



## Legislative proposals – The Finance Bill 2025

### Presentation to the Finance and National Planning Committee

**ROCHE KENYA LIMITED**

May 2025

# Roche Kenya Limited (“Roche”)



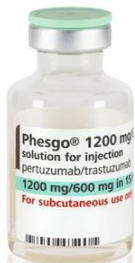
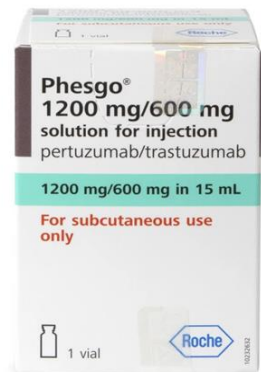
- Roche Kenya Limited is a subsidiary of F. Hoffmann-La Roche Limited (“Roche Basel”), a Swiss multinational health care company that has two divisions, i.e., pharmaceutical products division and diagnostics products division which also incorporates the diabetic care line.
- The company is part of the wider Roche Group, a research-based, global healthcare company with strengths in both pharmaceuticals and diagnostics. The group develops, manufactures and delivers innovative medicines and diagnostic instruments and tests for patients globally.
- Roche is a local distributor for Roche Basel and is responsible for the promotion, marketing and distribution of diabetic care, diagnostic and pharmaceutical products.
- Healthcare is evolving, but Roche’s vision is clear. We focus on preventing, stopping or altogether curing diseases with the highest societal burden for a healthier future for people, partners and our planet.
- The company partners with various players in the public sector, including the Ministry of Health (“MoH”), to ensure supply of pharmaceutical products at an affordable rate.

# Involvement in clinical trials



- As part of our vision, Roche is widely involved in medical research activities in Kenya in the form of clinical trials.
- Clinical trials are a critical component of medical research which supports the development of new medicines as well as new applications for existing ones. Clinical trials answer important questions in healthcare and drug development.
- Roche conducts several clinical trials in the country, adhering to relevant standards including the Pharmacy and Poisons Board's ("PPB") *Guidelines for the Conduct of Clinical Trials in Kenya*.
- Roche as the sponsor of these trials, bears the cost of the Investigational Medicinal Products (clinical trial kits and placebos) which it provides to its research partners.
- Partners include the Aga Khan University Hospital ("AKUH") and the University of Nairobi's Institute for Tropical and Infectious Diseases ("UNITID"). Example of partnership with AKUH: (1) A past global clinical trial for the treatment of COVID-19 associated pneumonia (2) Ongoing clinical trial on the treatment of breast cancer.

# A sample of Roche's products



# Healthcare and medical research as a priority (Global)



- Common forms of medical research include laboratory-based , epidemiological and clinical trials.
- Clinical trials are the most pivotal for healthcare research. Patients benefit by having access to life-changing treatments.
- For instance, the American National Cancer Institute provides guidelines on how cancer patients can apply and get access to investigations that are still under the clinical trial phases.
- Africa has the fastest growing population with a notable rise in non-communicable diseases.
- Even with the increase in Africa's disease burden, only 4% of clinical trials are done on the continent. According to the World Economic Forum ("WEF") this accounts for only 819 of the 20,825 clinical trials conducted world-wide in the year 2023.
- African governments spend relatively less on medical research leaving this area of the health sector heavily underfunded. According to World Bank on average, African countries only allocate **0.45% of their GDP** to R&D which is well below the global average of **1.7% of GDP**.

# Healthcare and medical research as a priority (Kenya)



- Devolution of healthcare in Kenya brought about substantial gains in the sector such as increase of medical infrastructure throughout the country.
- In making healthcare accessible to all Kenyans, the Government, as guided by the Bottom-up Economic Transformation Agenda, has made strides in Universal Healthcare Coverage (“UHC”).
- Kenyans still face high costs of healthcare owing to the high cost of medication which accounts for 20%-60% of healthcare costs.
- Under the Fourth Medium Term Plan 2023-2027 (“MTP IV”) Government acknowledges that there are low incentives for the private sector to invest in research and development. The Government currently allocates **0.8% of its GDP** to research and innovation, less than **2% of GDP** threshold under the Science Technology and Innovation Act, 2013.

# Healthcare and medical research as a priority (Kenya)



## Continued...

- Part of the 0.8% is allocated to government-funded medical research. 60% of the allocated funds are channeled towards training while the remaining 40% funds medical research activities, so not adequate.
- As such, the Government needs to create an attractive environment for investment by players in the private sector, including through tax policy considerations.

# The issue: VAT at 16% is applicable on clinical trial kits (3006.93.00)



- HS code 3006.93.00 covers '***Placebos and blinded (or double-blinded) clinical trial kits for a recognised clinical trial, put up in measured doses***'. Subject to import duty at a rate of 0% and taxable at 16%. **The VAT cost has an impact on the budget available for research activities, limiting the scope or scale of research projects.**
- Chapter 30 of the East African Community Common External Tariff ("EACCET") covers the tariff classification of various pharmaceutical products subdivided into six tariff headings which are further classified into HS codes.
- The import duty rate applicable for all pharmaceutical products listed in the EACCET is 0% with the exception of waste pharmaceuticals classified under HS code 3006.92.00 which have a duty rate of 25%.
- Since the commencement of the VAT Act in September 2013, the Government has consistently, and on an incremental basis, instituted VAT policies aimed at increasing access to healthcare products at affordable prices.
- At the VAT Act's commencement, pharmaceutical products were VAT zero rated (0%). Over time, pharmaceutical products have been transitioned from zero rated to VAT exempt as shown in the next slide.



# Trends in VAT treatment of pharmaceutical products in Kenya

VAT Act version	Number of exempted tariff codes	Number of zero-rated tariff codes	Legislative changes
2013	34	0	
2014	34	0	
2015	19	16	The Finance Act, 2015 introduced Medicants as Part C of the Second Schedule
2016	19	17	The Finance Act, 2016 added medicants of HS Code 3003.20.00 in Part C of the Second Schedule
2017	19	17	The Finance Act, 2017 retained the items previously covered in the schedules, only cleaning up the wording for medicants under HS Code 3003.10.00
2018	19	20	The Finance Act, 2018 removed medicaments of tariff 3004.40.00 from the Second Schedule but added medicants of HS Codes: 3004.41.00, 3004.42.00, 3004.43.00 and 3004.49.00
2019	19	20	The Finance Act, 2019 did not bring about any changes to the VAT treatment of pharmaceutical products
2020	37	0	The Tax Laws Amendment Act, 2020 moved the medicants previously zero-rated to the exempt schedule excluding tariffs, 3004.43.00, 3003.20.00. The Finance Act 2020 introduced no further amendments.
2021	45	0	The Finance Act, 2021 expanded the list of exempted pharmaceutical products.
2022	45	0	There were no changes relating to pharmaceutical products in the Finance Act, 2022
2023	47	0	The Finance Act, 2023 added to the number of pharmaceutical products that are exempt from VAT.
2024	47	0	There were no changes relating to pharmaceutical products proposed through the Finance Bill, 2024.

# Proposal and justification



- **HS 3006.93.00** was introduced by the World Customs Organization in 2022 as an update to the 2017 edition of the tariff book. It has been in use in Kenya w.e.f. 1 July 2022. Prior to that pharmaceutical products for clinical trials were classified with the usual (for sale and consumption) active medication which are currently VAT exempt.
  
- **We propose that the Government exempts from VAT items of HS code 3006.93.00 based on the below justifications:**
  - ✓ VAT exemption will reduce the cost of medical research. Lack of VAT exemption raises import costs for clinical trial kits and placebos, and since these products are supplied to research partners for free, Roche and other private sponsors incur more costs which in turn reduce the available funds for a wider scale of research.
  - ✓ VAT exemption for items of HS code **3006.93.00** will be consistent with the exemption of other pharmaceutical products. The VAT law currently excludes the bulk of pharmaceutical products from VAT which is in line with the Government's objective of providing/facilitating affordable healthcare to Kenyans.
  - ✓ VAT exemption will encourage innovation and medical research. The exemption of clinical trial kits and placebos from VAT will provide a reprieve for stakeholders who sponsor medical research and attract additional support in this area.

# Practice in other countries

Country	VAT treatment
<b>Nigeria</b>	Medical and pharmaceutical products are generally VAT exempted
<b>Ghana</b>	Pharmaceuticals are exempt from VAT
<b>South Africa</b>	Pharmaceutical products are generally subject to VAT
<b>Uganda</b>	Uganda generally zero-rates drugs and medicines manufactured in Uganda. However, it exempts imported drugs and medicines and medical sundries .
<b>Tanzania</b>	Medicine and pharmaceutical products are generally exempted from VAT
<b>Rwanda</b>	Exempts goods related to health purposes

**Doing now what patients need next**

**Thank you.**