

ZAMRA ENGAGES STAKEHOLDERS ON THE REVIEW OF THE MASA

The Zambia Medicines Regulatory Authority (ZAMRA) has started the process of engaging stakeholders on the draft Medicines and Allied Substances Bill, 2025.

The proposed provisions in the Bill are in a bid to align the Medicines and Allied Substances Act, No. 3 of 2013 to the African Union (AU) Model Law on Medical Products Regulation endorsed by African heads of states and government at the AU Summit held in January, 2016 in Addis Ababa, Ethiopia.

The AU Model Law is designed to assist African countries in addressing gaps and inconsistencies in regulatory legislation. The AU Model Law also provides a framework for national regulatory authorities, such as ZAMRA to regulate medicines and allied substances while also addressing issues relating to prohibition of substandard and falsified medicines and allied substances.

Addressing the meeting, ZAMRA Director-General Mr. Makomani Siyanga said it was imperative that the current Act is repealed and replaced to ensure that it is aligned to modern trends and practices in the regulation of medicines and allied substances.

"The proposed provisions in the Bill, once enacted, will result in strengthening the legislative framework for purposes of attaining the World Health Organisation (WHO) maturity level 3 (ML3) status, a global recognition of regulatory excellence, which is one of ZAMRA's highest strategic priorities."

Mr Siyanga also reiterated the critical role stakeholders play in protecting human and animal health, saying their recommendations are a vital requirement in the legislative process.

The stakeholder engagement took place at M'kango Cresta Golfview Hotel, Lusaka, from 9th to 10th October, 2025 and is expected to continue on Wednesday, 15th October, 2025.

