

AU Model Law on Medical Products Regulation



The African Union (AU) Model Law is a legislative framework that addresses these challenges by harmonizing requirements and processes as follows:

1



Registration and marketing of health technologies

2



Granting manufacturing and distribution licenses

3



Conducting quality and safety inspection of health technologies, as well as manufacturing facilities

4



Authorizing clinical trials through an established National Ethics Committee or Institutional Review Board

5



Overseeing appeals procedures through an established Administrative Appeals Committee.

