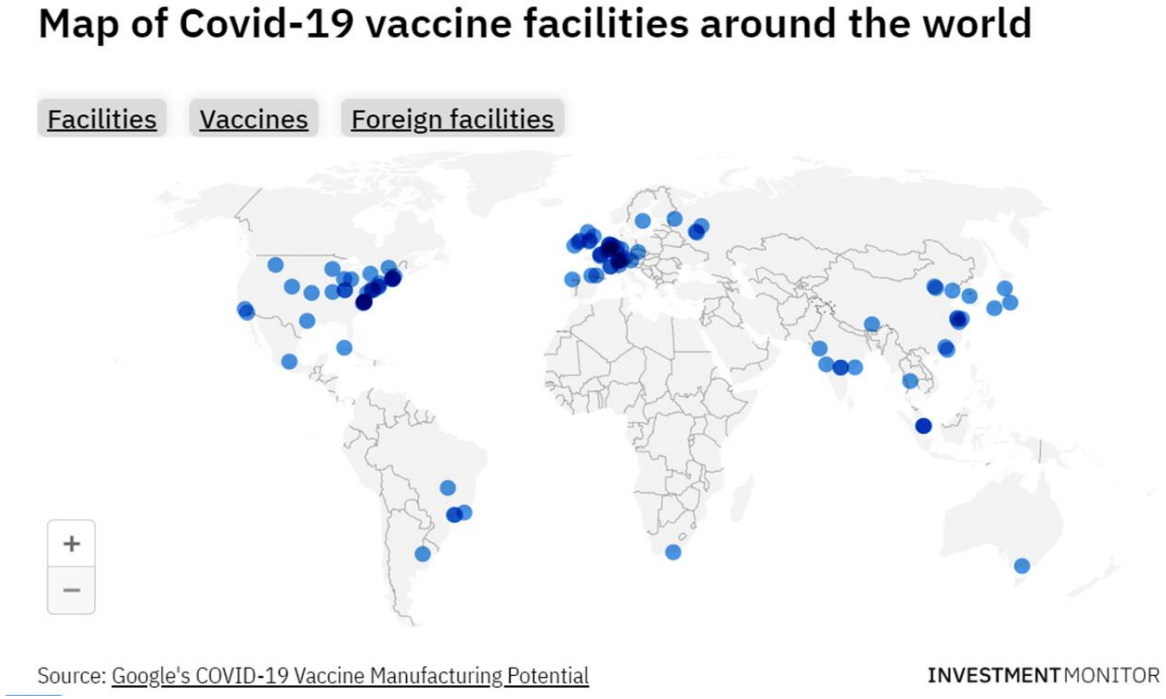
As vacinas só foram aprovadas para uso oficial no continente africano no final de 2021.
Nenhuma é produzida na África.

Fontes: WHO. Ebola vírus vaccines. https://www.who.int/news-room/questions-and-answers/item/ebola-vaccines?gclid=Cj0KCQjw1_SkBhDwARIsANbGpFtR-pZkJ134XIjdzSeik1NeWJDDOhJ95St5n7YJy1DnSdINk5nLCvEaAk9nEALw_wcB e Wolf et al (2020). https://www.nature.com/articles/s41541-020-0204-7

Caso II: COVID-19

ESPII declarada em 2020





Fonte: Viewhub. :https://view-hub.org/vaccine/ e Investment monitor, 2021. https://www.investmentmonitor.ai/manufacturing/covid-vaccine-regions-left-behind

Caso II: COVID-19

COVAX

CEPI Gavi unicef World Health Organization

High income countries: 3 in 4 people, or

72.96%

have been vaccinated with at least one dose as of Jun 29, 2023.

Low income countries: 1 in 3 people, or

35.36%

have been vaccinated with at least one dose as of Jun 29, 2023.

High income countries have to increase their health care spending by

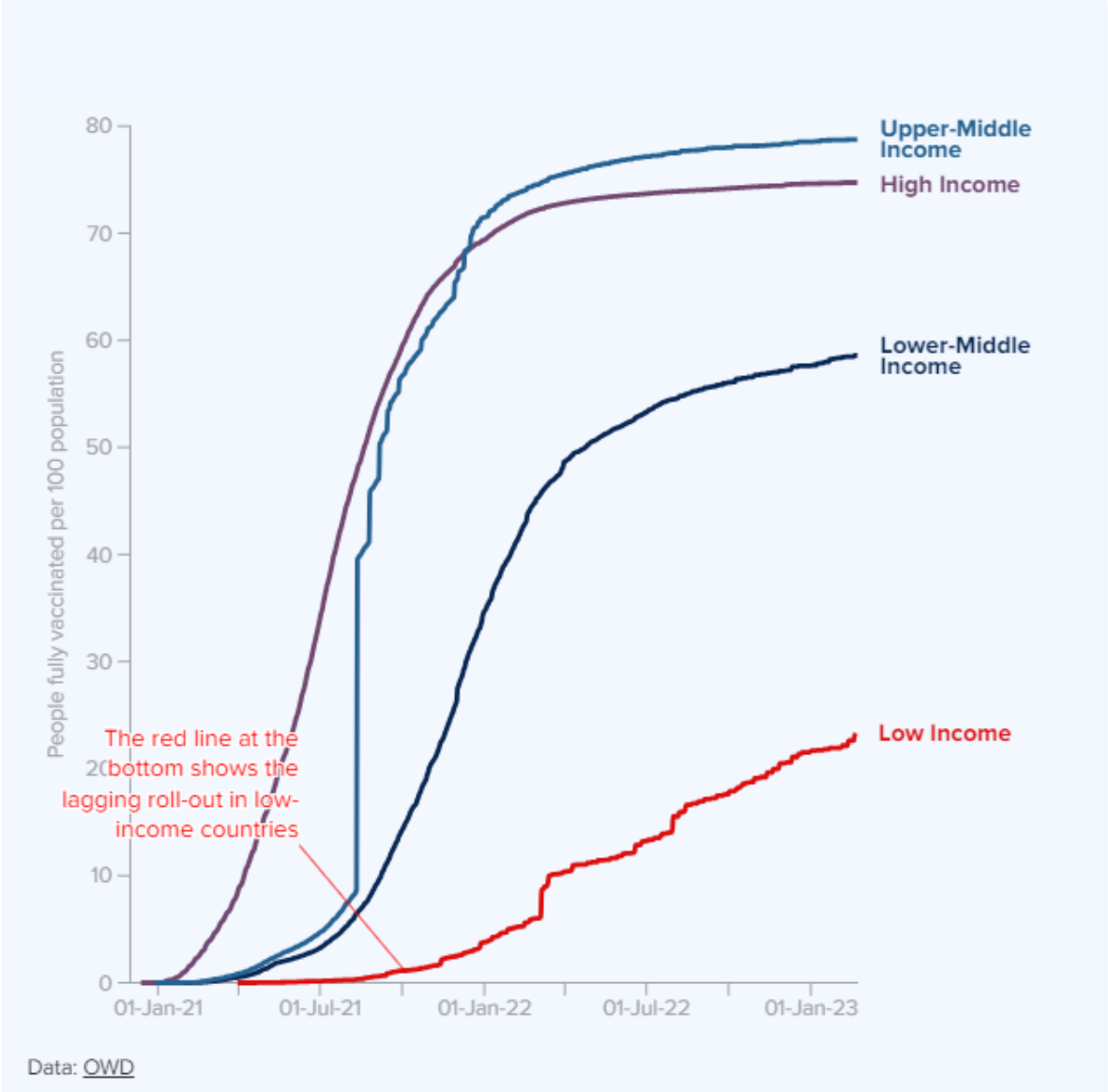
0.8%

on average to cover cost of vaccinating 70% of the population.

Low income countries have to increase their health care spending by

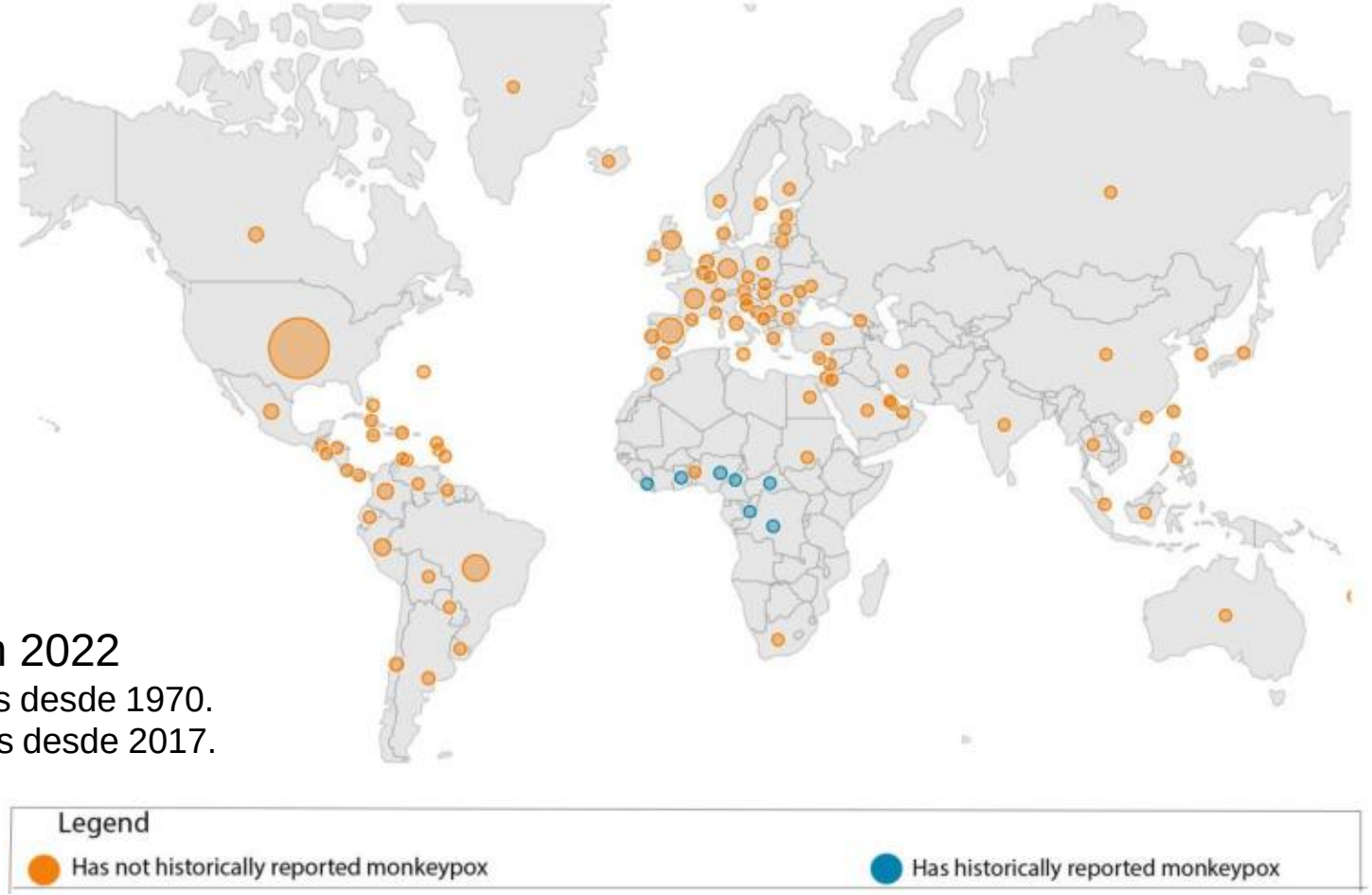
56.6%

on average to cover cost of vaccinating 70% of the population.



Fonte: Global dashboard for vaccine equity. https://data.undp.org/vaccine-equity/

Caso III: Monkeypox



ESPII declarada em 2022

Surtos na África são registrados desde 1970.

Surtos maiores são monitorados desde 2017.

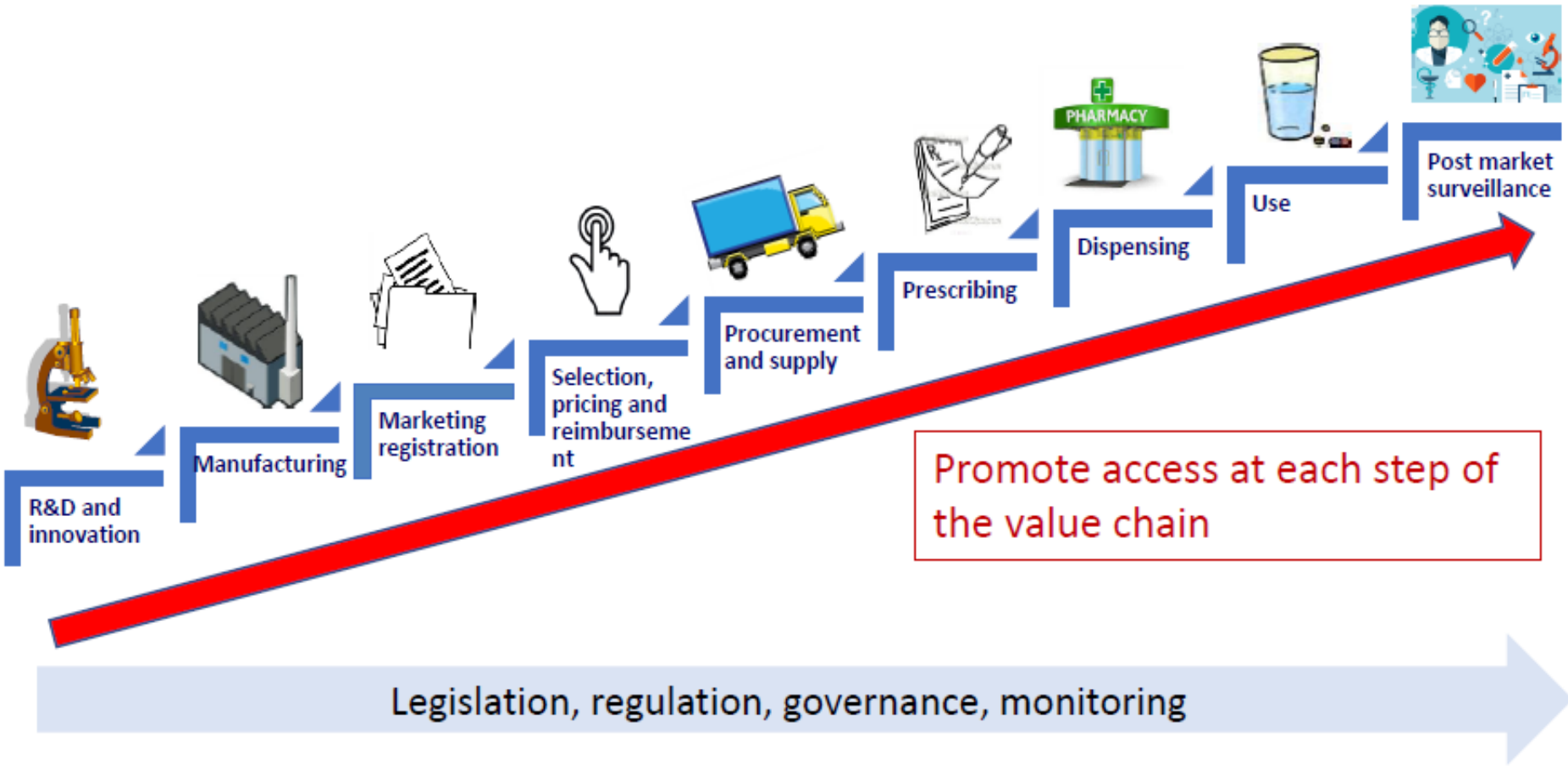
Apenas uma vacina disponível (JYNNEOS – Bavarian Nordic, 2 doses, vírus atenuado) desenvolvida primariamente para proteção contra a varíola.

A vacina foi aprovada pelo FDA e EMA em 2013.

Fonte: Tusabe et al, 2022. https://doi.org/10.2147%2FIDR.S384348

Fatores relacionados à falta de acesso a vacinas

Produção e dinâmica de mercado



1 Vaccine development

Universities & Institutes

Private sector

Governments

NGOs (e.g. corporate foundations)

Intellectual Property (IP*)

- Patents
- Trademarks
- Industrial designs
- Trade secrets & test data
- Copyright

IP status

IP sharing (including licensing)

Vaccine

Medical devices

Exchange of data & samples

Good laboratory practice

2 Domestic approval (Manufacture)

Environmental risk assessment?

Pharmaceutical quality
small scale studies

Non-clinical
in vitro in vivo

Clinical trials phase
I II III

Evaluation & decision
safety efficacy

WHO (including UN procurement)
- Emergency use listing
- Pre-qualification

Approval by regulator
- Emergency use authorization
- Standard approval

QUALITY ASSURANCE

3 Vaccine manufacture

Domestic & global sourcing

Intellectual Property

Export procedures

COVID-19 TRADE CONTROLS

Import procedures

Raw materials

Vaccine

Packaging materials

Packaging and labelling

Lot release

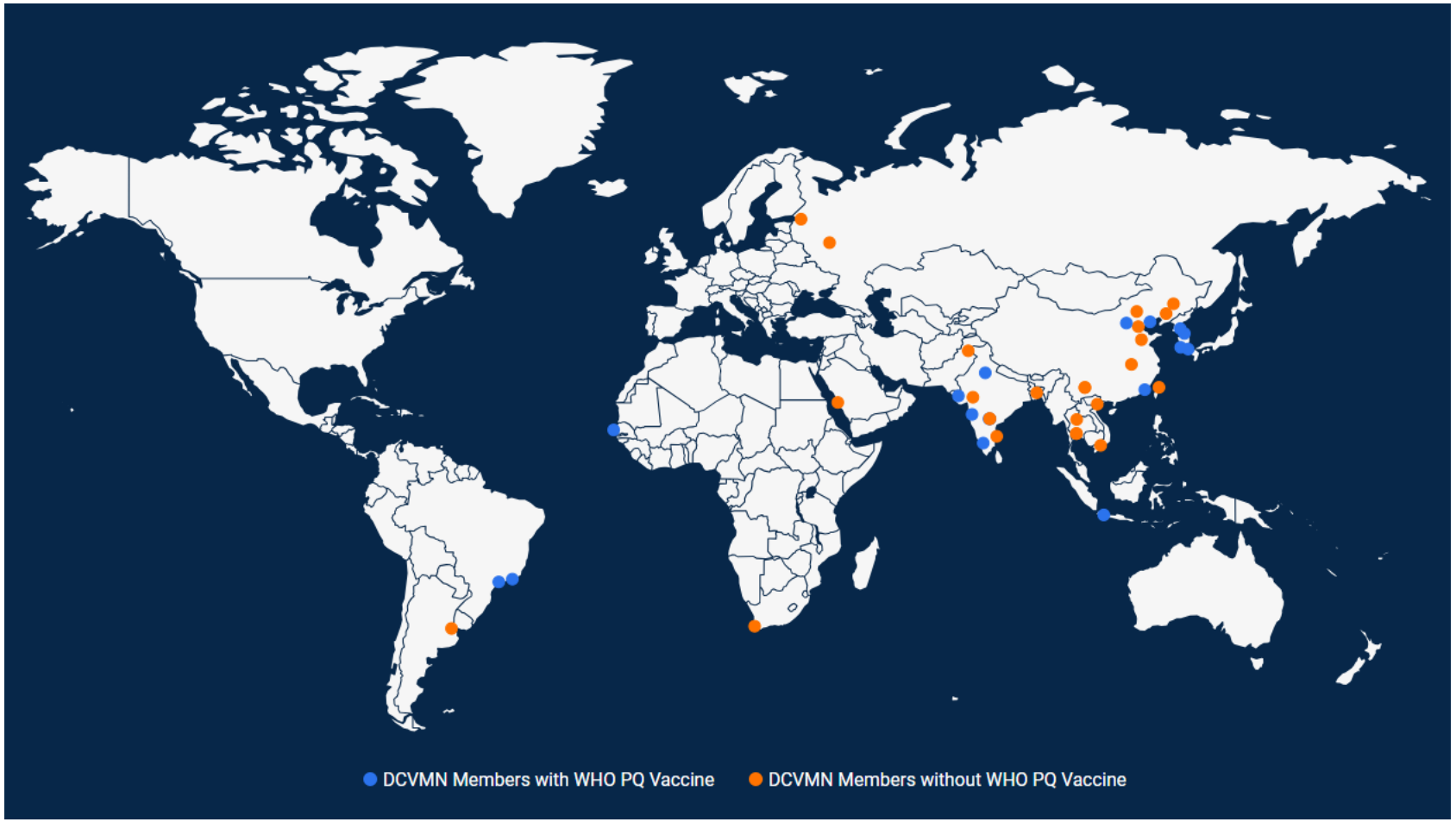
Approval by domestic authority (Exporter)

Quality control representing up to **70%** of manufacturing time

Several hundred quality control tests

Inspection by regulatory authority (exporter + importer)

Good manufacturing practice



A Rede de Fabricantes de Vacinas dos Países em Desenvolvimento (DCVMN) é uma aliança voluntária de mais de 40 fabricantes de vacinas de 15 países em desenvolvimento, firmemente engajados na inovação, pesquisa, desenvolvimento, fabricação e fornecimento de vacinas de alta qualidade para 170 países que se esforçam para permitir o acesso equitativo a vacinas

4 Domestic approval

(Importer)

Domestic approval
(repeat step 2)

OR

Use step 2 approval
(WHO or foreign regulator)

Procurement

Public — COVAX — Private

APPROVED ✓

- Approved by regulator
- Approval of manufacture facility
- Approved for market (labelling, packaging)

5 International distribution

Transit

Customs

IP border measures

Shipment

Cold chain integrity

COVID-19 TRADE CONTROLS

QUALITY ASSURANCE

A vaccine typically travels through several different sites before being ready for shipment

Good distribution practice

Mercado global de vacinas

Fig. 7: Manufacturers by headquarter location, 2021

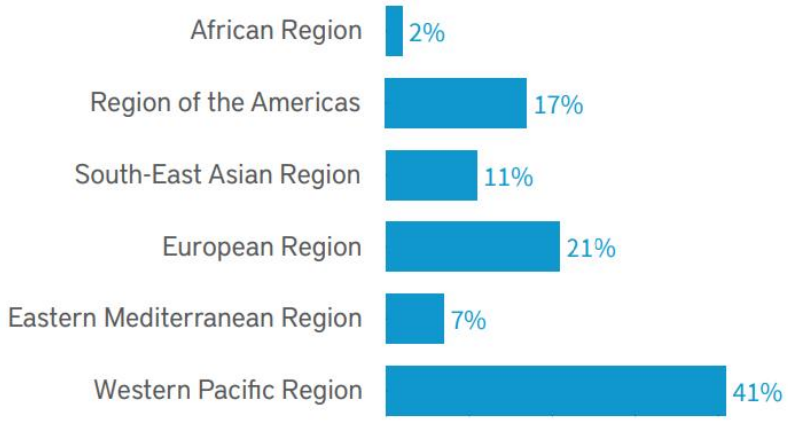


Fig. 8: Top 10 manufacturers by value, 2021

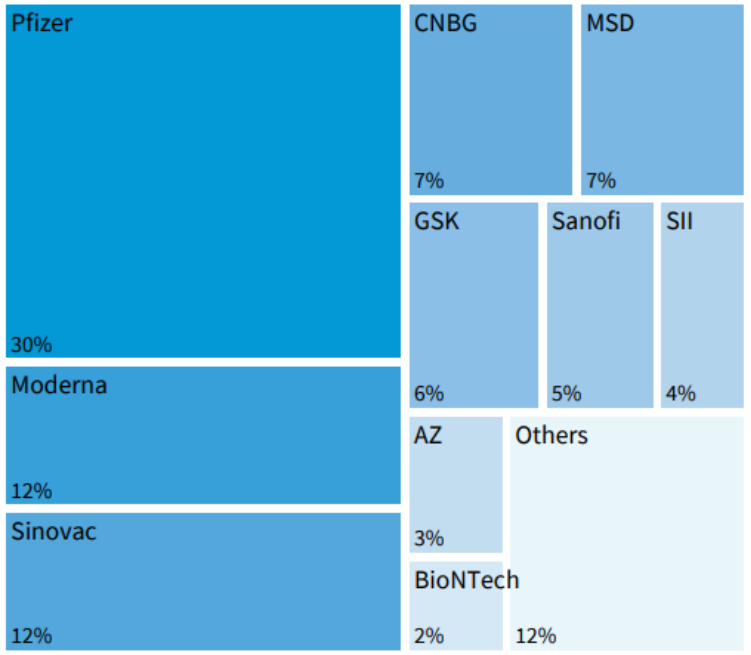
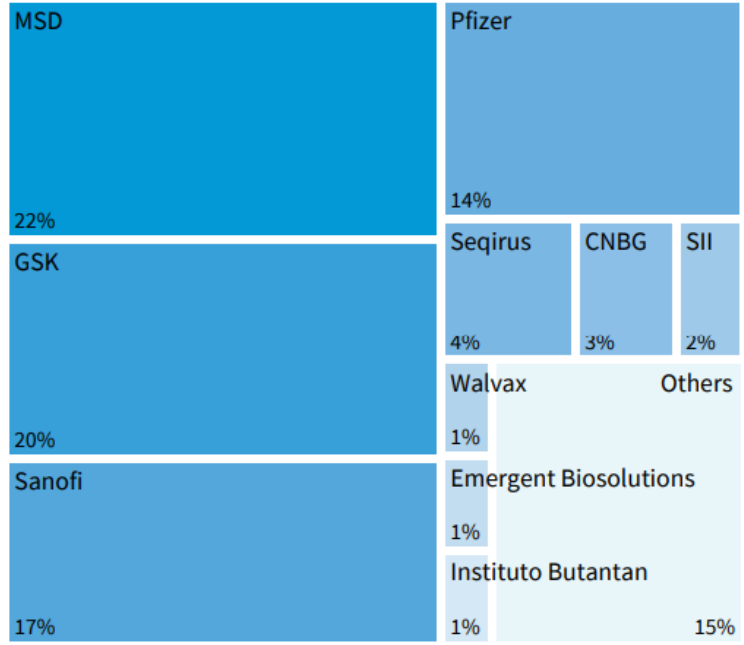


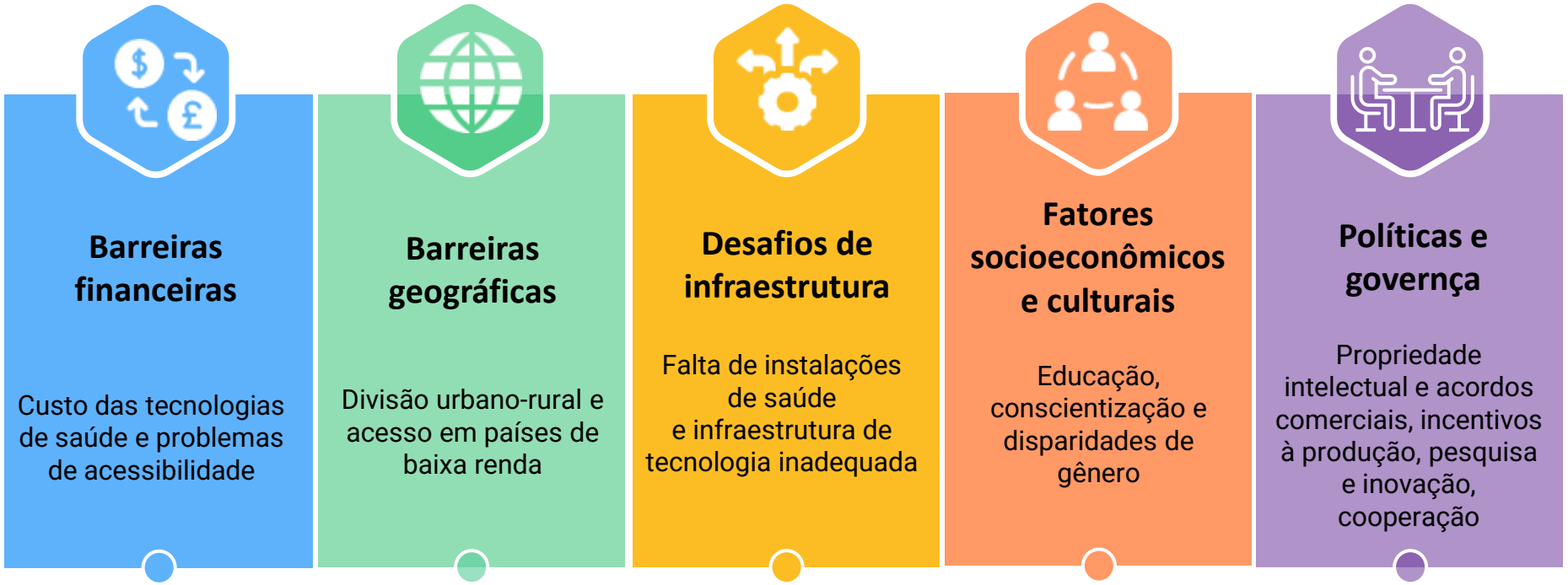
Fig. 9: Top 10 manufacturers by value (excluding COVID-19), 2021



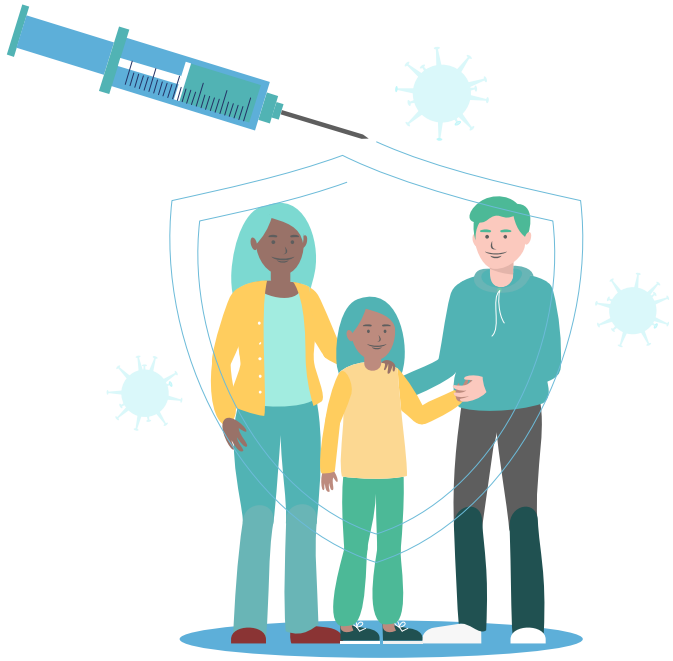
Vacinas são extremamente custo-efetivas. Por exemplo, o CDC estima que nos EUA para cada **US$1** gasto com vacinação infantil o país economiza **US$10,90** em outros gastos com saúde.

Fonte: Global vaccine market report 2022: a shared understanding for equitable access to vaccines. https://www.who.int/publications/i/item/9789240062726 e The value of immunization compendium. https://immunizationevidence.org/key-concepts/vaccines-are-among-the-most-cost-effective-health-interventions-available/

Ainda existem outros fatores...



Equidade no acesso a vacinas na atual agenda de saúde global

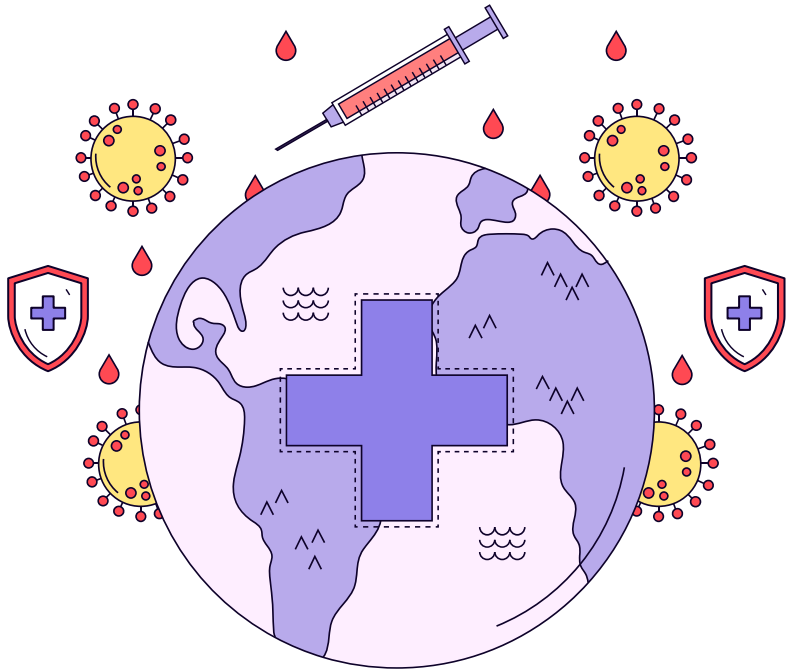


Vacinas como bens públicos globais

Bem público global[1] é uma política que trata alguns itens ou bens sendo comuns a todo o planeta. Ou seja, nenhum país possui posse sobre tal item, como por exemplo, os oceanos, onde cada país possui a liberdade de navegar sobre ele sem restrições.

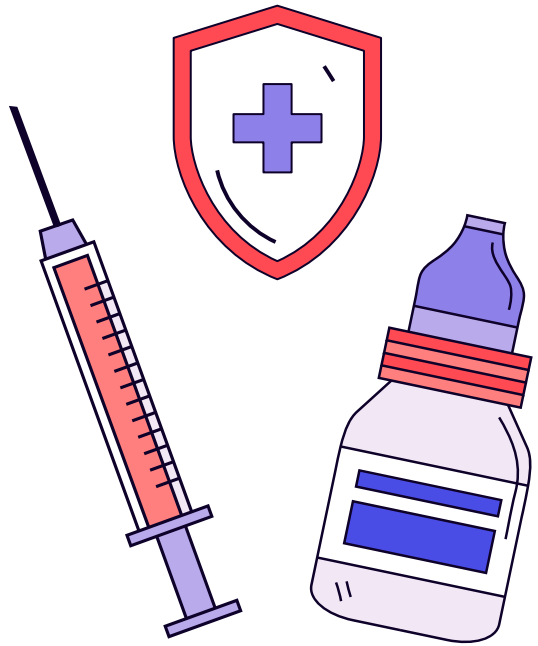
Para algo ser um bem público global deve ter as seguintes propriedades:

- **Não é competitivo**. O consumo deste bem por uma pessoa não diminui a quantidade disponível para outra pessoa;
- **Não é excluível**. Ser impossível de proibir alguém de consumir tal bem;
- **Estar disponível numa escala, mais ou menos, global**.

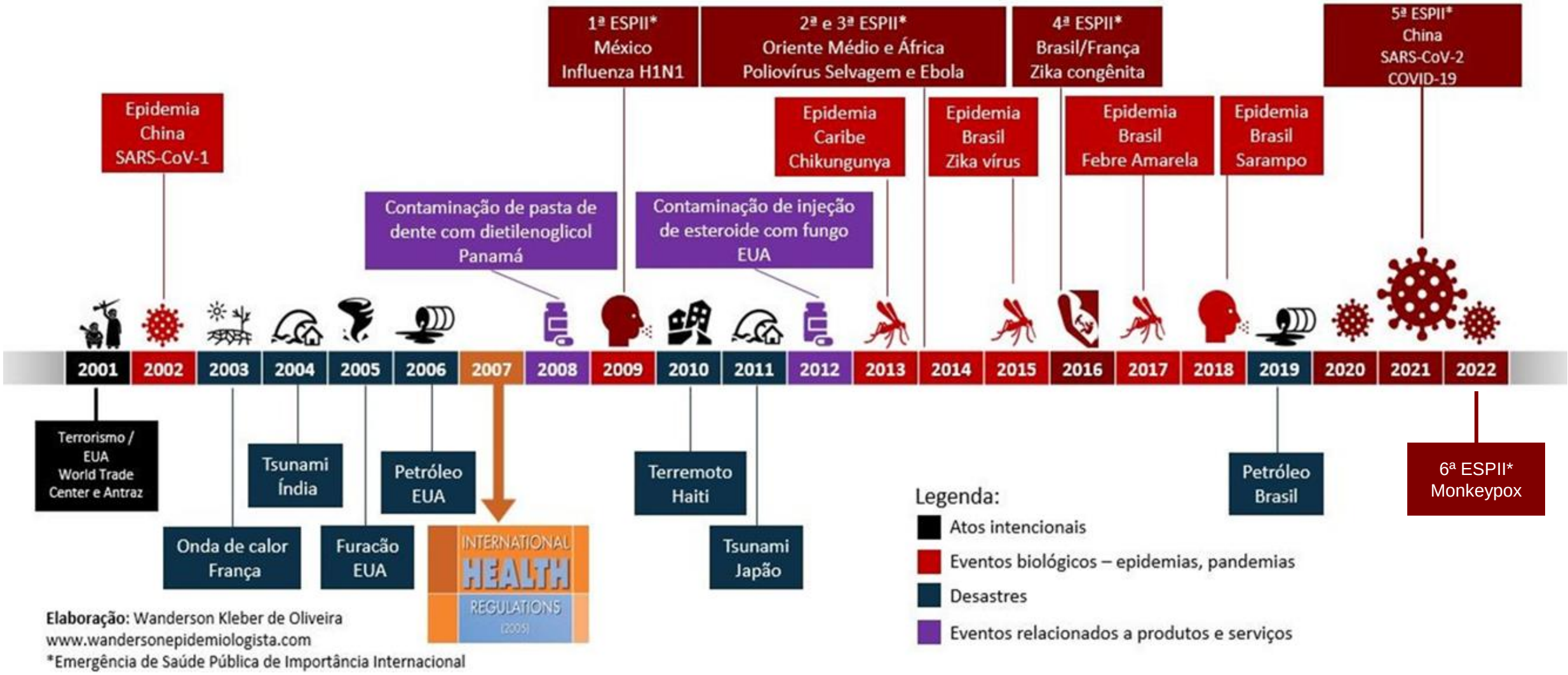


Fonte: Le diplomatique. Bens públicos globais, um conceito revolucionário. https://diplomatique.org.br/bens-publicos-globais-um-conceito-revolucionario/#:~:text=%C3%89%20necess%C3%A1rio%20repensar%20o%20equil%C3%ADbrio,e%20o%20dom%C3%ADnio%20p%C3%BAblico%20mundial.

Segurança sanitária



20+ anos de emergências nacionais e mundiais



Elaboração: Wanderson Kleber de Oliveira
www.wandersonepidemiologista.com
*Emergência de Saúde Pública de Importância Internacional

Second meeting of the Working Group on Amendments to the International Health Regulations (2005)

العربية 中文 Español

World Health Organization

SECOND MEETING OF THE WORKING GROUP ON AMENDMENTS TO THE INTERNATIONAL HEALTH REGULATIONS (2005)
Provisional agenda item 6

A/WGIHR/2/6
6 February 2023

Proposed amendments to the International Health Regulations (2005) submitted in accordance with decision WHA75(9) (2022)

The Working Group on Amendments to the International Health Regulations (2005) (WGIHR) at its first meeting on 14-15 November 2022 decided that "the Secretariat shall publish the proposed amendments online, as submitted by Member States unless otherwise informed by the submitting Member States."[1]

In furtherance of the WGIHR's decision above, this document includes proposals for amendments to the International Health Regulations (2005) (IHR), as submitted by Member States.

The proposals are listed in alphabetical order by Member State.

Reforma do RSI

Fonte: OMS.https://www.who.int/news/item/25-02-2023-governments-hold-first-detailed-discussions-on-proposed-amendments-to-the-international-health-regulations-(2005)

"The World Together": the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response

Tratado para pandemias

World Health Organization

FOURTH MEETING OF THE INTERGOVERNMENTAL NEGOTIATING BODY TO DRAFT AND NEGOTIATE A WHO CONVENTION, AGREEMENT OR OTHER INTERNATIONAL INSTRUMENT ON PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE

Provisional agenda item 3

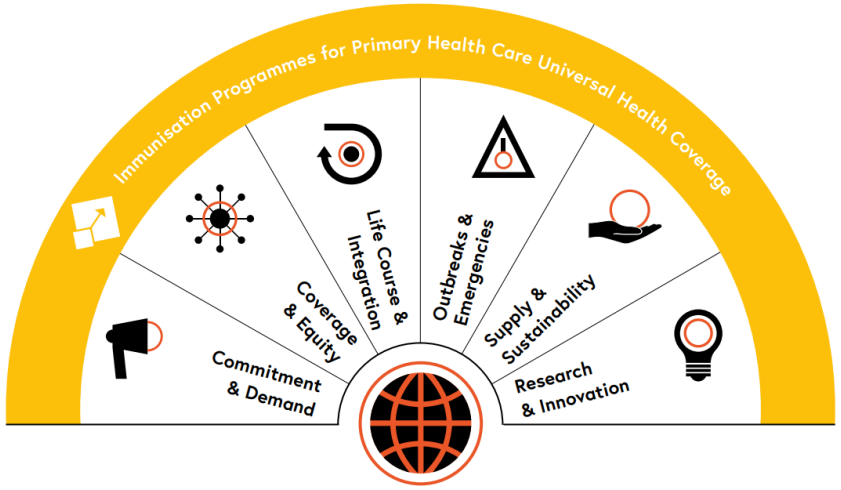
A/INB/4/3
1 February 2023

Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting

WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response ("WHO CA+")

Fonte: OMS. Intergovernmental Negotiation Body. https://inb.who.int/

A Agenda de Imunização 2030



Immunisation Programmes for primary health care/universal health coverage	• Ensure adequate health workforce availability • Build and strengthen comprehensive vaccine-preventable disease surveillance supported by strong and reliable laboratory-based systems • Secure high-quality supply chains and effective vaccine management to facilitate equitable coverage in immunisation and establish synergies with other primary health care supply chains where possible • Generate fit-for-purpose immunisation data for evidence-based decision-making • Ensure functional vaccine safety systems in close collaboration with national regulatory agencies
Commitment & Demand	• Build and sustain strong social, financial and political commitment for immunisation • Strengthen leadership, management and coordination for immunisation at all levels • Ensure people and communities value, actively support and seek out immunisation services
Coverage & Equity	• Reach high equitable immunisation coverage at national level and in all districts • Increase coverage of vaccines among the most disadvantaged populations • Reduce the number of children not reached through the immunisation programme ("zero-dose" children)
Life course & Integration	• Strengthen policies and service delivery to provide new and underused vaccines and appropriate catch-up vaccination across the life-course • Establish integrated delivery touchpoints for immunisation and other public health interventions across the life course
Outbreaks & Emergencies	• Decrease the number and magnitude of outbreaks of epidemic-prone vaccine-preventable diseases • Ensure timely, well-organized responses to outbreaks of epidemic-prone vaccine-preventable diseases • Establish timely and appropriate vaccination services in acute emergencies and humanitarian crises
Supply & Sustainability	• Build and sustain healthy markets across all antigens at the global level • Safeguard access quality assured vaccines in a timely fashion in all countries • Ensure sufficient financial support for immunisation programmes across all countries to achieve universal coverage • Increase immunisation expenditure from domestic resources for aid dependent countries, and when transitioning away from aid, secure government domestic funding to sustain coverage of all vaccines after transition
Research & Innovation	• Establish and strengthen country capacity to identify, create and manage innovation • Develop new vaccines and technologies and improve existing products and services for immunisation programmes • Introduce and scale up new and underused vaccines and improved technologies, services and practices

Fonte: Immunization agenda 2030. https://www.who.int/teams/immunization-vaccines-and-biologicals/strategies/ia2030

Estratégia 5 Cs da OMS: preparação e resposta a futuras ESP

Collaborative surveillance

Strong national integrated disease, threat, and vulnerability **surveillance**

Effective diagnostics and **laboratory** capacity for pathogen and genomic surveillance

Collaborative approaches for event detection, risk assessment, and response monitoring

Safe and scalable care

Scalable clinical care during emergencies

Protection of health workers and patients

Maintenance of **essential health services**

Emergency coordination

Strengthened **workforce capacity** for health emergencies

Strengthening health emergency preparedness, readiness, and resilience

Health emergency **alert and response coordination**

Community protection

Community **engagement**, **risk communication** and **infodemic management**

Population and environmental **public health interventions**

Multisectoral action for **social and economic protection**

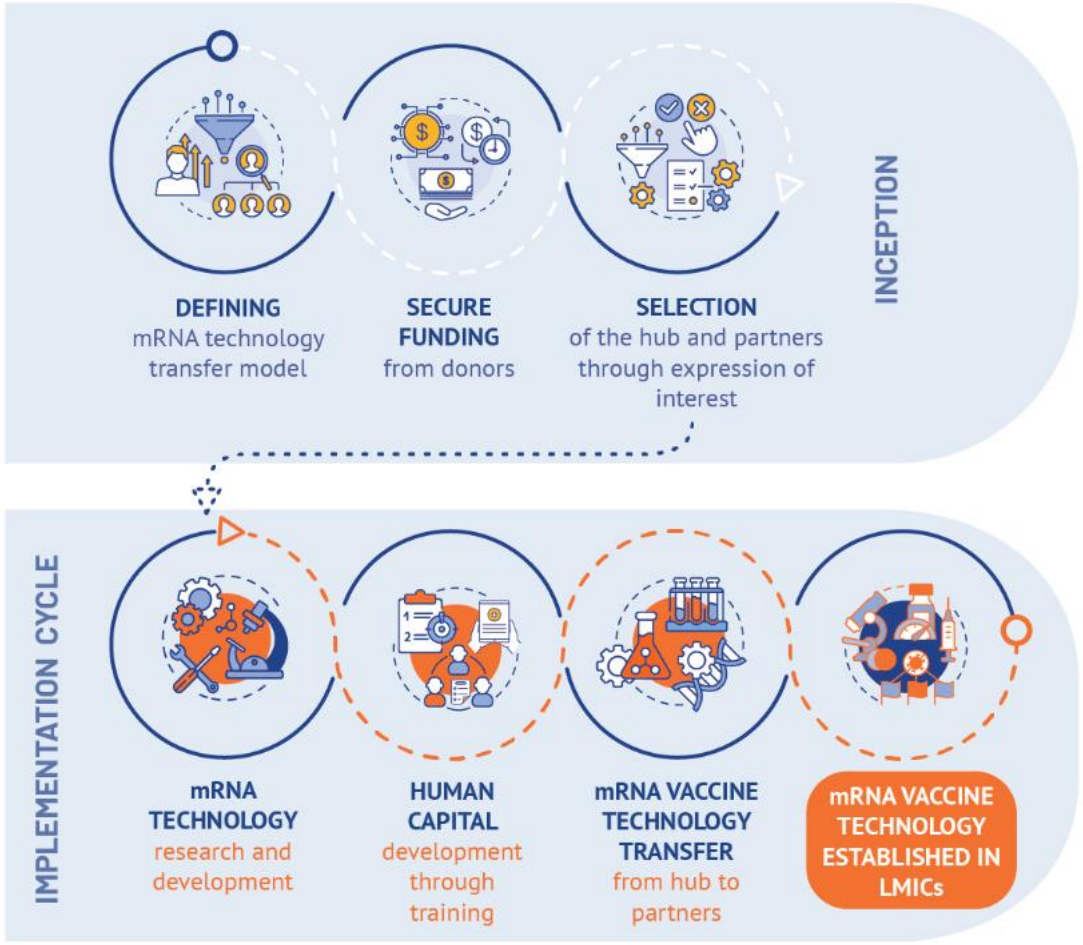
Access to countermeasures

Fast tracked **R&D**

Scalable **manufacturing platforms**

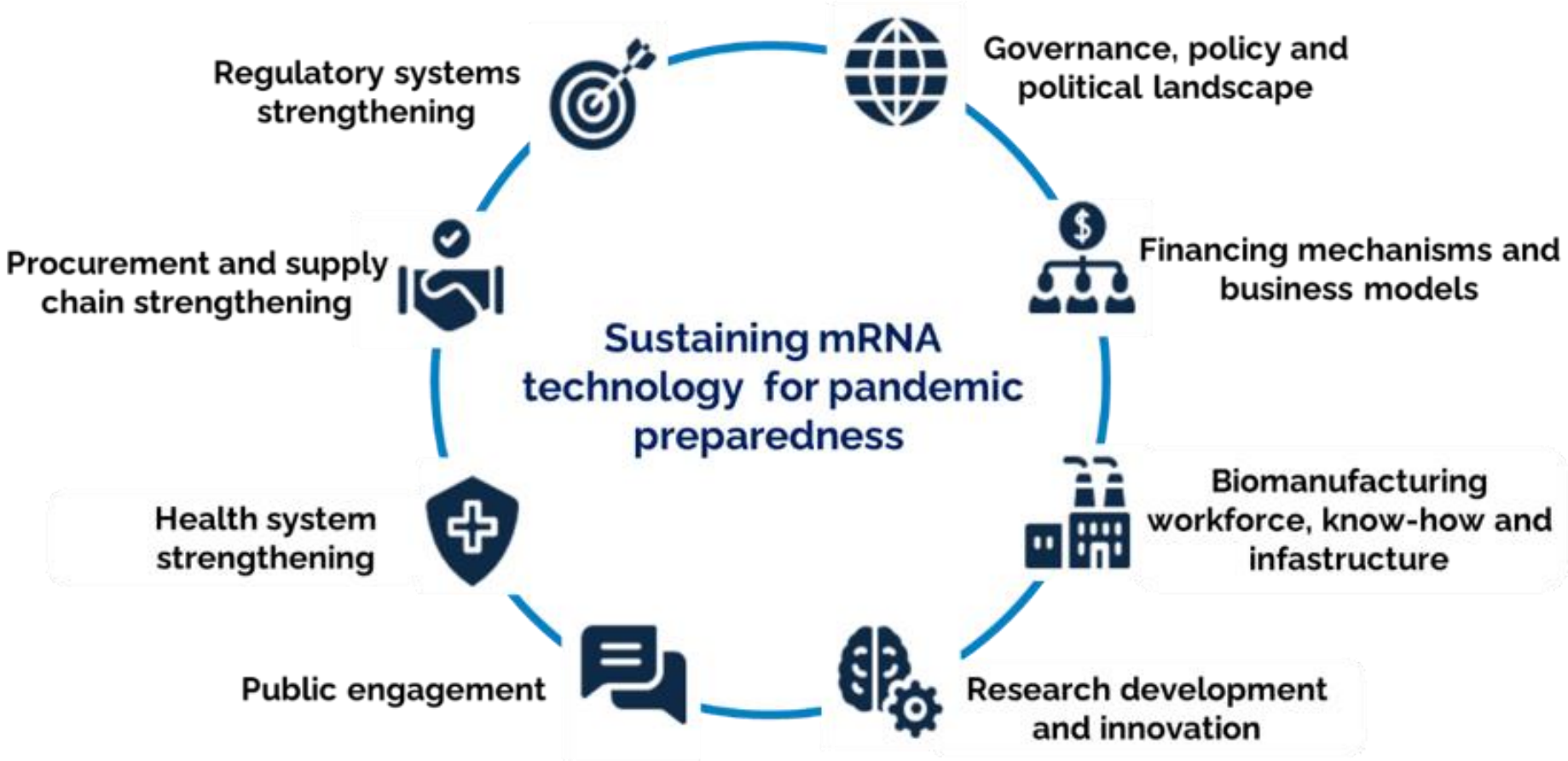
Coordinated **supply chains** & emergency distribution

mRNA Technology Transfer Programme



Fonte: mRNA technology transfer programme. https://medicinespatentpool.org/what-we-do/mrna-technology-transfer-programme

A grande aposta: ecossistema sustentável de P&D



Obrigada!

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