



REPÚBLICA DE MOÇAMBIQUE

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MINISTÉRIO DA SAÚDE

AUTORIDADE NACIONAL REGULADORA DE MEDICAMENTO, I.P.

## Effective Use of Phamacopoeias in Mozambique

GLOBAL REGULATORS CONCLAVE

“International Regulatory Convergence to Promote Accessibility and Affordability of Quality Medicines”

21 – 23 September 2022, IEML Knowledge Park, Greater Noida

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ANARME, I.P

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# Mozambique Informations

## Mozambique



**Population:** 32.16 M (2021)

**Population growth (annual %):** 2.9% (2021)

**Area:** 786,380 (sq. km)

**Health Expenditure (total, % of GDP):** 7.83% (2019)

**GDP growth (annual %):** 2.2 (2021)

Source: <https://data.worldbank.org>





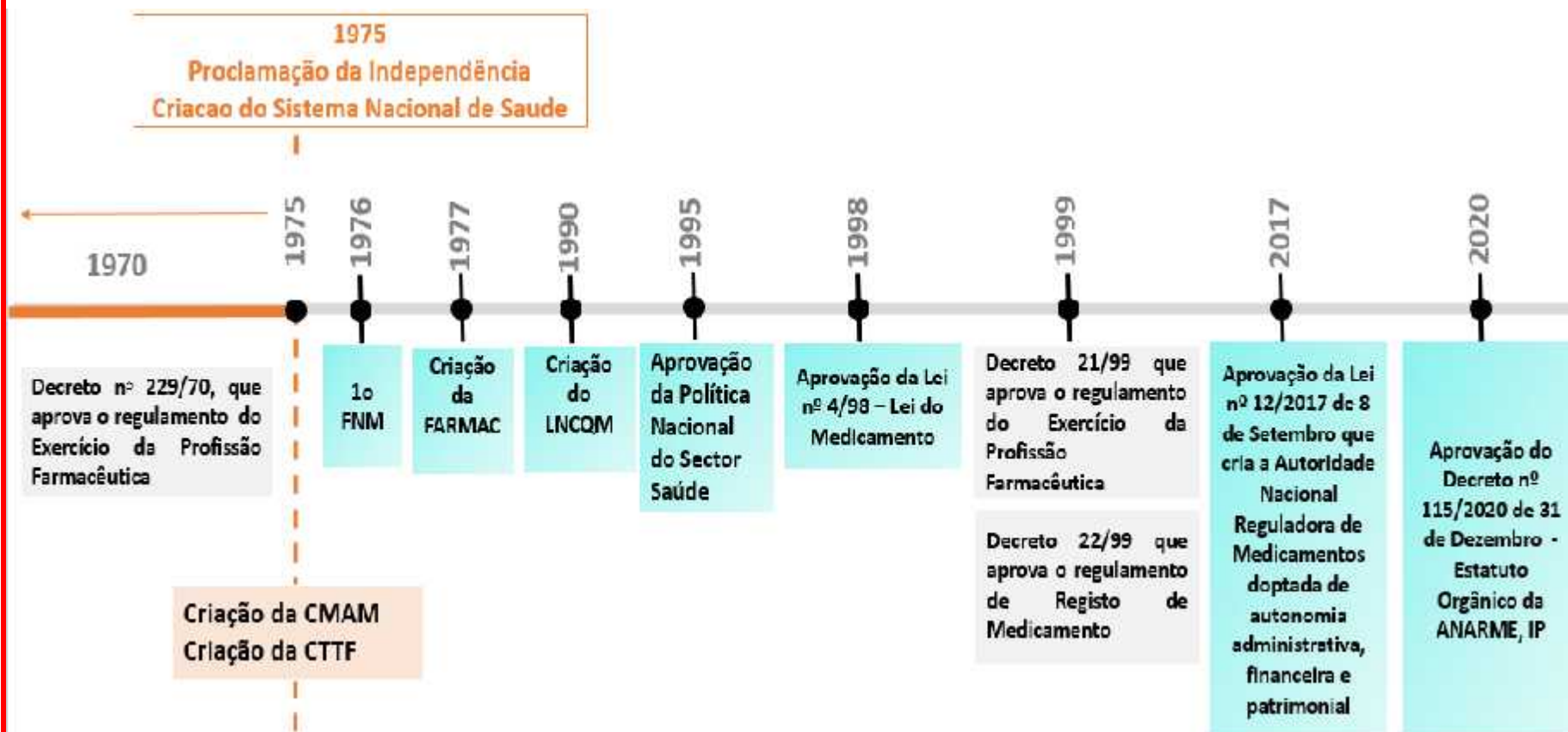
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# **Mozambican Medicines Regulatory Authority - ANARME, IP**



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# Brief History





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## Mozambican Medicines Regulatory Authority - ANARME, IP

ANARME, IP is a public institution, category A, endowed with legal personality, administrative, financial and patrimonial autonomy, which performs the functions of regulation, supervision, inspection, sanctioning and representation in accordance with the Medicines Law, the Organic Statute of these Internal Regulations and other applicable legislation.



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# Organizational Identity

## MISSION

Regulate and supervise the area of medicines, vaccines and other biological products for human use, for the promotion and protection of public health, ensuring the circulation of quality, safe, effective and affordable medical products

## VISION

To be a national and international model of excellence and reference, in the regulation of medicines, according to the highest standards of quality assurance.

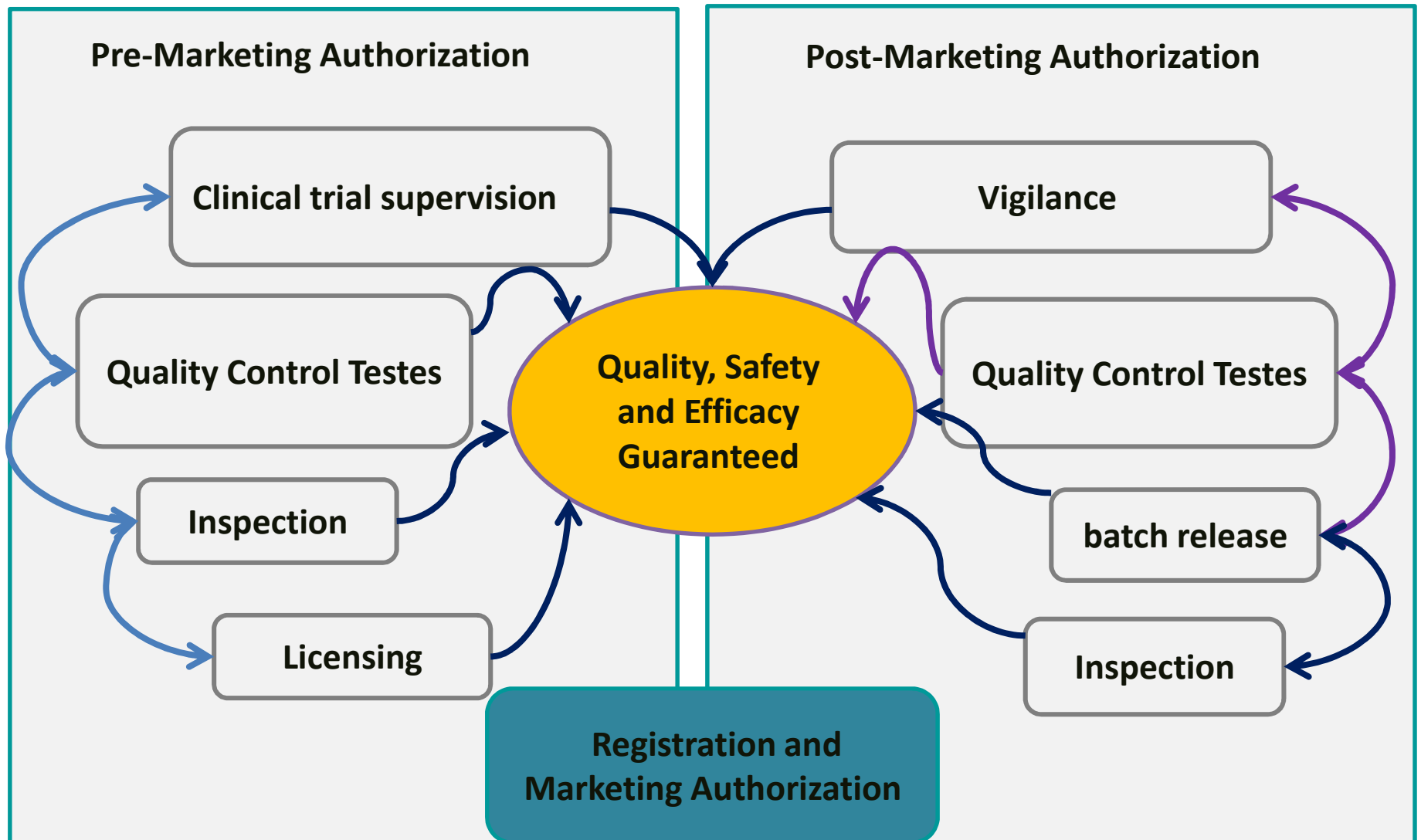
## VALUES

- Rigor
- Focus on the client
- Transparency
- Team spirit
- Ethic
- Appreciation of knowledge
- Innovation
- Equity
- Social and environmental responsibility
- Legality
- Integrity



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# Regulatory Functions of ANARME

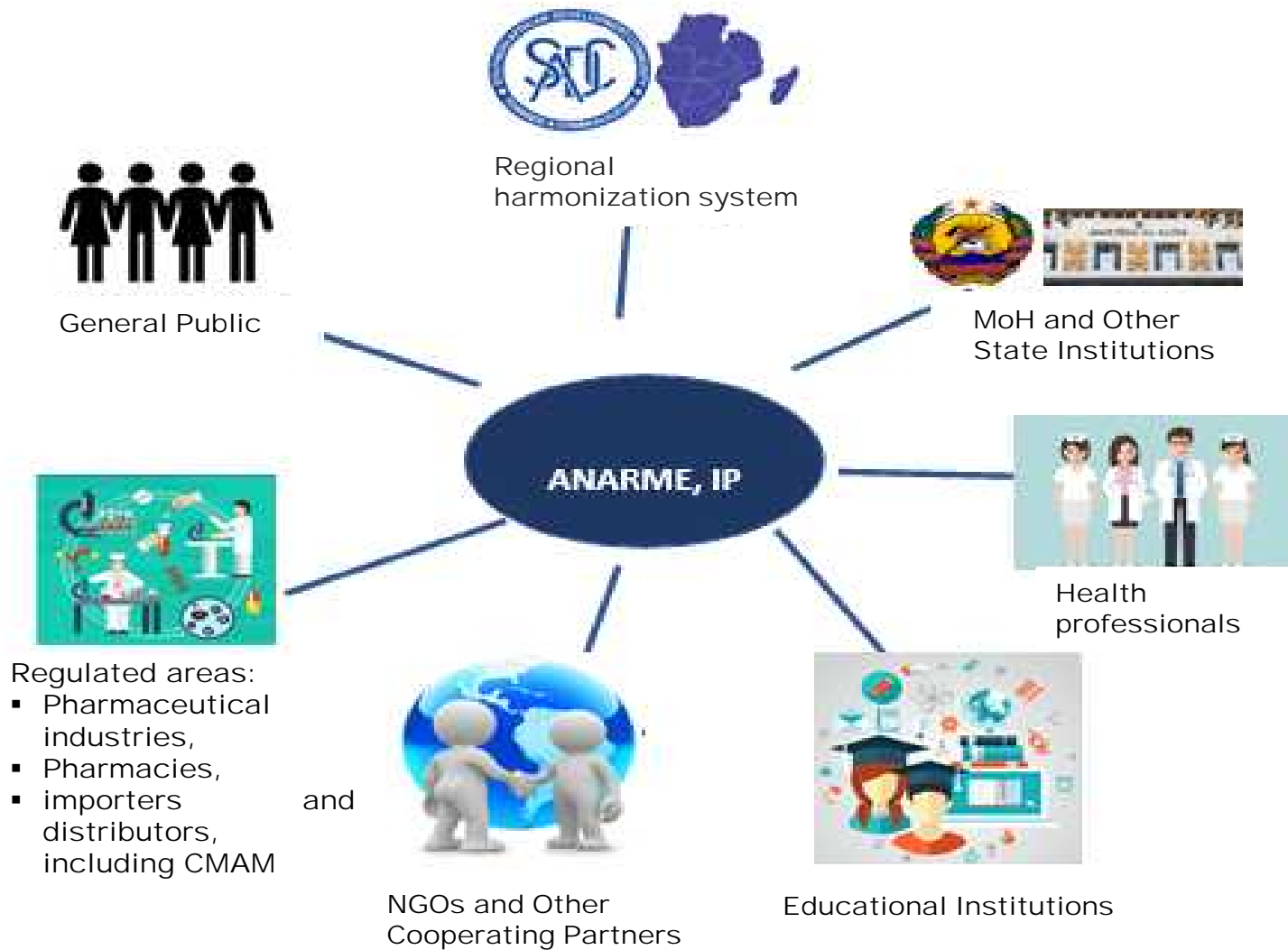






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# Stakeholders





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# Use of Pharmacopoeias in Mozambique



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# Introduction

Medicine legally introduced on the market:

- ❖ Efficacy,
- ❖ Safety and
- ❖ Quality.

Pharmacopoeias set quality standards for manufacturers to produce medicines and vaccines which are safe and of quality.

Regulators ensure that manufacturers comply with these quality standards, before medicines are authorised to be put on the market.

The quality of drugs, pharmaceutical adjuvants or preparations listed in a modern pharmacopoeia must be considered by the industry as the minimum level of the acceptable standard for medical use, to ensure efficacy under proper storage conditions.



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# Use of Pharmacopoeia in Mozambique

Mozambique does not have an own pharmacopoeia

ANARME Resolution - July 20, 2022: Quality Control and Marketing Authorization process

We adopt/approve the following pharmacopoeias:

- ✓ US Pharmacopoeia (USP)
- ✓ British Pharmacopoeia(BP);
- ✓ European Pharmacopoeia (EP);
- ✓ Internacional Pharmacopoeia (Int. P).



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# Use of Pharmacopoeia in Mozambique

Exceptions upon prior request:

- ❖ Portuguese Pharmacopoeia (FP);
- ❖ Brazilian Pharmacopoeia (FB);
- ❖ Indian Pharmacopoeia (IP);
- ❖ Chinese Pharmacopoeia (CP);
- ❖ Japanese Pharmacopoeia (JP);



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## Final Considerations:

- ❖ The new registration of medicines in Mozambique must follow the resolution.
- ❖ This process will be implemented gradually for the products already registered



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Thank You