The Union

International Union Against Tuberculosis and Lung Disease

Developed in collaboration with

Alstonia Impact

EXECUTIVE SUMMARY

Enhancing Access to Inhaled Medicines

Lessons from Insulin Access



Diabetes (insulin) is ahead of the curve within NCDs in LMICs, and can offer key lessons for asthma and COPD (inhaled medicines)

- The objective of this work is to translate insulin access lessons to inhaled medicines for asthma and COPD and create recommendations for the broader field. Both insulin and inhaled medicines are life-saving medicines for Non-Communicable Diseases (NCDs) which rely on drug-device combinations.
- The work focuses on inhaled medicines with limited access (long-term controller/management therapies including Inhaled corticosteroids (ICS) and long-acting bronchodilators, which come in 2 types, long-acting beta-agonist (LABA) and long-acting muscarinic antagonists (LAMA), plus their combinations) in LMICs; we consider a global view but also deep-dive into four countries with distinct health systems: Kenya, Kyrgyzstan, Peru, and Tanzania.
- Over 240 documents were reviewed, and 15 global and country experts on diabetes (insulin), and Asthma and COPD (inhaled medicines) were interviewed for this work.
- Diabetes imposes a large burden on LMICs; Insulin, a biological product, is required for all Type 1 Diabetes (T1D) patients and for a significant proportion of Type 2 Diabetes (T2D) patients as a second-line treatment. Currently, most insulin used in LMICs is human insulin delivered in vials and administered via injections in contrast with HICs where a pen/devices with pre-filled analogue insulin are standard. WHO currently endorses human insulin in vials as the costs are lower compared to analogue insulin in pens and the clinical benefits are not significantly different.
- Along with hypertension, diabetes is one of the first non-communicable diseases (NCDs) that have seen significant attention from LMICs governments and has seen several successes worth learning from:
  - Countries have largely addressed hygiene factors for treatment with insulin, i.e. updated guidelines, inclusion in EMLs, inclusion in reimbursements, registration of products by regulatory authorities.
  - Most countries have moved screening and diagnosis of diabetes to the primary level, ensuring that more people are diagnosed. WHO's PEN guidelines have been influential in this regard.
  - Three major companies have significant LMIC presence. They engage in LMICs through donations (usually for T1D) and tiered pricing. Major companies like Novo Nordisk have capped pricing in many LMICs, e.g. Novo has a pricing of $3 / vial in many LMICs, and $2 / vial in crisis/humanitarian settings.

Lessons can be drawn both from success and missteps of the insulin experience

- It is important to note that several challenges still impede access to insulin in LMICs, and this work learns from successes as well as areas of improvement.
- There are many challenges that persist for diabetes patients in LMICs:
  - Across countries, financing is nascent and fragile. There are challenges in service delivery centralization with high dependence on specialists. In addition, for insulin, there are affordability concerns as it may not be fully reimbursed or available in public facilities. Out-of-stock in public systems is common, which leads to private purchase and high out of pocket spending for patients.
  - A highly concentrated market with three players dominating LMICs has led to some adverse consequences, including lack of reliability of supply and barriers to entry to generics and biosimilars. Many countries have high dependence on a single supplier. As of mid-2026, this may be changing as the major pharma companies shift their priorities away from human insulin and WHO and other global health players are supporting the entry of LMIC-based quality assured players.
  - Across four countries analysed, similar issues were seen:
    - Kenya: Major gaps in financing, limited or delayed diagnosis, and poor treatment adherence due to stock-outs and incorrect beliefs among those diagnosed;
    - Kyrgyzstan: Insufficient government budgets; many missed / delayed diagnoses; treatment requires specialists, causing a bottleneck and limiting access to care, and out of pocket spending despite mandate for free insulin;
    - Peru: High centralization affects remote populations; low diagnosis rate, limited access to free insulin as supply fails often leading to high out of pocket costs;
    - Tanzania: Low diagnostic rates; among those in treatment, limited adherence due to personal beliefs / stigma, poor supply, and resulting high out of pocket spending.
- Some lessons can be learnt from initiatives to improve access to insulin:
  - Most global/multi-country initiatives are supported by big 3 insulin firms; donation programs (esp. for T1D for children) and voluntary lower pricing have helped. Unlike other areas such as maternal and child health, and infectious diseases, there are no major philanthropic donors and engagement of pharma players has partly filled a gap. However, valid questions around sustainability and effects on competition exist. Lower promised prices by firms do not always translate into real purchase prices due to intermediaries and taxes.
  - Notable LMIC based country initiatives include centralized procurement (e.g., by Kyrgyzstan) to reduce prices and running decentralized fixed day clinics for diabetes (e.g. Tanzania). Making insulin free (vs. copay) has also reduced financial burdens on patients, if sufficient supply exists. Procurement and supply chain efforts are necessary to bring products to people who need them, especially in view of insulin's cold storage requirements (Efforts by ACCISS around supply chain transparency).
  - Isolated initiatives that address only part of the problem (e.g. inclusion in EML without significant procurement) have usually failed.

Asthma and COPD see much lower attention across the board, including from LMIC governments and the industry

- Asthma and COPD impose a large burden on LMICs; access to inhaled corticosteroids and bronchodilators is essential to prevent exacerbations and premature deaths, with the strongest evidence for mortality prevention in asthma. For COPD, long-acting bronchodilators (LABA-LAMA combination), are effective in improving symptoms and quality of life.
- Some early success in access to inhaled medicines must be noted:
  - Asthma and COPD have been included in the influential WHO PEN guidelines, which promote the integration of NCD care into primary health care.
  - A key resolution at the World Health Assembly (WHA78.5) was passed in 2025 focused on promoting and prioritizing an integrated lung health approach.
  - UN Political Declaration on NCDs was adopted in 2025 requiring all Member States to achieve 80% access to affordable, WHO-recommended, inhaled medicines in primary-care facilities and for at least 60% of countries to have financial-protection measures that limit the cost of inhaled medicines by 2030.
- Key challenges impeding access to inhaled medicines:
  - Overall, very low uptake of ICS/LABA with inappropriate overuse of short-acting relievers: in most LMICs, ICS+LABA being available only in small private markets. For Asthma, a new model of care is emerging which involves short acting ICS+LABA in a single inhaler; this plays the role of a reliver and controllers. However, this needs to be endorsed by WHO and others for broader LMIC adoption
  - Globally, low political prioritization and financing; service delivery poorly organized leading to very low diagnosis rates (in part due to impractical diagnostic - spirometry), very low uptake of ICS and sub-optimal treatment with stigma as a major challenge.
  - Challenges are largely similar across the four countries:
    - Kenya: Systemic underfunding, lack of focus leads to low capabilities, equipment, and medicines esp. at primary level; social stigma compounds challenges;
    - Kyrgyzstan: Low govt. attention, high specialist dependence and stigma as cross-cutting challenges; poor availability of ICS inhalers outside capital and high out-of-pocket payments due to high co-payments;
    - Peru: Low diagnosis for COPD; shortages of control therapies lead to poor adherence and/or private purchase and high out-of-pocket spending;
    - Tanzania: Insufficient funding leads to limited diagnostic equipment and untrained providers; among few diagnosed, adherence poor due to stigma and limited medicines in public facilities.
- Very few initiatives to improve access to inhaled medicines:
  - Barring Brazil's case where access to inhaled medicines was made free, most other initiatives were small and not many have succeeded; some early research efforts are ongoing.
  - Pharma industry has not engaged in the same way as it has for diabetes and insulin.

Several key similarities and differences between diabetes (insulin) and, asthma and COPD (inhaled medicines) were noted before making recommendations

- Key similarities between diabetes (insulin), and asthma and COPD (inhaled medicines):
  - Both insulin and inhaled medicines face challenges due to mode of administration vs. conditions that require oral medicines.
  - Centralization of prescription, diagnosis and treatment, with high reliance on specialists.
  - Major availability/affordability challenges for LMIC contexts.
  - Provider fear of prescribing both insulin and inhaled medicines.
- There are also notable differences, including those that are favourable to improved access to inhaled medicines and those that are not:
  - Favourable differences:
    - Cold chain is not needed for most inhaled medicines.
    - Products for HICs and LMICs are largely the same (for insulin, products used in HICs and LMICs are very different which results in the shift in attention of insulin suppliers to more expensive analogue insulin or new products (e.g. GLP-1), LMICs largely rely on the cheaper human insulin market. Barring the triple therapy and advanced biologics, treatment options are largely the same in LMICs and HICs for inhaled medicines.
    - Relevant generics that sell inhaled medicines in HICs can theoretically leverage their SRA registrations to enter more LMICs using WHO's Collaborative Registration Procedure (CRP). In case of insulin, there are no SRA registered generics for human insulin, the relevant product in LMICs.
    - Opportunity for economies of scale: the originator for formoterol / budesonide (AstraZeneca) has significant manufacturing capacity, and they have dry power device that overcomes many of the issues with MDI/CFCs, and they have the capacity to deliver at very low cost (so willingness to do it is a key driver here).
  - Unfavourable differences:
    - Much lower attention of donors, public health stakeholders, pharma players.
    - Much lower attention and budgets from LMIC governments.
    - Guidelines that are not always updated, lower knowledge of product use even among health care providers that leads to much lower screening and diagnosis rates (note: the upcoming WHO PEN update would improve this point).
    - Major diagnostic product (spirometer) difficult for most people to use and expensive, with limited availability in primary care centres, very low availability in referral centres, and no option for patients to diagnose themselves.
    - Presence of accessible products that offer short-term relief (SABAs) is also a deterrent to proper treatment management which is less of an issue for diabetes
    - Stigma around conditions, inhaled medicines, and steroids are significantly higher for asthma and COPD.
    - Lack of patient groups for effective advocacy.

Our preliminary recommendations for the field

Group: Drive greater global attention towards and COPD via targeted advocacy

Recommendations	Details / examples
1. Keep the spotlight on WHA and UN political resolutions and declarations to bring greater attention and resources to problem	• Support also the ongoing effort towards WHA resolution on Access to NCD Medicines for Children to ensure focus on asthma inhalers • Support the NCD Alliance to take on advocacy campaigns for asthma and COPD, including tracking government commitment to addressing these diseases/conditions • Support The Union, FIRS, ERS, GOLD and GINA to champion the need for more attention to asthma and COPD
2. Drive greater attention to field by strategically piggybacking on topics that already have traction	• UHC movement (high-level UN meeting 2027) • PEN and PEN Plus have momentum • TB -> Lung health integration (lung health unique for NCD and infectious integration) • Environmental/Clean Air agenda and climate change/health
3. Support formation and engagement of patient advocacy groups	• Strong voice of patients is needed, similar to diabetes • Global, regional, and national respiratory societies could support (e.g., as part of FIRS or of the NCD Alliance). Leverage groups like NCD Alliance and MSF in advocacy and community engagement

Group: Update relevant global guidelines to align with latest science

Recommendations	Details / examples
4. Provide technical assistance to support countries to align their guidelines to the latest versions	• The GOLD (for COPD >>) and GINA (for asthma >>) reports include the latest international standards used by healthcare providers to diagnose, manage, and treat chronic obstructive lung diseases • The WHO PEN package is the operational vehicle by which most LMIC primary-care systems implement NCD management; it currently does not include the latest guidelines aligned with the latest evidence base, but an updated version should be released in 2026/2027 • Country support to align to latest guidelines, tapping on all relevant sources

Group: Demonstrate value of inhaled medicines in a limited set of high-readiness countries

Recommendations	Details / examples
5. Holistic country implementation work in selected LMICs to prove the case that demand exists and can be served	• Select a mix of countries where program would be under Primary care[1] MoH dept and others where TB programming is being widened (Global Fund and other resources may be available for these); most importantly, pick countries which are ready, e.g., multiple products already registered • Need to address demand and supply factors together (taking together all relevant stakeholders including suppliers) • Major effort needs to de-stigmatize inhalers and steroid use with populations and with healthcare providers • Prioritize asthma at the primary-care level, where diagnosis and ongoing management can often be delivered using clinical assessment and simple tools such as peak-flow meters. A pathway for referral to secondary care for people who do not improve with first line therapy delivered in primary care should also be clearly defined • Train primary care workers to think of COPD as a cause of cough and breathlessness that should be differentiated from TB and heart failure, and establish pathways for treatment

Group: Provide opportunistic TA support in non-demonstration countries

Recommendations	Details / examples
6. Provide opportunistic support by piggybacking on other adjacent efforts	• Opportunistic support could include governance, financing and operational advice for inclusion of Asthma and COPD in ongoing efforts (e.g., lung health integration for TB – push by Global Fund, PEN-Plus expansion) • As part of broader NCD / UHC expansion, ensure that asthma and COPD find a “home” at the highest level of governance at MoH (either within TB expansion -> lung health OR with NCD departments) • Advocate for inclusion in UHC package and budget lines for Asthma and COPD • Support countries to improve diagnoses and prescriptions at least at secondary, tertiary levels (primary is hard work and may happen later once demonstrations present compelling evidence)

[1] Even if asthma and COPD are NCDs, most patients show up with respiratory symptoms at primary care / emergency centers, not to NCD clinics

Group: Address selected supply-side challenges globally

Recommendations	Details / examples
7. Increase in-country competition by supporting firms esp. generics with WHO's CRP procedure to register in more LMICs	• Note: many of the generic ICS+LABA products are already registered with some SRAs
8. Support LMIC NRAs with capacity building for inhaled medicines	• There are currently no standard ways of showing that generic inhalers have the same effectiveness as originators
9. Negotiate more affordable prices with pharma companies in LMICs	• Experience from insulin shows direct price negotiations with pharma companies proved more effective than tenders to reduce purchase price • Options to be explored include: tiered pricing, volumes guarantees, long-term agreements (e.g., like Medicines Patent Pool, UNICEF, CHAI), demand consolidation through global or regional platforms (e.g., like the TB Drug Facility, UNICEF, PAHO Strategic Fund)

Group: Develop knowledge products

Recommendations	Details / examples
10. Develop knowledge products to help better articulate challenges, potentially in collaboration with the WHO	• State of inhaled medicines market covering key market developments (released at a pre-defined frequency)[2] • End-to-end analysis of access to care for asthma / COPD patients, including access to inhalers, but extending also to diagnostics, referrals, etc.

[2] This could include: Status of registration of key medicines in LMIC; Capability landscaping of NRAs for assessing inhaled medicines; ACCISS-style studies around pricing and its determinants, supply chain and availability in LMICs: map the current value chains and introduce systems to increase their transparency (e.g., visibility on transfer prices, on stock levels at different steps of the value chain, on tariffs and taxes, etc.), leading to its streamlining (e.g., removing intermediaries, etc.). A source of inspiration for this can be the annual HIV Market Report produced by CHAI

Group: Support R&D efforts

Recommendations	Details / examples
11. Support innovators that try to improve current medications	• Possible innovations currently explored by innovators include non-steroidal medicines, new delivery methods other than inhalers, etc. • Note: These are unlikely to become available in the short-term

Group: Support broader market shaping

Recommendations	Details / examples
12. Support the development of pooled procurement efforts	• Data generation could be the first step in supporting pooled procurement and long-term agreements for lower pricings • Support and actively engage in procurement across health areas including TB (e.g., APPM, TDF, UNICEF, Global Fund) • Develop technical assistance modules to support governments in integration of treatment for asthma and COPD across other disease areas including TB and in primary care clinics • Look for inspiration from other experiences such as Africa CDC, African Pooled Procurement Mechanism (APPM), TB Drug Facility

Note: While limited diagnosis was identified as a major challenge, the focus of this report was access to inhaled medicines, so no specific recommendations about diagnosis were included.

Recommendations rated on potential impact along likely timelines (indicative)

	SHORT TERM (within 3 years)	MID TERM (3+ years)
HIGH IMPACT	1. Keep the spotlight on WHA and UN political resolutions and declarations to bring greater attention and resources to problem. 4. Provide technical assistance to support countries to align their guidelines to the latest versions. 5. Holistic country implementation work in selected LMICs to prove the case that demand exists and can be served. 9. Negotiate with pharma companies more affordable prices in LMICs.	3. Support formation and engagement of patient advocacy groups 12. Support the development of pooled procurement efforts
MID IMPACT	2. Drive greater attention to field by strategically piggybacking on topics that already have traction 6. Provide opportunistic support by piggybacking on other adjacent efforts	7. Increase in-country competition by supporting firms esp. generics with WHO's CRP procedure to register in more LMICs 8. Support LMIC NRAs with capacity building for inhaled medicines 10. Develop knowledge products to help better articulate challenge, potentially in collaboration with the WHO 11. Support innovators that try to improve current medications

Full report

The full report, inclusive of additional considerations and supporting sources, is available on the Union website: https://theunion.org/technical-publications/enhancing-access-to-inhaled-medicines-lessons-from-insulin-access.