The patent regime in Zambia is governed by the Patents Act of 1958 (Chapter 400). Zambia became a member of ARIPO in 1986 and joined the Patent Cooperation Treaty (PCT) in 2001. It has yet to acceded to the Banjul Protocol of ARIPO and specific provisions of PCT have yet to be introduced to the act. The new Patents Act, No. 40 of 2016 will replace the Patent Act of 1958 until then, the previous regulations under the repealed acts shall be applicable. Zambia launched IP draft policy in 2009 and in 2010 the Implementation Plan of the National Intellectual Property (IP) Policy 2010-2014. As per the Implementation Plan a revision of the Patent Act took place. No new or revised version of the implementation plan nor a new IP Policy has been made public.

**Policy Recommendations**

1. Advocate for the expeditious finalisation of the regulations to effect the implementation of the The Industrial Designs Act, 2016 (Act No. 22 of 2016).

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**Country Indicator**

- Population (2016): **16,59 m**
- GDP Per Capita (2016): **1 178,39 USD**
- Health Expenditure of GDP (2014): **5.0%**
- Human Development Index (2016): **139**
- LDC Status: **Yes.**

**Disease Indicator**

- Malaria New Cases per 1000: **365** (2016)
- TB Estimated Cases per 100.000: **374** (2016)
- HIV Prevalence aged 14-49: **12.4%**
- Non-Communicable Diseases: **23%**

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**Harnessing Trade Related aspects of Intellectual Property Rights (TRIPS) Flexibilities**

- Member of World Trade Organisation (WTO): **Yes.** January 1, 1995.
- Acceded to TRIPS Agreement: **Yes.** January 1, 1995.
- Voluntary Licenses: **Yes. [Refer to Medicines Patent Pool (MPP)].**
- Past Use of TRIPS Flexibilities: **Yes.** 2004, compulsory license, 3TC, NVP, D4T, GSK, BI, BMS HIV/AIDS. 2004, paragraph 7, ARV's, All types of diseases. 2006, paragraph 7, ARV's and other medical supplies for all types of diseases.
- Research Exception: **No.**
- Early Working (Bolar) Exception: **No.**
- Compulsory Licenses / Government Use: **Yes.** Section 37 and 40-41, Chapter 400.
- Parallel Importation (International exhaustion): **No.**
- Patentability Criteria: **No.**
- Pre and Post patent Grant Opposition Procedures: **Pre grant only.** Section 22, Chapter 400.
- Importation of HIV, TB and Malaria drugs from SADC member states: **No.**
- Pharmaceutical Act: **Yes.** Medicines and Allied Substances Act No. 3 of 2013.
- Regulatory Authority: **Yes.** Zambia Medicines Regulatory Authority (ZAMRA).
**Zambia Timeline**

1. **1958** - National IP Law
   - The Patents Act of 1958 (Chapter 400) is still applicable until the new Patents Act, No. 40 of 2016 regulations have been issued.

2. **1978** - Lusaka Agreement
   - The creation of the African Regional Intellectual Property Organization (ARIPO).

   - Patents and industrial designs within the framework of the African Regional Industrial Property Organization.

4. **1995** - TRIPS Agreement
   - The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).

5. **2001** - Patent Cooperation Treaty
   - The Patent Cooperation Treaty (PCT) makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an "international" patent application.

6. **2004** - Compulsory License
   - On September 21, 2004 the Zambian Minister of Domestic Trade and Consumer Affairs issued a compulsory license for lamivudine, stavudine and nevirapine.

7. **2007** - Cobicistat Compound
   - Filed with Medicines Patent Pool (MPP). Used for the treatment of human immunodeficiency virus infection.

8. **2009** - Final Draft IP Policy
   - The Ministry of Commerce Trade and Industry (MCTI), through the Patents and Companies Registration Office (PACRO) formulated a National Intellectual Property Policy.

9. **2016** - New National IP Law
   - The new Patents Act, No. 40 of 2016 will replace the Patents Act of 1958 (Chapter 400) of the law once the regulations are issued. Until then, the previous regulations under the repealed acts shall be applicable.

**Intellectual Property Policy Environment**

- **IP/Patent Act:** The Patents Act of 1958 (Chapter 400).
  - Date of entry into force: April 1, 1958.

- **Competition Act:** Yes. The Competition and Consumer Protection Act, 2010.

- **Regional IP Member:** Yes. African Regional Intellectual Property Organization (ARIPO).

- **Regional/ Multilateral Legislation:** TRIPS/Paris/Harare/Lusaka.


- **Online searchable patent database:** No. ARIPO online database only.

**Cost Saving Mechanism**

A wide range of medicines can be profitably manufactured at very low cost and/or through the procurement of generic medicines. Should voluntary license options not be available, then governments could consider the use of other TRIPS flexibilities. This is especially urgent as newer and less toxic essential medicines are now needed for diseases such as HIV-Tuberculosis co-epidemics (and their drug-resistant strains), Hepatitis C and other Non-Communicable Diseases (NCD’s) such as cancer and diabetes.

It is estimated that on average generics medicines are 20-80% cheaper than originator drugs and often push down price of originator drugs.

**Prescription drug cost comparison**

- **Generic:** $25
- **Brand Name:** $82