



## CT-Luso

Ethics and Regulatory Capacity Building Partnership for Clinical Trials in Portuguese-speaking African Countries (PALOP)

Project 101145790

WP3 - Analysis of legislative gaps and recommendations for scientific research policies and public policies implementation

**Deliverable 3.2** - Organisational charts illustrating the relationship between National Regulatory Agencies for Medicines and Research Ethics Committees in the PALOP countries

28/02/2025



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## 1. Contextualising introduction

### 1.1. General context

CT-Luso is an ethical and regulatory training project in the area of clinical trials, which is being carried out in five Portuguese-speaking African countries (PALOPs): Angola, Cape Verde, Guinea-Bissau, Mozambique and São Tomé and Príncipe. Approved under the "European and Developing Countries Clinical Trials Partnership Programme (EDCTP3)" and funded by the European Commission, CT-Luso has a duration of 40 months and is developed through 8 work packages, structured as a continuation of the BERC-Luso Project, which ran from 2018 to 2022.

The main goals are to establish and/or strengthen an ethical and legal framework for conducting clinical trials, to strengthen the operating structure of the institutions involved in biomedical research, articulating and streamlining their relationship, and to invest in the construction of a broad scientific community. The first stage, which is now underway, aims to promote the harmonisation of national legislative frameworks in line with international best practices in the field of biomedical research, as well as the way the National Regulatory Agencies for Medicines and Research Ethics Committees work and the coordination of their joint work, especially regarding clinical trials. This will improve the quality and safety of research processes, as well as speeding up the processes for assessing clinical trial proposals. To this end, an international team of lawyers was formed, consisting of Walter Van-Trier (Angola), João Semedo (Cape Verde), Miguel Pereira (Guinea-Bissau), Virgílio Uamba (Mozambique) and Bernardett Santos (São Tomé and Príncipe)<sup>1</sup>, all appointed by their respective Ministries for Health, under the leadership of the Centro de Direito Biomédico da Universidade de Coimbra (Biomedical Law Centre of the University of Coimbra), through André Dias Pereira, Ana Elisabete Ferreira, Carla Barbosa and Daniela Dias. To carry out this work, we also had the collaboration of the heads and/or representatives of the National Regulatory Agencies for Medicines and the National Research Ethics Committees of all the partner countries, namely: Magna Barroso (Angola) and Joana Morais (Angola), Eduardo Tavares (Cape Verde) and José António Reis (Cape Verde), Carlos Costa (Guinea-Bissau) and Mouhammed Ahmed

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<sup>1</sup> <https://ct-luso.com/mod/page/view.php?id=21>

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(Guinea-Bissau), Tânia Sitoie (Mozambique) and Esperança Sevene (Mozambique), Jeryson Ramos (São Tomé and Príncipe) and Eula Maquengo (São Tomé and Príncipe).

In this context, WP3 plays a crucial role, focusing both on analysing legislation and regulations in the partner countries, identifying any gaps with reference to international best practice, and on the structure, competences and regulations of the key institutions in the field of clinical research: the National Regulatory Agencies for Medicines and the National Research Ethics Committees. Its mission is to signal challenges and opportunities in the existing regulatory and institutional framework, formulating recommendations to fill any gaps identified or possible entropies in the articulated functioning of the institutions, favouring the development of a robust legislative and institutional framework. This work contributes to promoting a harmonised regulatory environment, in line with international best practice, allowing for safer and more effective development of biomedical research and clinical trials in the PALOP countries.

The impact of CT-Luso goes far beyond technical training, bringing wide-ranging benefits for the modernisation and structuring of health and research policies in the PALOP countries. This project aims to make a significant contribution to increasing quality and confidence in conducting clinical trials, both nationally and internationally. By strengthening the regulatory and ethical frameworks for biomedical research, CT-Luso not only boosts the scientific capacity of these countries, but also promotes greater transparency and security in clinical trial processes, bringing them into line with international best practice. This impact thus results in a solid foundation that favours the continued development of clinical research and ensures that trials carried out in these countries are conducted in accordance with high ethical and scientific standards.

## **1.2. Specific objectives**

This record, drawn up as part of WP3, presents a detailed legal survey of the legislative framework of the National Regulatory Agencies for Medicines and the National Research Ethics Committees in order to provide a comprehensive and detailed understanding of the panorama related to the competent authorities in the PALOP countries. The proposal aims to map the National Research Ethics Committees and the National

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Regulatory Agencies for Medicines in these countries in a clear and structured way. The aim is to provide an integrated and accessible overview of the main bodies involved in ethics supervision and pharmaceutical regulation in each PALOP, including crucial aspects such as the nature, composition, appointment and competences of these bodies.

Understanding the existing institutional network is a fundamental step towards ensuring the harmonisation of processes and promoting good practices in ethical evaluation. This mapping not only allows a clear and precise visualisation of the entities responsible, but also makes it easier to identify areas where improvements can be implemented, helping to strengthen regulation and public trust. In addition, the organisational charts presented in this dossier serve as a strategic tool for observing the operating structure of each of the institutions and the collaboration between different actors in the sector, supporting informed decision-making and promoting the development of effective public policies in line with international best practice.

To achieve this goal, WP3 adopted a robust methodology based on a detailed analysis of the legislation in force and the legislation in the process of being approved or revised in the PALOP countries. This survey was carried out on the basis of documents provided by the national lawyers involved in the project, but also by the National Regulatory Agencies for Medicines and the National Research Ethics Committees, ensuring that all information was obtained directly from official sources. The analysis was systematic and conducted in a collaborative and continuous manner, with the active participation of a team of national and international lawyers and professionals (<https://ct-luso.com/>), guaranteeing a broad, precise and contextualised approach to the legal and legislative needs of the countries in question.

The methodology employed, which favoured joint work between the parties involved, ensures that the survey is solid and effective, making it possible to identify gaps and opportunities for improving the normative and regulatory framework in the PALOP countries. This collaborative process was undoubtedly fundamental in building a clear and precise diagnosis of current regulatory needs, which will serve as a basis for drawing up future strategies to strengthen legislation and clinical and pharmaceutical research practices in these countries. Ultimately, this work aims to promote the construction of a more robust legal and regulatory system which can guarantee the protection of citizens' rights, the safety of treatments and the continuous improvement of scientific and medical practices in the PALOP countries.

## **2. Legislative survey (legislation in force and in progress)**

The legislative survey carried out as part of WP3, in close collaboration with legal experts and institutional leaders from the PALOP countries, resulted in an in-depth analysis of current national legislation and rules in the legislative process relating to the regulation of National Research Ethics Committees and National Regulatory Agencies for Medicines. This work required a detailed effort, involving the identification and mapping of current legislation and legislative projects in the publication phase which could have an impact on these regulations.

Continuous collaboration between Portuguese lawyers and PALOP representatives was crucial to ensure an up-to-date and complete survey. The exchange of information between the different parties involved played a key role in validating sources and ensuring that all relevant documents were accurately included in the process. Each jurisdiction presented particularities which required an adapted approach, ensuring that all regulatory aspects were duly considered.

This collaborative work not only facilitated access to the documents, but it will also ensure that, in the next phase of the development of the deliverables, an in-depth analysis of the laws and draft laws is carried out. This way, it will be possible to identify gaps and opportunities for improvement in a clear and well-founded manner. In addition, the direct involvement of national lawyers and leaders ensured that the legal and cultural realities of each country were respected, guaranteeing greater precision and relevance in the legislative analysis. This cooperation also made it possible to identify commonalities between the legal systems, which in the medium term will facilitate the harmonisation of legislative practices and the strengthening of a more integrated and efficient regulatory framework.

The following tables and organisation charts clearly and visually present the legislative survey carried out in WP3 for each country, highlighting the legislation in force and the legislative projects underway regarding the National Regulatory Agencies for Medicines and the National Research Ethics Committees. In these tables, the legislation regulating these bodies is highlighted, providing a comprehensive overview of the current legislative landscape in each participating country.

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As well as illustrating the standards that have already been established, the tables also highlight the documents in the legislative process, signalling the changes and developments underway. This representation makes it easier to understand the stage each country has reached, allowing you to quickly identify areas with consolidated regulations and those which are still in the development or revision phase.

The frameworks therefore represent a crucial analysis tool for the legal experts involved, but also offer an accessible overview for all *stakeholders*, including researchers, regulators and legislators. They are an essential part of understanding legislative progress in the different countries, providing a solid basis for subsequent actions aimed at filling the gaps identified and promoting the harmonisation of legislation between the countries participating in the project.

## 2.1. Existing institutions

The following table gives an overview of the institutions responsible for the ethical evaluation and regulation of clinical trials in the PALOP countries. This includes the National Regulatory Agencies for Medicines, which are responsible for supervising clinical research and regulating pharmaceutical products, guaranteeing an assessment of the safety, quality and efficacy of medicines. At the same time, we have included the National Research Ethics Committees in each country, which have the task of ensuring that research/clinical trials respect ethical principles and good international practice.

This table therefore allows a comparison between the existing structures in each of the countries for regulating biomedical research and, in particular, clinical trials in the PALOP countries. The first cell of the table identifies the country being analysed, the second cell identifies the National Regulatory Agency for Medicines, the third cell identifies the legislation relating to this entity, the fourth cell identifies the National Research Ethics Committees and the fifth cell identifies the legal regulations for these Committees. The cells shaded in blue refer to institutions whose legislation is still in the legislative process and those in white refer to approved legislation.

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Table 1 - National Regulatory Agencies for Medicines and National Research Ethics Committees

Country	National Regulatory Agency for Medicines	Legislation	Ethical Assessment Body/Entity	Legislation
Angola	Regulatory Agency for Medicines and Health Technologies (ARMED)	Presidential Decree no. 136/21, of 1 <sup>st</sup> June	National Institute for Health Research	Presidential Decree no. 177/19, of 22 <sup>nd</sup> May
			Ethics Committee of the Ministry of Health (CEMS)	Order no. 2378/GAB.MIN/MS/2019 Internal Regulations (final version)
Cape Verde	Independent Health Regulatory Authority (ERIS)	Decree-Law no. 3/2019, of 10 <sup>th</sup> January (Creates ERIS)	National Health Ethics Council (CNES)	(preliminary draft)
Guinea-Bissau	Regulatory Authority for Pharmacy, Laboratory, Medicines and Other Health Products, IP (ARFAME, IP)	Decree no. 13/2023 (Creation)	National Health Research Ethics Committee (CNEPS)	(proposal for a decree)

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Country	National Regulatory Agency for Medicines	Legislation	Ethical Assessment Body/Entity	Legislation
<b>Mozambique</b>	Autoridade Nacional Reguladora de Medicamento, IP (National Regulatory Authority for Medicines) (ANARME)	Decree no. 115/2020, of 31 <sup>st</sup> December (Statute Organic)  Ministerial Diploma no. 20/2022, of 9 <sup>th</sup> February (Internal Regulations)	National Bioethics Committee for Health (CNBS)	Order no. 58/2017 (Creation)  (proposed Organic Statute of the CNBS) CNBS Internal Regulations
<b>São Tomé and Príncipe</b>	Regulatory Authority for Pharmacy, Medicines and Health Technologies and approval of its Statute (ARFAMED)	Decree-Law no. .../2024 (Proposed Decree-Law for creation)	National Ethics Commission of the Ministry of Health	Order no. 01/GMS/2022 (Team)  Resolution no. 02 of 21 <sup>st</sup> June 2024 (approves CESIC's internal regulations)  Order no. 59/2024 (Creation of CESIC)

**Caption:** The table provided gives a comprehensive overview of the National Regulatory Agencies for Medicines and National Research Ethics Committees in each country involved in the project.

As far as the National Regulatory Agencies for Medicines are concerned, only São Tomé and Príncipe is still working on the legislation that will regulate the activities of this national body. On the other hand, regarding the National Research Ethics Committees, we can see that Cape Verde,

Angola, Guinea-Bissau and Mozambique are currently in the process of drafting legislation, be it initial or revision. We therefore conclude that, whether the processes have already been approved or are in the process of being drafted, all the countries involved recognise the need to regulate the activity of these two bodies, demonstrating a growing commitment to improving regulation and ethics in clinical research.

## **2.2. National Regulatory Agencies for Medicines**

After surveying the existing institutions, as shown in the table in the previous point, it is essential to carry out an in-depth analysis of the medicines regulatory bodies. This study should focus on their legal nature, organisational structure and composition, including the appointment of their members and their competences. Through this detailed analysis, it will be possible to gain a clearer understanding of the degree of independence, transparency and effectiveness of these bodies, particularly as regards guaranteeing the safety and efficacy of clinical trials involving medicines.

In addition, in order to establish a solid benchmark of international best practice, a first table was drawn up including Portuguese legislation, which is aligned with European and international guidelines. This alignment is crucial, as it makes it possible to compare and contextualise PALOP regulatory practices with standards which are already recognised worldwide. Only this way will it be possible to achieve the primary objective of this study: to identify the existing gaps in the regulatory structures of the PALOP countries, as well as the opportunities for improvement which could be implemented, with the aim of optimising the regulation and supervision of clinical trials and guaranteeing the protection of public health and the quality of medicines in the context of these countries.

To make the diagram more comprehensible, sub-sections will be introduced for each of the five countries involved in the project. In each of these sub-sections, we will not only introduce a table which aims to summarise some of the characteristics of each National Regulatory Agency for Medicines (in the left-hand column we will find the name of the Authority and the corresponding country; in the following columns we will highlight the main aspects of its nature, structure and composition, appointment and competences), but also an organisation chart which reflects how the entity works. In the case of the tables, the cells shaded in blue reflect legislation which is currently in the legislative process.

Before moving on to subsections for each country, we will present a table for Portugal.

Table 2 - INFARMED, Portugal

Country	Nature	Structure and Composition	Appointment	Competences
<p><b>Portugal</b></p> <p>National Authority for Medicines and Health Products, IP (INFARMED)</p>	<p>A special regime public institute, under the terms of the law, part of the state indirect administration, endowed with administrative and financial autonomy and its own assets.</p>	<p>Board of Directors, Statutory Auditor, Advisory Board, Specialised Technical Committees, National Council for the Advertising of Medicines and Health Products.</p>	<p>The members of the Technical Committees who are employees of the Ministry of Health or who do not have any legal relationship of public employment are appointed, on the proposal of the Board of Directors of INFARMED, I. P., by order of the member of the Government responsible for the area of health, and the members belonging to other ministries are appointed by order of the</p>	<p>To regulate and supervise the human medicines and health products sectors, in accordance with the highest standards of public health protection, and to guarantee access to quality, effective and safe medicines and health products for health professionals and citizens. (specifically, article 3 of Decree-Law no. 46/2012, of 24<sup>th</sup> February (approves the organic structure of INFARMED, IP).</p>

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Country	Nature	Structure and Composition	Appointment	Competences
			members of the Government responsible for the area of health and their respective tutelage.	(Article 4 of Presidential Decree 136/21 of 1 <sup>st</sup> June)

**Caption:** Main characteristics in terms of the nature, composition, appointment and competences of INFARMED, Portugal Regulatory Agency for Medicines.

INFARMED plays a crucial role in regulating the pharmaceutical and health products sector in Portugal. Its organisational structure, the appointment of its members and its wide-ranging competences are designed to guarantee the independence and effectiveness of its work, in line with international best practice.

### 2.2.1. Angola

Table 3 - ARMED, Angola

Country	Nature	Structure and Composition	Appointment	Competences
<b>Angola</b>  Regulatory Agency for Medicines and	Public establishment with legal personality and capacity, endowed with administrative,	Management Bodies (Board of Directors, Managing Director, Supervisory Board)	Director General appointed by the Head of the Ministerial Department	Developing actions of regulation, orientation, licensing, supervision and control of activities

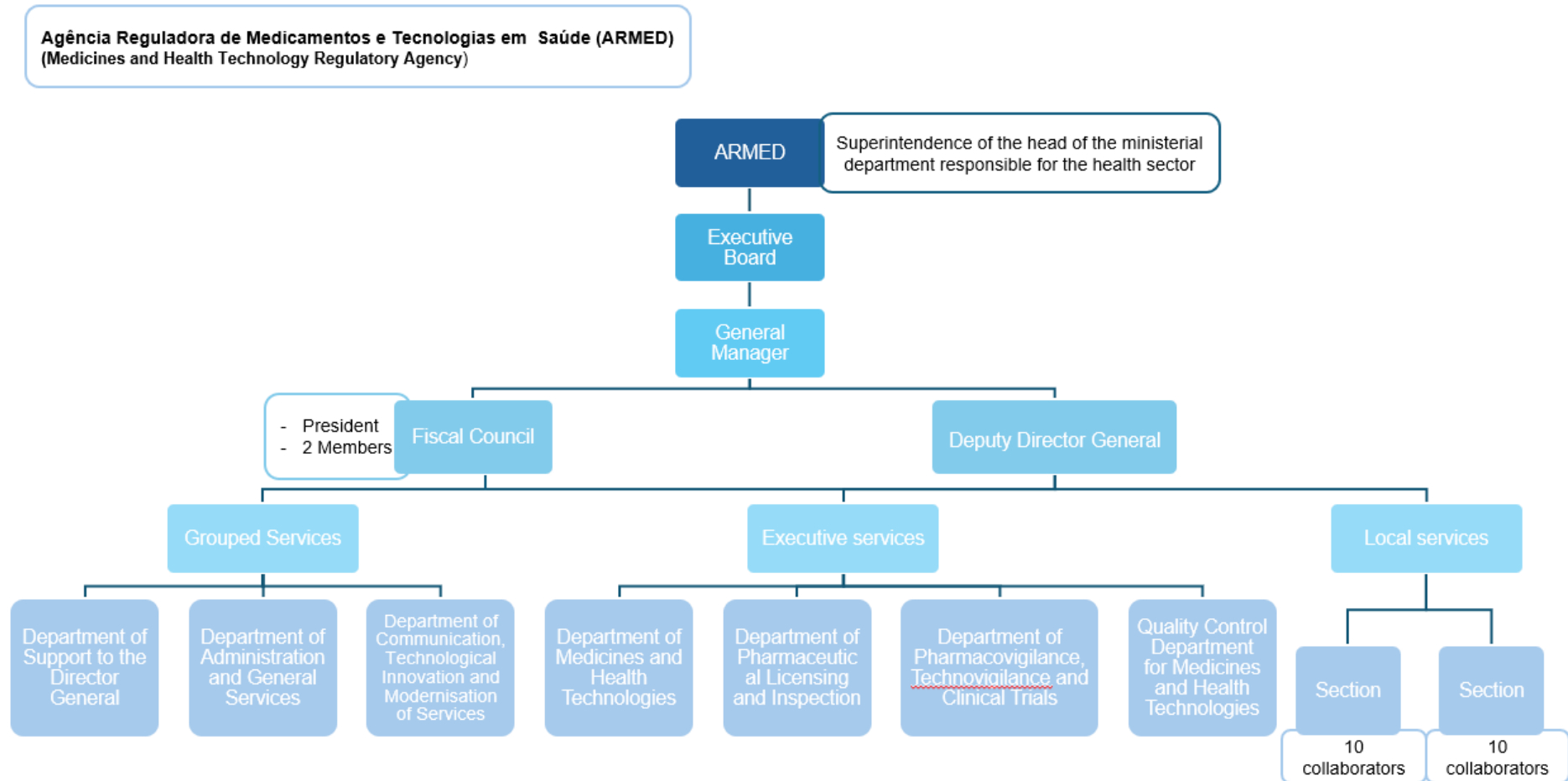
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Country	Nature	Structure and Composition	Appointment	Competences
Health Technologies (ARMED)	patrimonial and financial autonomy.	Executive Services (Departments of Medicines and Health Technologies; Pharmaceutical Licensing and Inspection; Pharmacovigilance, Technovigilance and Clinical Trials; Quality Control of Medicines and Health Technologies) Grouped Support Services; Local Services.	responsible for the Health Sector. Board of Auditors appointed by the Head of the Ministerial Department Responsible for the Health Sector. Executive Services appointed by the Director General. Group Support Services appointed by the Director General.	in the field of medicines for human use and health technologies, with the aim of guaranteeing their quality, efficacy and safety.  (Article 4 of Presidential Decree 136/21 of 1 <sup>st</sup> June)

**Caption:** The table shows some of the characteristics of ARMED, an autonomous public body with a regulatory role in the health sector, particularly in the area of medicines and health technologies.

The creation of ARMED aims to guarantee compliance with safety and quality standards in the pharmaceutical products and medical devices market in Angola, in line with best international practices, such as those of the World Health Organisation (WHO) and the Medicines and Health Products Regulatory Agency of the Community of Portuguese Speaking Countries (CPLP).

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Organisational chart 1 - ARMED, Angola

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**Caption:** The organisational chart represents the structure of ARMED (Medicines and Health Technologies Regulatory Agency), which is under the supervision of the head of the Ministerial Department responsible for the health sector. ARMED is made up of a Board of Directors, a Director General and several Deputy Directors General, who are responsible for managing various grouped services and executive services. ARMED's internal organisation is structured to ensure effective supervision and regulation of the pharmaceutical and health technology sector. The Board of Directors is responsible for defining the general policies of the agency and supervising its activities, while the Director General leads the implementation of strategic decisions and the overall coordination of the institution.

### 2.2.2. Cape Verde

Table 4 - ERIS, Cape Verde

Country	Nature	Structure and Composition	Appointment	Competences
<b>Cape Verde</b>  Independent Health Regulatory Authority (ERIS)	Independent, institutionally-based administrative authority. It enjoys administrative, financial and property autonomy.	Board of Directors, Advisory Board and Statutory Auditor.	Members of the Board of Directors are appointed by Resolution of the Council of Ministers, on a proposal from the member of the Government responsible for the area of Health. The Advisory Board is appointed by members	Technical and economic regulation of the activity of healthcare establishments in the pharmaceutical and food sectors. Specifically, see article 10 of Decree-Law no. 3/2019.

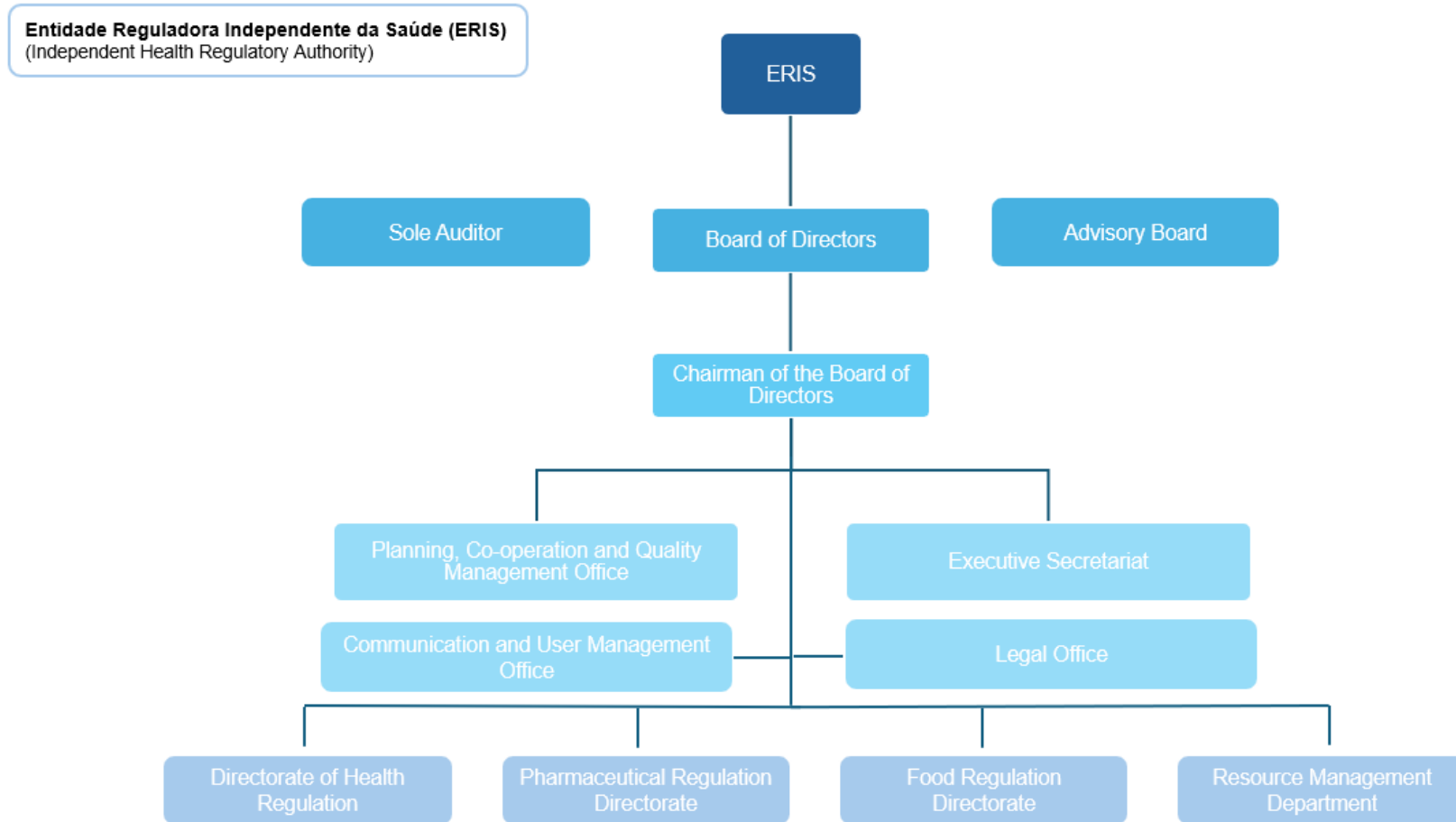
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Country	Nature	Structure and Composition	Appointment	Competences
			<p>of the Government responsible for Health, Finance and the Economy. The Statutory Auditor is appointed by joint order of the members of the Government responsible for Finance and Health.</p>	

**Caption:** The table lists some of the characteristics of ERIS.

The Independent Health Regulatory Authority (ERIS) plays a crucial role in regulating and overseeing the health sector in Cape Verde, with the aim of ensuring that medicines, health products and services provided to the population meet quality and safety standards. Its independence, together with its technical capacity and competences, is fundamental to building a more efficient and reliable health system in the country.

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Organisational chart 2 - ERIS, Cape Verde

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**Caption:** The organisational chart reflects the structure of the Independent Health Regulatory Authority (ERIS), which, under the supervision of a Board of Directors, coordinates several key departments for regulating the health sector. Among the main departments highlighted are the Health Regulation Directorate and the Pharmaceutical Regulation Directorate.

The Board of Directors is responsible for defining ERIS's strategic policies and overseeing its activities, ensuring that healthcare regulation is effective, efficient and in line with best practices.

### 2.2.3. Guinea-Bissau

Table 5 - ARFAME, Guinea-Bissau

Country	Nature	Structure and Composition	Appointment	Competences
<p><b>Guinea-Bissau</b></p> <p>Regulatory Authority for Pharmacy, Laboratory, Medicines and Other Health Products, IP (ARFAME, IP)</p>	<p>Public Institute with legal personality, administrative and financial autonomy and its own assets.</p> <p>Under the supervision of the member of the Government responsible for public health.</p>	<p>Board of Administration; General Management; Advisory Board; Specialised Technical Committees; Auditing Committee.</p>	<p>Directorate-General appointed by order of the Prime Minister and on the proposal of the Minister responsible for Public Health.</p> <p>Members of the Technical Committees who work in</p>	<p>Regulate and supervise the sectors of medicines for human use and other health products, including medical devices, cosmetic products and nutritional supplements; guarantee citizens and health</p>

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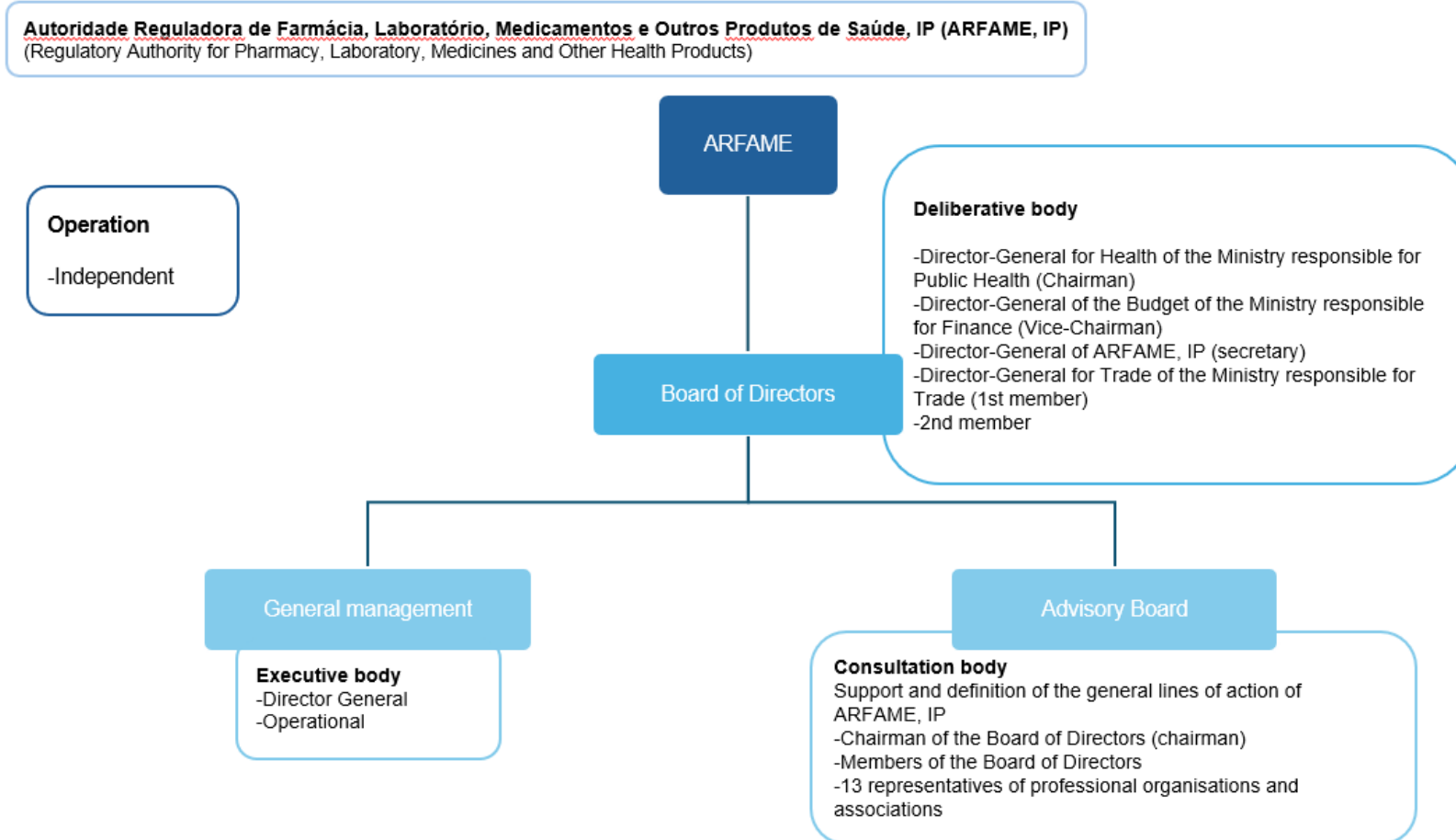
Country	Nature	Structure and Composition	Appointment	Competences
			<p>public service in the Ministry of Health or who do not have any legal relationship of public employment are appointed by order of the Government responsible for the area of Health, on a proposal from the Board of Administration of ARFAME, IP; members belonging to other ministries are appointed by joint order of the members of the Government responsible for the area of health and their respective tutelage.</p>	<p>professionals access to quality, safe and effective medicines and other health products. (specifically, Article 4 of Decree 13/2023)</p>

**Caption:** The table lists some of ARFAME's characteristics.

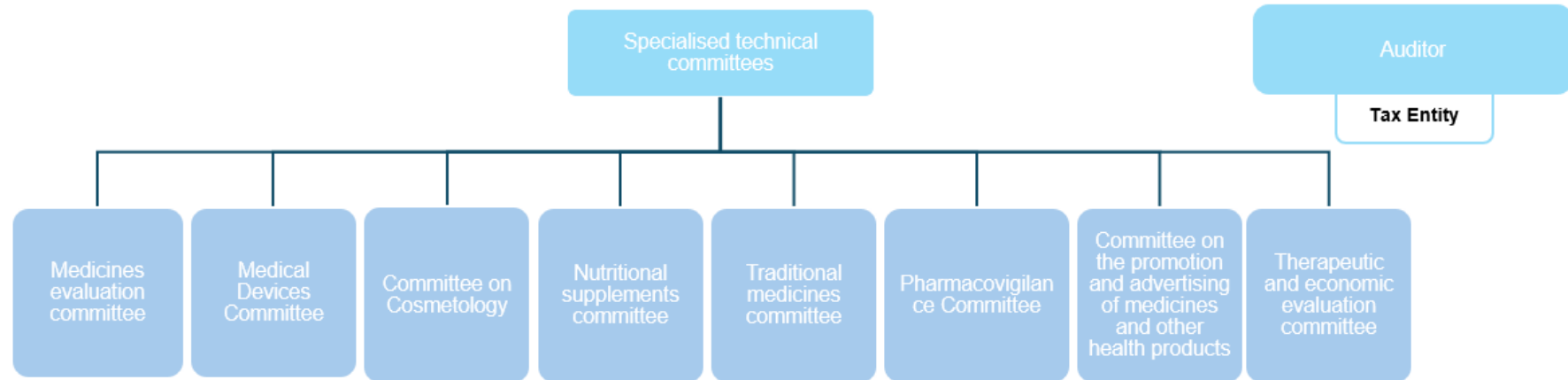
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ARFAME, IP plays a vital role in regulating the health sector in Guinea-Bissau, and is responsible for ensuring that medicines, health products and services provided to the population are safe, effective and of high quality. Its autonomy, the technical expertise of its members and its international collaboration are essential for strengthening public health in the country and for ensuring that Guinean citizens have access to safe, quality healthcare.

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Organisational chart 3 - ARFAME, Guinea-Bissau

**Caption:** From an analysis of the organisational chart of ARFAME (Autoridade Reguladora de Farmácia, Laboratório, Medicamentos e Outros Produtos de Saúde, IP) (Regulatory Authority for Pharmacy, Laboratory, Medicines and Other Health Products), we can see that the entity is made up of various bodies and departments that carry out specific functions in the regulatory process of the health sector. There is a Board of Directors, a General Directorate, an Advisory Board and various Specialised Technical Committees. The table above shows the requirements for appointing members of each of these structures within ARFAME, which include technical and professional criteria that guarantee the competence and experience of the members. These requirements are designed to ensure that the decisions made are based on specialised knowledge and that ARFAME fulfils its mission of transparently and effectively regulating the health sector in accordance with national and international standards.

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#### 2.2.4. Mozambique

Table 6 - ANARME, Mozambique

Country	Nature	Structure and Composition	Appointment	Competences
<p><b>Mozambique</b></p> <p>National Regulatory Authority for Medicines, IP (ANARME)</p>	<p>A public institution with legal personality and administrative, financial and property autonomy.</p>	<p>Board of Directors, Supervisory Board, Advisory Board, Technical Board, ANARME Advisory Forum, IP, Specialised Technical Committees.</p>	<p>The Chairman of the Board of Directors is appointed by the Council of Ministers, on the proposal of the Minister who oversees the area of Health, while the other members are selected in a public competition.</p> <p>The members of the Supervisory Board are appointed by joint order of the Ministers overseeing the areas of finance, state administration and the civil service, and health.</p> <p>The Chairman of the Board of Directors of</p>	<p>Regulation, supervision, inspection, sanctioning and representation in accordance with the Medicines Law. (specifically, Article 7 of Decree 115/2020 of 31<sup>st</sup> December).</p>

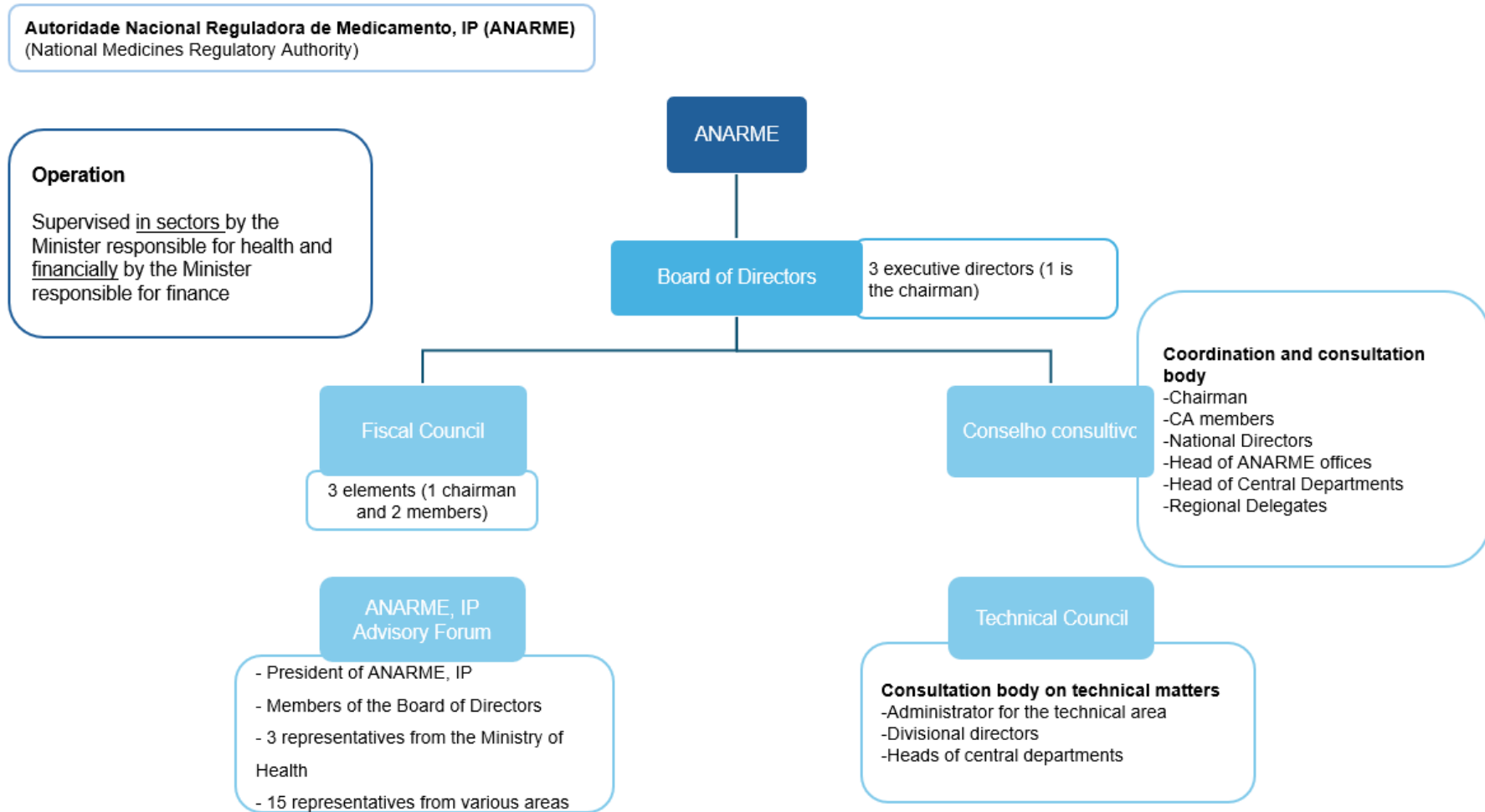
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Country	Nature	Structure and Composition	Appointment	Competences
			ANARME, IP appoints the Directors of the Divisions.	

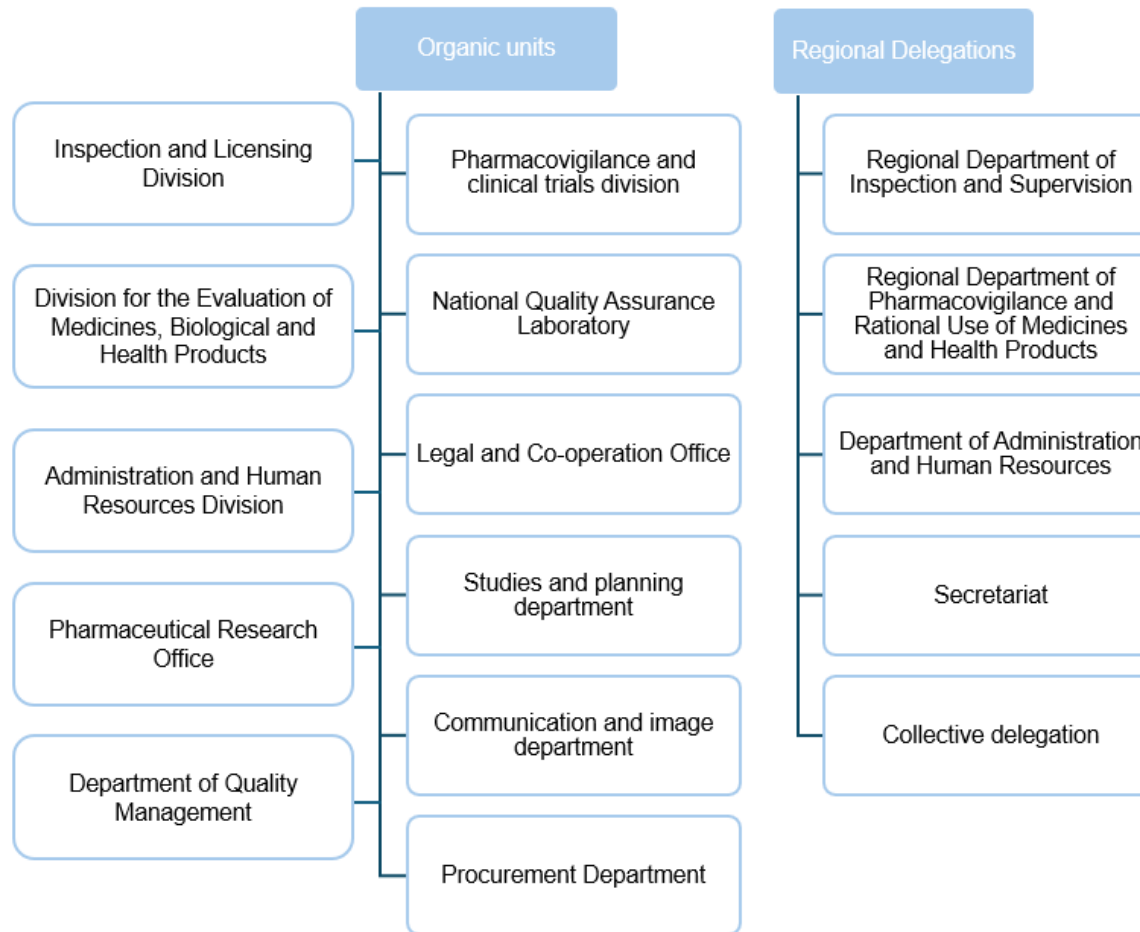
**Caption:** The table lists some of ANARME's characteristics.

The Autoridade Nacional Reguladora de Medicamento, IP (National Regulatory Authority for Medicines) (ANARME) plays a crucial role in regulating and supervising the medicines and health products market in Mozambique, guaranteeing the safety and quality of the products and services offered to the population. Its autonomy, technical independence and transparency are fundamental to strengthening the health system of the country and protecting public health. By acting efficiently, ANARME contributes to the improvement of healthcare in Mozambique and to compliance with international best practices.

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Organisational chart 4 - ANARME, Mozambique

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**Caption:** ANARME, IP is supervised, by sectors, by the Minister who oversees the health area and, financially, by the Minister who oversees the finance area. ANARME, IP bodies are: the Board of Directors, the Supervisory Board, the Advisory Board, the Technical Board and the ANARME, IP Advisory Forum. ANARME, IP also includes specialised technical committees, which are advisory bodies to ANARME, IP, made up of personalities with proven qualifications and experience in ANARME, IP areas of intervention, and act with technical and scientific independence, in accordance with their respective competences. The way in which the specialised technical committees are organised and operate is laid down in specific regulations, to be approved by the Minister who oversees the health area.

### 2.2.5. São Tomé and Príncipe

Table 7 - ARFAMED, São Tomé and Príncipe

Country	Nature	Structure and Composition	Appointment	Competences
<p><b>São Tomé and Príncipe</b></p> <p>Regulatory Authority for Pharmacy, Medicines and Health Technologies and approval of its Statute (ARFAMED)</p>	<p>Special authority integrated into the indirect administration of the State, with administrative, financial and patrimonial autonomy, under the superintendence of the Minister responsible for health.</p>	<p>Board of Directors, General Management, Regulatory and Legal Department, Administrative and Financial Department, Cooperation Department, Technical Department.</p>	<p>The members of the Board of Directors, as well as their alternates, are appointed by order, on the proposal of the institutions mentioned in Article 11 of the Draft Decree-Law.</p> <p>The Director General of ARFAMED shall be</p>	<p>Implementing regulatory functions within the framework of national pharmaceutical policy, monitoring the pharmaceutical sector and ensuring compliance with laws and regulations in the areas under its jurisdiction. Responsible</p>

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Country	Nature	Structure and Composition	Appointment	Competences
			<p>appointed by joint order of the Prime Minister and the Minister of Health, on a proposal from the Board of Directors.</p> <p>The Heads of Departments and Heads of Section are appointed by the Board of Directors on a proposal from the Director General.</p>	<p>for monitoring policy and programmes in the field of pharmaceutical products, medicines and health technologies.</p> <p>(specifically, Article 7 of the Proposed Decree-Law for the creation of ARFAMED).</p>

**Caption:** The table lists some of ARFAMED characteristics. The blue shading indicates what is in the legislative circuit.

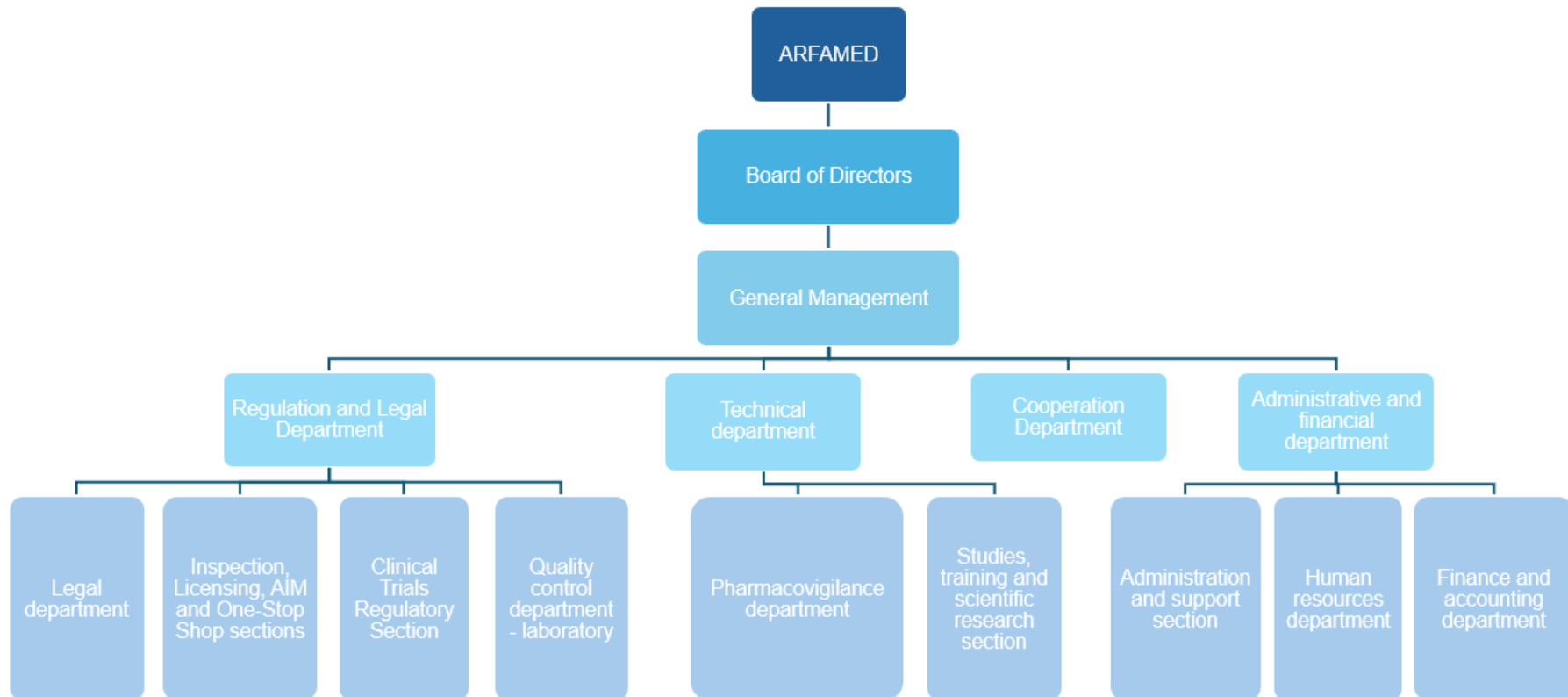
São Tomé and Príncipe ARFAMED (Regulatory Authority for Pharmacy and Medicines) is the organisation responsible for regulating, supervising and controlling medicines, pharmaceuticals and other health products in the country. Its mission is to ensure that medicines and other health products marketed in the country meet quality, safety and efficacy standards, thus protecting public health. São Tomé and Príncipe has the particularity of having ARFAMED and CAME. In the case of CAME - Central de Abastecimento de Medicamentos e Produtos de Saúde, it is solely responsible for the acquisition and distribution of medicines. It is a public institution of the Ministry of Health. It has functional, decision-making, administrative and financial autonomy. It is made up of a Board of Directors, a General Directorate, an Administrative and Financial Department, a Pharmaceutical Technical Department and a Legal and Co-operation Department. The members of the Board of Directors, as well as their

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alternates, are appointed by order, at the proposal of the institutions mentioned in Article 11 of the proposed Decree-Law for the creation of CAME. The General Directorate appoints staff. The Director General is appointed by joint order of the Minister for Health, on a proposal from the Board of Directors. The Heads of Departments are appointed by the Board of Directors at the proposal of the Director General. Its competences include the acquisition and distribution of medicines and health products (specifically, Article 7 of the proposed Decree-Law for the creation of CAME).

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**São Tomé e Príncipe – Autoridade Reguladora da Farmácia, Medicamentos e Tecnologias de Saúde (ARFAMED)**  
(Pharmacy, Medicines and Health Technology Regulatory Authority)



Organisational chart 5 - ARFAMED, São Tomé and Príncipe

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**Caption:** ARFAMED's organisational chart shows that it is run by a Board of Directors. Under the coordination of this Board, there is a General Directorate which is subdivided into various Departments. Of particular note is the Technical Section with its pharmacovigilance and scientific research and studies sections. And in the Regulation and Legal Department, the clinical trials regulation section. ARFAMED organisational structure aims to ensure efficient coordination between the different areas, promoting effective, specialised management that complies with national and international standards in the field of health, pharmacology and drug regulation.

### 2.3. Ethical evaluation bodies/entities

The following is a detailed analysis of the ethical review bodies, focusing on their legal nature, organisational structure and composition, as well as the criteria for appointing their members and their competences. This study will allow us to understand how these bodies work and the degree of independence and rigour with which they assess biomedical research, especially clinical trials. In contrast to the National Regulatory Agencies for Medicines, here we find much more legislation that has not yet been approved. This is the case in Angola, with the Ethics Commission of the Ministry of Health (CEMS), which still has legislation which has not been approved and published, but it is also the case in Cape Verde, Guinea-Bissau and Mozambique, which are awaiting approval of the legislation that will regulate their respective National Research Ethics Committees. In terms of analysing the tables presented, the cells that refer to entities with legislation not yet approved are shaded in blue, while the rest, with approved legislation, is in white.

In order to establish a benchmark of international best practices, Portuguese legislation was once again used, which is aligned with European and international guidelines on biomedical research. This way, it is possible to identify any gaps and opportunities for improvement in PALOP organisations, fostering a robust regulatory and ethical framework for conducting clinical trials in these countries.

Regarding the composition, it should be noted that the option adopted by each of the countries does not offend against independence, conflict of interest is prevented and the competence of the members in the area in which they work is verified. Aspects such as composition, independence, evaluation capacity and role in scientific research were taken into account.

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Table 8 - CEIC, Portugal

Country	Nature	Structure and Composition	Appointment	Competences
<p><b>Portugal</b></p> <p>Ethics Committee for Clinical Research (CEIC)</p>	<p>It is an independent body that operates under the Ministry for Health. The CEIC has technical and scientific independence and operates under the supervision of INFARMED, I.P., under the supervision of the member of the Government responsible for the health area.</p>	<p>Made up of health professionals and others.</p>	<p>The members are appointed by order of the member of the Government responsible for the health area.</p>	<p>Ensuring the protection of the rights, safety and well-being of participants in clinical studies and guaranteeing the same to society (Specifically, Article 35 of Law 21/2014 of 16<sup>th</sup> April).</p>

**Caption:** The table shows some of the characteristics of the CEIC.

In Portugal, CEIC is the organisation responsible for the ethical assessment and supervision of clinical trials and other forms of biomedical research with the mission of ensuring that research involving human beings is conducted ethically, transparently and in accordance with international best practices.

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### 2.3.1. Angola

Table 9 - INIS and CEMS, Angola

Country	Nature	Structure and Composition	Appointment	Competences
<p><b>Angola</b></p> <p>National Institute for Health Research (INIS)</p>	<p>A legal person governed by public law, part of the state indirect administration, as an institute of the public administrative sector, endowed with legal personality, administrative, financial, patrimonial, scientific and technical autonomy.</p>	<p>Collegiate Bodies (Board of Directors, Scientific Council, Supervisory Board)</p> <p>Management Bodies (Director General, Deputy Director for the Administrative Area)</p> <p>Grouped Support Services</p> <p>Support Services for the Management of Scientific Research, Technological Development and Innovation</p> <p>Regional Services.</p>	<p>The members of the Board of Directors are appointed by Order of the Head of the Ministerial Department responsible for the Health Sector.</p> <p>The Scientific Council is approved by the Head of the Supervisory Body.</p> <p>The Supervisory Board is appointed by the Head of the Ministerial Department responsible for Health.</p>	<p>Responsible for generating, developing and disseminating scientific, technological and strategic knowledge on health and its determinants, with the aim of contributing to strengthening public policies and improving the National Health System, in favour of the well-being of the Angolan population.</p> <p>(Article 6 of Presidential Decree no. 177/19 of 22<sup>nd</sup> May)</p>

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Country	Nature	Structure and Composition	Appointment	Competences
Ethics Committee of the Ministry of Health (CEMS)	A collegiate, interdisciplinary, multidisciplinary, independent body with a public consultative, deliberative, normative and educational role.	A coordinator, a deputy coordinator, eleven members (two of whom have outstanding experience in the field of research ethics, six with experience in health research or a similar speciality and three members from different areas of knowledge (lawyers, theologians or similar and civil society), a secretariat. It can count on "ad hoc" consultants, whether or not they belong to the Ministry.	The CMES is constituted by order appointing the members, issued by the Minister of Health. The Coordinator, Deputy Coordinator, members and Secretariat are suggested by the appointed Members.	Enforcing compliance with the ethical aspects of current international standards for research involving human beings carried out by researchers, including undergraduate and postgraduate students (specifically, Article 8 of the CEMS Internal Regulations).

**Caption:** The table reflects the institutional reality of Angola. The blue shading indicates what is in the legislative circuit.

In Angola there are two organisations: the National Institute for Health Research (INIS) and the Ethics Commission of the Ministry of Health (CEMS). While the former is responsible for disseminating scientific knowledge, the latter is responsible for assessing national and international ethical aspects in the field of research involving human beings.

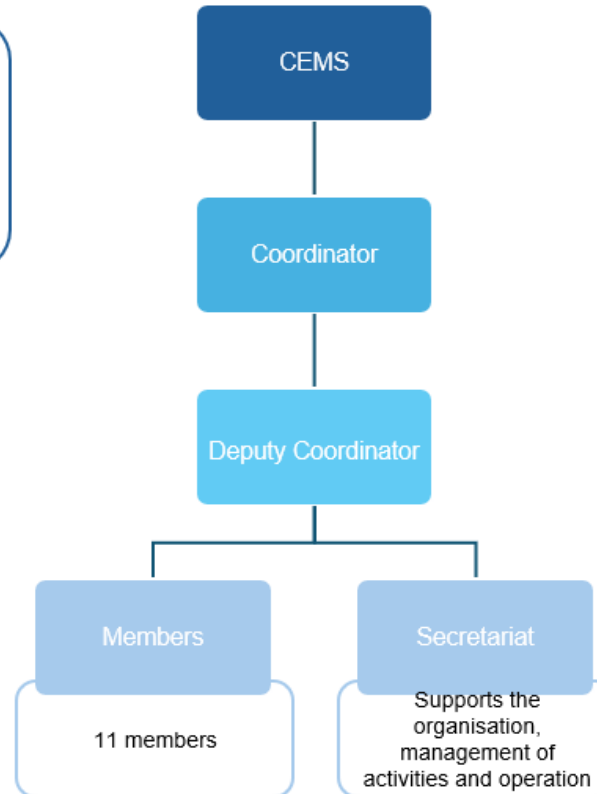
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**Comissão de investigação em saúde (CEMS)**  
(Health research commission)

**Operation**

-In plenary

-At INIS premises (unless it proves necessary to meet elsewhere, subject to the approval of the duly substantiated members)



Organisational chart 6 - CEMS, Angola

**Caption:** The CEMS will work in plenary session and will have a coordinator, a deputy coordinator and 11 members

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### 2.3.2. Cape Verde

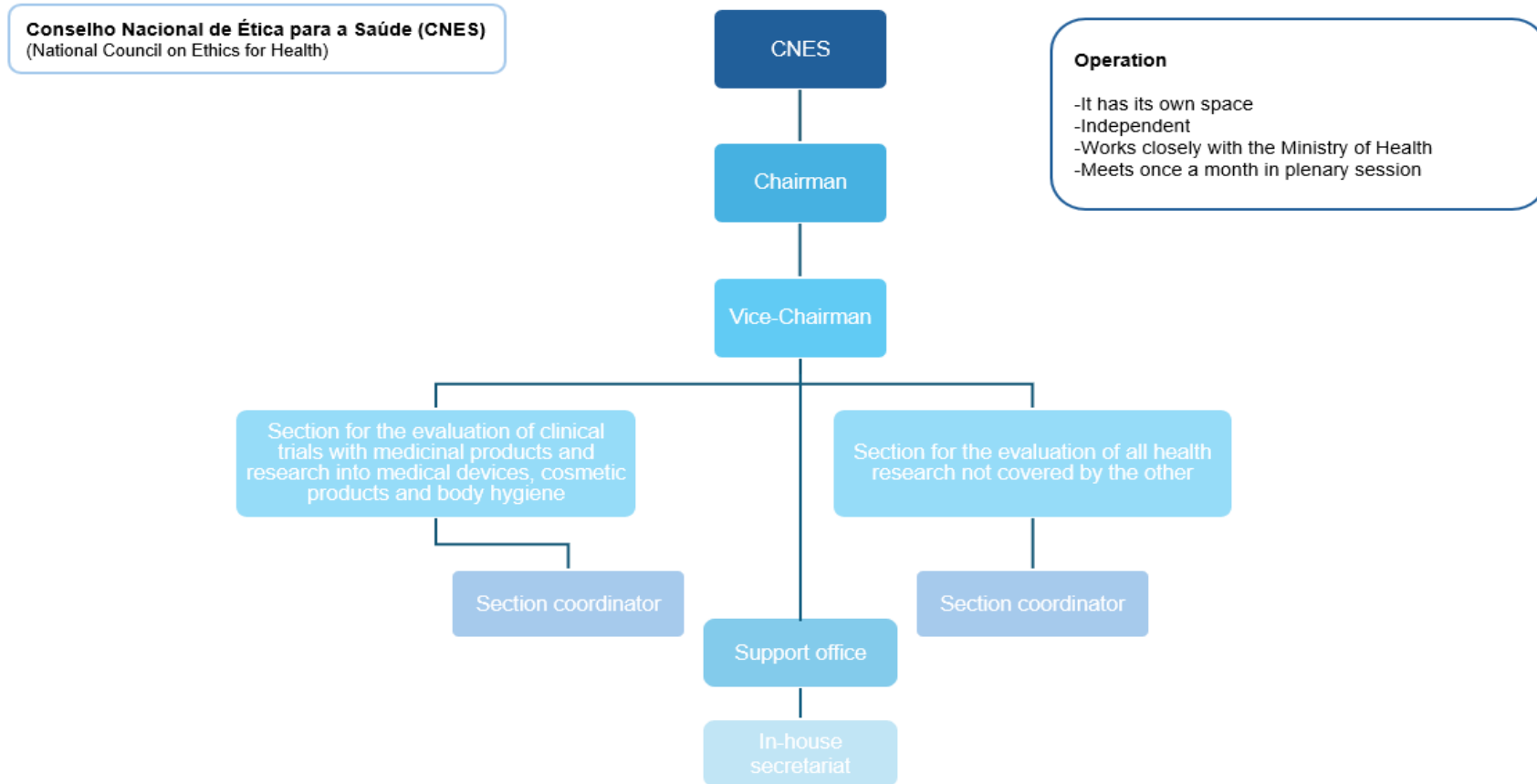
Table 10 - CNES, Cape Verde

Country	Nature	Structure and Composition	Appointment	Competences
Cape Verde National Health Ethics Council (CNES)	Autonomous entity, independent, multi-sectoral and multidisciplinary, endowed with technical and scientific independence.	Personalities of recognised merit and suitability, chosen for their competence and professional experience in their respective areas of intervention, preferably with knowledge of ethics, bioethics and health research. (Article 5 of the Preliminary Draft)	CNES members are appointed by order of the member of the government responsible for the health area, published in the Official Bulletin.	Independently assess the ethical compliance of health research in relation to the health research projects submitted to it, with the competences assigned to it in the Health Research Law; analyse the ethical problems raised by scientific progress in the field of life sciences and the use of new health technologies. (Article 3 of the Draft).

**Caption:** The table refers to the relevant aspects of the National Council of Ethics for Health (CNES, in Cape Verde). Blue shading indicates what is in the legislative pipeline.

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The CNES is a fundamental body for guaranteeing ethical compliance in the areas of health and clinical research. The legislation currently in the process of being approved guarantees independence, preventing conflicts of interest and verifying the competence of members in the area in which they work.



Organisational chart 7 - CNES, Cape Verde

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**Caption:** The CNES is an independent commission that works with the Ministry of Health. It is headed by a President and in his absence by a Vice-President. It has its own Support Office and secretariat and has two sections: one for evaluating clinical trials and another for evaluating health research which is not included in the first section.

### 2.3.3. Guinea-Bissau

Table 11 - CNEPS, Guinea-Bissau

Country	Nature	Structure and Composition	Appointment	Competences
Guinea-Bissau  National Health Research Ethics Committee (CNEPS)	A technically and scientifically independent body, transdisciplinary and pluralist in its composition and transparent in its procedures. Its mission is advisory and binding.	The bodies are the President, Vice-President and Permanent Secretary. They will be full members with recognised academic-scientific standing and professional experience in the fields of biological sciences, medicine, pharmacological sciences, law and social and human sciences, as well as in aspects of religion and		

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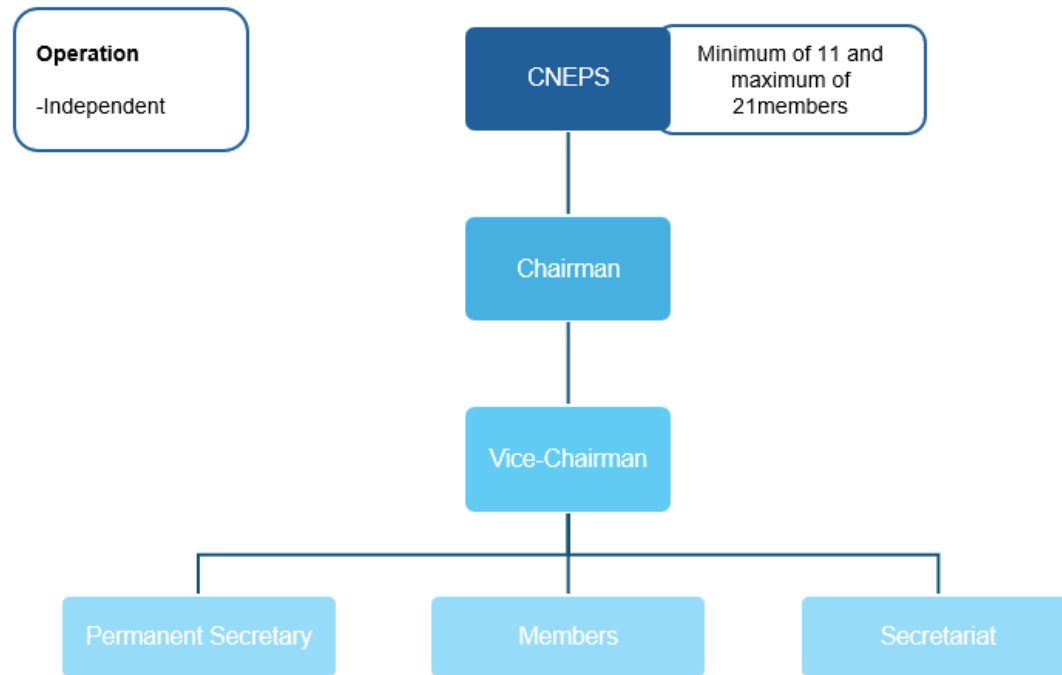
Country	Nature	Structure and Composition	Appointment	Competences
		ethics, they are also members of civil society who guarantee the cultural and moral values of the community.  (Articles 5 and 6 of the Draft CNEPS Statute)		

**Caption:** The table refers to the relevant aspects of the National Health Research Ethics Committee (CNEPS). Blue shading indicates what is in the legislative pipeline.

In Guinea-Bissau, the CNEPS is a fundamental body for guaranteeing ethical compliance in the areas of health and clinical research. The legislation currently in the process of being approved guarantees independence, preventing conflicts of interest and verifying the competence of the members in the area in which they work.

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**Comité Nacional de Ética em Pesquisa na Saúde (CNEPS)**  
(National Committee for Ethics in Health Research )



Organisational chart 8 - CNEPS, Guinea-Bissau

**Caption:** CNEPS organisational chart showing that it is an independent commission, made up of a minimum of 11 members and a maximum of 21, headed by a President assisted by a Vice-President.

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### 2.3.4. Mozambique

Table 12 - CNBS, Mozambique

Country	Nature	Structure and Composition	Appointment	Competences
<p><b>Mozambique</b></p> <p>National Bioethics Committee for Health (CNBS)</p>	<p>Non-profit legal person governed by public law, with legal personality, technical, administrative and financial autonomy and its own assets, under the supervision of the Ministry of Health.</p>	<p>Plenary; President; Vice-President; Executive Secretary; Disciplinary Board.</p>	<p>Members are selected through open competition, according to their speciality. Health, social sciences and humanities professionals with experience in research will be selected by open competition.</p> <p>Members from professional and religious associations are appointed by their groups at the request of the CNBS.</p> <p>The President is chosen by the entire membership.</p> <p>The Vice-President and</p>	

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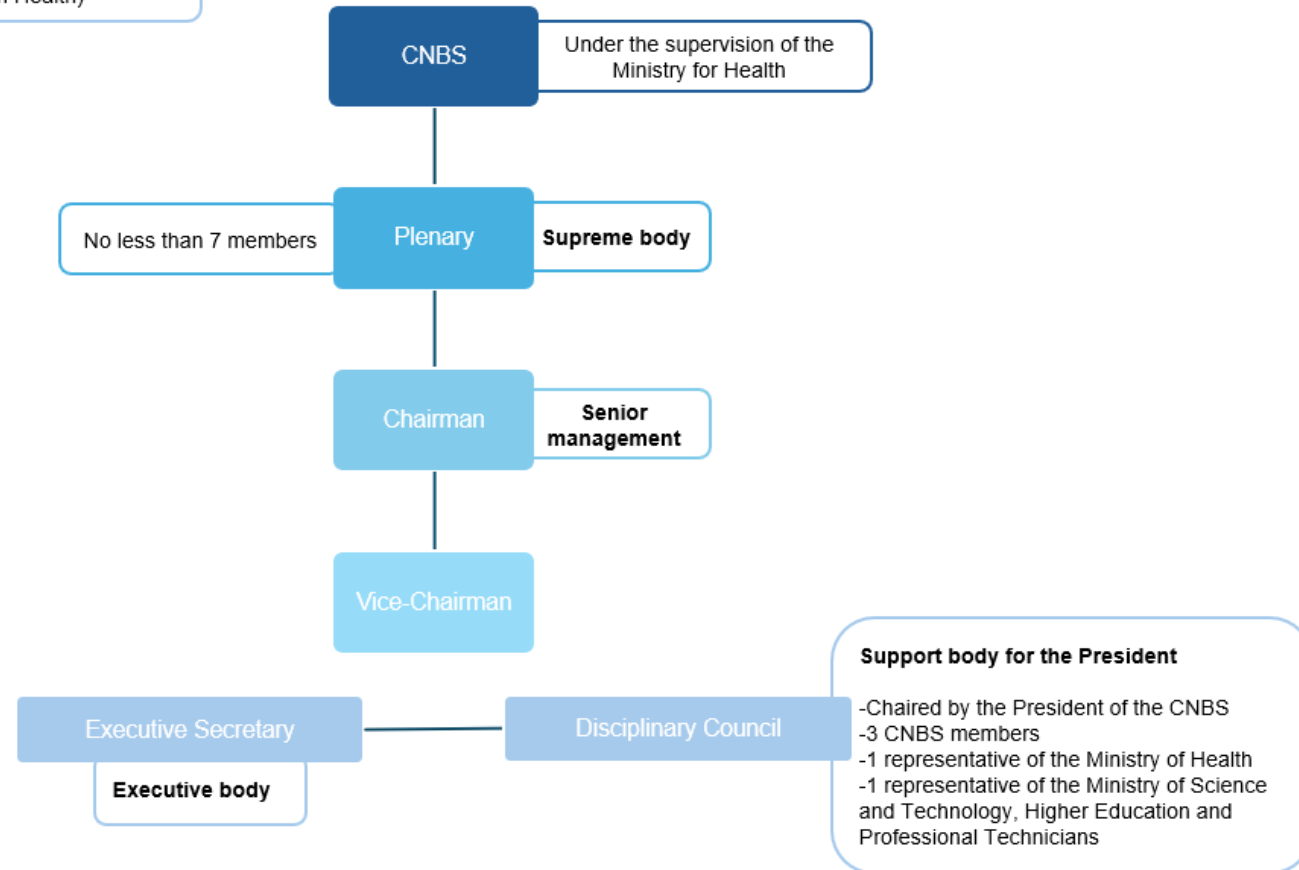
Country	Nature	Structure and Composition	Appointment	Competences
			the Executive Secretary are elected from among the CNBS members.	

**Caption:** The table refers to the relevant aspects of the National Bioethics Committee for Health (CNBS). Blue shading indicates what is in the legislative pipeline.

In Mozambique, the CNBS is a fundamental body for guaranteeing ethical compliance in the areas of health and clinical research. The legislation currently in the process of being approved guarantees independence, preventing conflicts of interest and verifying the competence of the members in the area in which they work.

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**Comité Nacional de Bioética em Saúde (CNBS)**  
(National Committee on Bioethics in Health)



Organisational chart 9 - CNBS, Mozambique

**Caption:** The CNBS operates under the supervision of the Ministry of Health. Its head is the President and it works in Plenary with no fewer than 7 members.

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### 2.3.5. São Tomé and Príncipe

Table 13 - CESIC, São Tomé and Príncipe

Country	Nature	Structure and Composition	Appointment	Competences
<p><b>São Tomé and Príncipe</b></p> <p>National Ethics Commission of the Ministry of Health</p>	<p>Commission of the Ministry of Health and Women's Rights. It has complete independence from the management and governing bodies of the Ministry of Health and Women's Rights.</p>	<p>President, Assistance Section; Research Section, which operates under the direction of the President.</p>	<p>The representatives were appointed by Ministerial Order no. 59/GMS/2024, of 22<sup>nd</sup> April.</p>	<p>Regulate, analyse and supervise clinical, experimental and social research involving human beings within the scope of the MSDM complex, or that of another institution, when requested by the latter. Technically analysing a set of documents that make up the research process. Contribute to the observance of ethical and bioethical principles in scientific research taking place on national territory, ensuring respect for</p>

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Country	Nature	Structure and Composition	Appointment	Competences
				ethical principles in matters in which it is called upon to intervene, in the light of the principle of the dignity of the human person. (specifically, Article 8 of CESIC's Rules of Procedure).

**Caption:** The table refers to the relevant aspects of the Ministry of Health's National Ethics Commission.

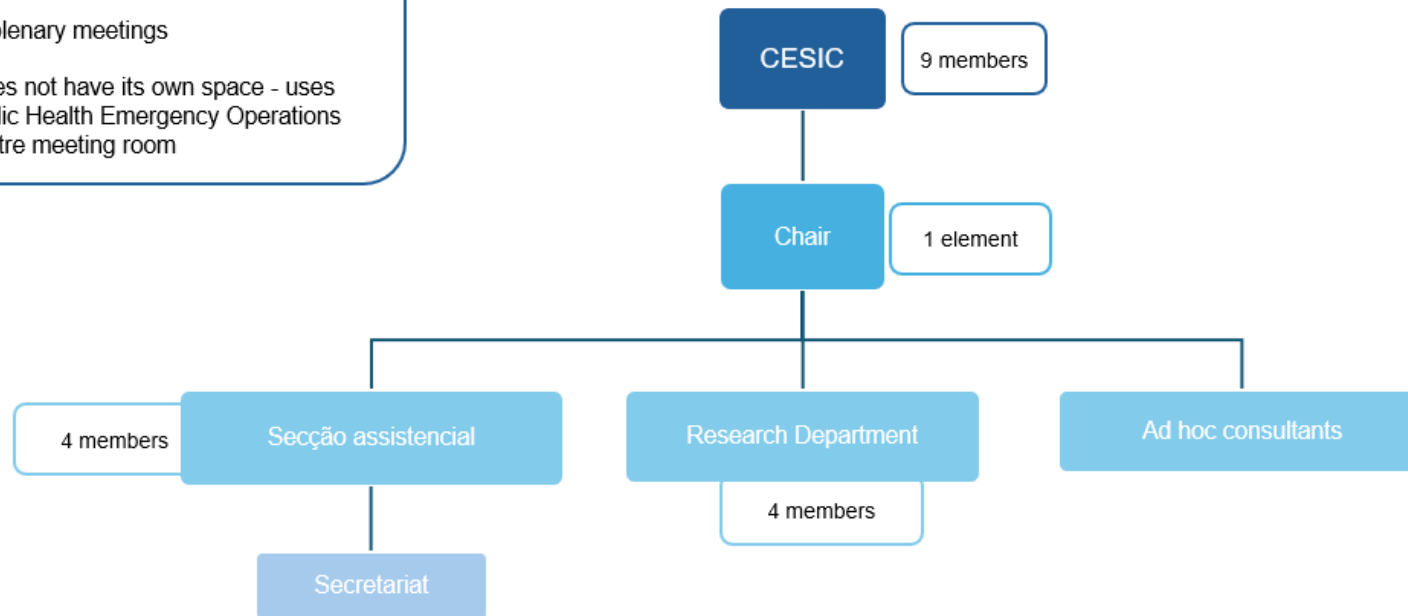
In São Tomé and Príncipe, this organisation is key to ensuring ethical compliance in the areas of health and clinical research.

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**Comissão Nacional de Ética de Ministério da Saúde (CESIC)**  
(National Ethics Commission of the Ministry of Health)

**Operation**

- In plenary meetings
- Does not have its own space - uses Public Health Emergency Operations Centre meeting room



Organisational chart 10 - CESIC, São Tomé and Príncipe

**Caption:** CESIC meets in plenary sessions and has nine members, one of whom is its president. It has an assistance section, a research section and ad hoc consultants.

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### **3. Relationship between National Research Ethics Committees and National Regulatory Agencies for Medicines**

The analysis also made it possible to understand whether there is a relationship between the National Research Ethics Committees and the National Regulatory Agencies for Medicines in each of the PALOP countries, and in what way.

3.1. In Portugal, the Ethics Committee for Clinical Research (CEIC) operates within INFARMED, IP, as stipulated in article 1, no. 3 of Ministerial Order no. 135-A/2014, of 1 July. CEIC's main function is to assess the ethical compliance of clinical trials carried out in the country, ensuring that they comply with established ethical, legal and scientific principles.

3.2. In Angola, INIS (Instituto Nacional de Investigação em Saúde (National Institute for Health Research)) is the coordinating institution for health research, in accordance with article 6, no. 1, a) of the INIS Organic Statute (Presidential Decree no. 177/19, of 22<sup>nd</sup> May). The CEMS (Ethics Committee for Medicine and Health) carries out its work on INIS premises, unless it is necessary to carry it out elsewhere. However, an analysis of the documents to which WP3 had access does not reveal a clear definition of the relationship between CEMS and ARMED, as the country's medicines regulator.

3.3. In Cape Verde, as in Angola, there is no explicit definition of the relationship between the CNES (National Ethics Commission for Health) and ERIS (Independent Health Regulatory Authority). This suggests a lack of clarity in the guidelines on how the two entities interrelate in the process of regulating and ethically evaluating health research.

3.4. Similarly, in Guinea-Bissau, the relationship between the CNEPS (National Ethics Commission for Health Research) and ARFAME, IP (Regulatory Authority for Pharmacy, Laboratory, Medicines and Other Health Products) is not clearly defined in the current regulations, leaving open the guidelines on how these two entities should coordinate regarding the regulation and supervision of clinical trials and medicines.

3.5. As far as Mozambique is concerned, although it is not explicit, the relationship is revealed by the fact that ANARME, IP has the power to "authorise the carrying out of clinical trials, subject to the opinion of the Bioethics Committee" (article 10, b) and insofar as the Board of Directors

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is responsible for "deciding on the carrying out of clinical and therapeutic trials, after hearing the ethics committee" (article 9(2)(s) of ANARME's Organic Statute (Decree no. 115/2020, of 31 December).

3.6 Finally, in São Tomé and Príncipe, it is possible to affirm the existence of a relationship between ARFAMED and CESIC, firstly because of the competences of each body: CESIC's main objective is to analyse and reflect on issues related to ethics and bioethics in the context of any scientific research intended to be carried out on human beings (article 3 of the Proposal). This is related to ARFAMED's role of regulating clinical trials with medicinal products for human use (Article 7(2)(e) of the Proposal). In addition, the Director General of ARFAMED is responsible for "authorising or prohibiting, on the basis of a technical opinion from the ethics committee, the carrying out of clinical trials on medicinal products" (cf. Article 27(g) of the Proposed Decree-Law for the creation of the Regulatory Authority for Pharmacy, Medicines and Health Technologies and approval of its respective statute). Furthermore, this collaboration is mentioned in the Clinical Trials Regulation Section of the Regulation and Legal Department (Article 28(2)(b) of the aforementioned Proposal).

The fact that in some countries there is a lack of clear definition about the interrelationship between ethical evaluation bodies and regulatory authorities may indicate the need for an opportunity to harmonise and develop standards and procedures to strengthen collaboration between these institutions and ensure greater effectiveness in the regulation and supervision of clinical trials and medicines.

#### 4. General Appreciation

The tables and organisational charts presented show the substantial development that has taken place in recent years, with the aim of strengthening the bodies responsible for ethical evaluation and the national drug regulatory authorities in the countries involved in the project. Regarding the National Research Ethics Committees, it can be concluded that Angola and São Tomé and Príncipe already have legislation in place, while the other countries are still in the legislative process of achieving this goal.

As far as the National Medicines Regulatory Bodies are concerned, it can be seen that, with the exception of São Tomé and Príncipe, all the countries analysed already have regulations in place, demonstrating significant progress in formalising the regulatory processes needed to supervise biomedical research.

The analysis carried out indicates that there is remarkable harmonisation between the National Research Ethics Committees and the National Regulatory Agencies for Medicines in the five countries studied, particularly reflected in the competences and duties assigned to these bodies. This proximity in the roles and responsibilities performed contributes decisively to strengthening trust in regulatory and ethical practices, promoting not only safety and transparency in clinical trial processes, but also ensuring that local policies and practices are aligned with the highest international standards of good scientific and ethical practice. Adherence to international good practices, such as Good Clinical Practice (GCP), and compliance with international regulations, such as WHO or African Union standards, is also an important point to note.

This alignment not only facilitates the implementation of a cohesive normative and regulatory framework, but also strengthens the integrity and credibility of the biomedical research systems in the countries in question, favouring the development of high-quality clinical trials and the exchange of information and experiences between the different nations. This way, continued progress in the regulation and ethical evaluation of biomedical research can ensure that PALOP countries are increasingly prepared to deal with the challenges and advances of the sector in a safe, efficient and ethical manner.