CORONAVÍRUS • COVID - 19 • VACINA

Assessment of Vaccines and Medicines Using Emergency Use Authorization: Anvisa perspectives

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ANVISA
Agência Nacional de Vigilância Sanitária

Emergency Use Authorization

- **Requested by:** Holder with Authorization at Anvisa
- **Required Data**: Critical Quality/Safety/Efficacy Points and Approval by other agencies.
- **Reviewed by**: Anvisa
- **Deadline**: 7 working days (Development in Brazil or Technical Report of reference agency) and up to 30 days (Development abroad or absence of report)
- **Legislation**: RDC no. 475 of 10 March 2021

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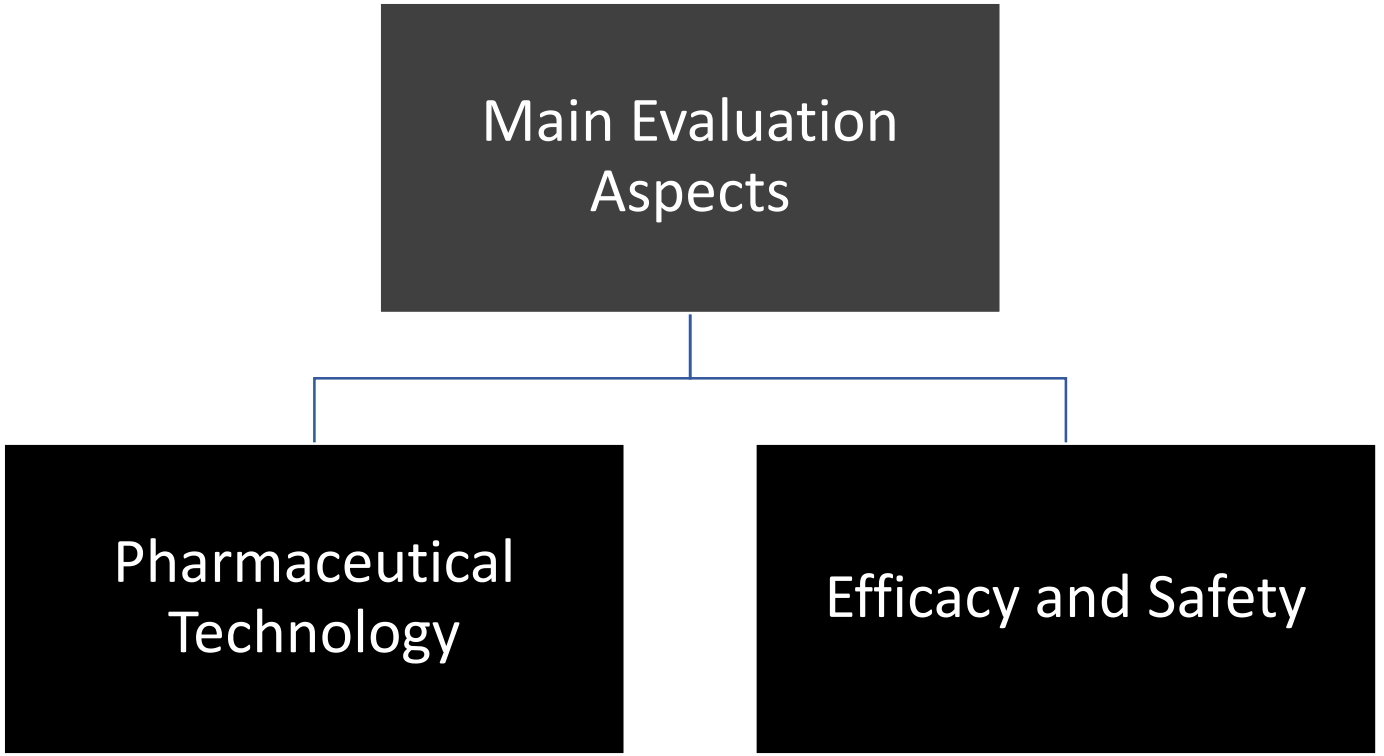
What is checked to assess a vaccine or medicine by EUA?

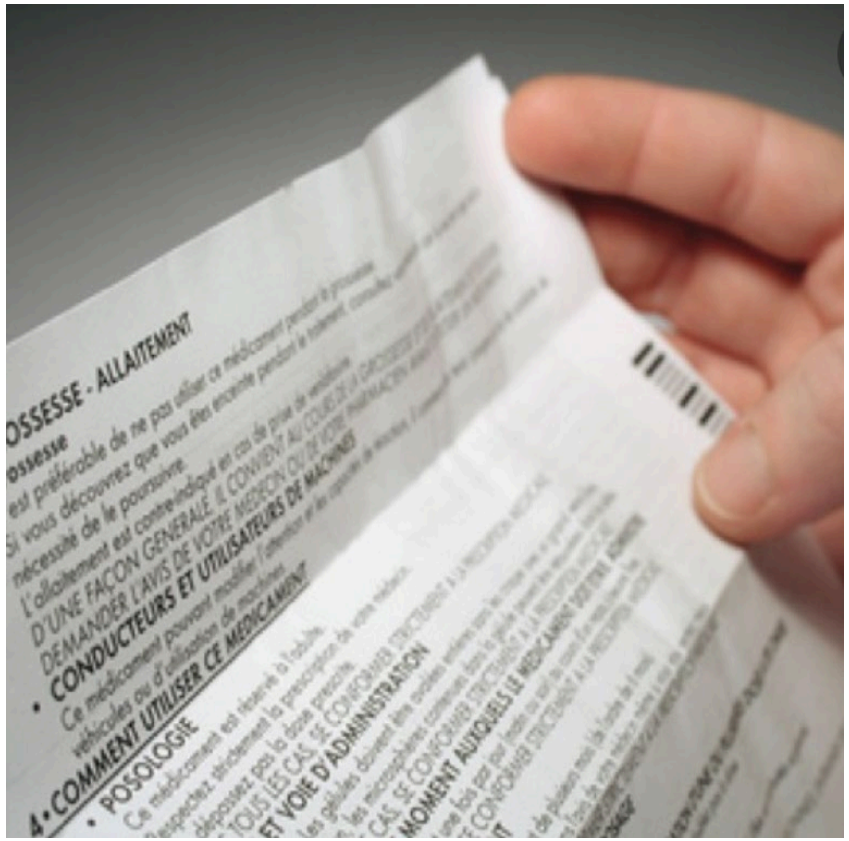
General Office of Medicines and Biological Products



Biotechnology

- **Formulation;**
- **Production;**
- **Quality Control;**

Efficacy and Safety



- **Non-Clinical Studies;**
- **Clinical Studies;**

General Office of Monitoring

Pharmacovigilance Plan

“identification, assessment, understanding and prevention of adverse effects or any problems related to the use of.”

General Office of Inspections

Good Manufacturing Practices

- ***Quality System;***
- ***Robustness of the Production Process;***

Types of Vaccine and Drug Approvals against COVID-19

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Conditional Marketing Approval

- **Requested by:** Holder with Authorization at Anvisa
- **Required Data:** Complete Studies of Quality, Safety and Efficacy
- **Reviewed by:** Anvisa
- **Deadline:** Up to 60 days (Term of Commitment**)**
- **Legislation**: RDC No 415 of 26 August 2020

Exceptional and Temporary Import

- **Requested by:** Ministry of Health, States, Municipalities and Federal District
- **Required Data:** Authorization by Foreign Agency, Declaration of Non-compliance with the National Plan for The Operationalization of Vaccination against Covid-19
- **Reviewed by:** Anvisa
- **Deadline:** 7 working days or 30 days (in the absence of technical report of the foreign agency)
- **Legislation:** RDC no. 476 of 10 March 2021

Trends and Legacy

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Trends and Legacy for Emergency Use Authorization

- ✓ **Improvement of Reliance Strategies;**
- ✓ **Innovative Adminitrative Tools;**
- ✓ **Focusing on critical aspects of technical evaluation;**
- ✓ **Closer approach with products developers.**

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