**Report of the Portfolio Committee on Health on the Ratification of the Treaty for the establishment of the African Medicines Agency (AMA), dated 26 May 2024**

The Portfolio Committee on Health (the Committee), having considered the ratification of the treaty for the establishment of the African Medicines Agency, referred to it reports as follows:

1. The Ratification for the establishment of the African Medicines Agency Treaty was tabled in Parliament and referred to the Committee.
2. The establishment of the AMA was first discussed at the meeting of African Ministers of Health jointly convened by the African Union Commission (AUC) and the World Health Organization (WHO) in Luanda, Angola, in April 2014. The focus was to prioritise investment for regulatory capacity development and to pursue the efforts towards convergence and harmonisation of medical products regulation at the Regional Economic Communities (RECs) level.
3. The Task Team for AMA was established by the AUC to develop the modalities for the opera ionisation of AMA and the development of the Treaty on AMA.
4. The African Union (AU) Assembly of Heads of State and Government adopted the Treaty in their 32nd Ordinary Session of 10-11 February 2019, in Addis Ababa, Ethiopia.
5. Rwanda was selected to host the headquarters of AMA by the Executive Council of the AU at a meeting held in Lusaka, Zambia in July 2022.
6. The main objectives of AMA are to enhance capacity of State Parities and RECs to regulate medical products in order to improve access to quality, safe and efficacious medical products in the African continent.
7. At a continental level, AMA’s mission is to:

* Coordinate and strengthen ongoing initiatives to harmonise medicines regulation, promote cooperation and mutual recognition of regulatory decisions.
* Conduct regulatory oversight of selected medical products and providing technical guidance to State Parties and RECs.
* Pool expertise and capacities and strengthening networking for optimal use of resources.

1. In order to achieve its mandate, AMA intends to work with technical partners such as the WHO, European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) for alignment with normative standards, technical cooperation and capacity building.
2. AMA intends to develop improved access to quality-assured medical products that are expected to ensure an enhanced regulatory environment for the continent. Further, AMA plans to be more visible by facilitating the following core activities:

* Safety monitoring;
* Market surveillance;
* Marketing authorisation;
* Oversight of clinical trials;
* Coordination of quality control laboratory services; and
* Joint assessments and Good Manufacturing Practice (GMP) Inspections.

1. The Committee received its briefing on the AMA Treaty from the Department of Health on the 17th May 2023.
2. In its presentation, the Department of Health highlighted South Africa’s value proposition of the African Medicines Agency as follows:

* Globalisation means regulation is no longer solely a national responsibility;
* Reducing the prevalence of substandard and falsified medicines and vaccines;
* A consistent voice on regulatory issues, the pooling of expertise from across the continent;
* Regulatory harmonisation and convergence such as standards, and guidelines for quality, safety, and efficacy;
* Participation in Africa Free Trade Continental Agreement (AfCFTA) - anchored pharmaceutical initiative: localised production, pooled procurement, and harmonised regulatory and quality frameworks;
* Harmonisation is cost-effective such as speed of access to essential medicines and ensuring efficient use of resources through work-sharing; and
* Opportunity to mitigate the effects of COVID-19 pandemic by allowing the free movement of pharmaceuticals and PPE.

Votes **in favour** of the ratification of the Treaty: 7 Members (Dr KL Jacobs, Ms A Gela, Dr X Havard, Mr N Xaba, Dr J Nothnagel, Dr S Thembekwayo and Ms MD Hlengwa)

Votes **rejecting** the ratification of the Treaty: None

Abstinence: 3 Members (Ms M Clarke, Ms ERL Wilson and Mr P Van Staden)

The Committee recommends that the House, in terms of section 231(2) of the Constitution of the Republic of South Africa 1996, approves the said Treaty.

**Report to be considered.**