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Promotion and protection of human rights: human rights questions, including alternative approaches for improving the effective enjoyment of human rights and fundamental freedoms

# Elimination of discrimination against persons affected by leprosy (Hansen's disease) and their family members

# Note by the Secretary-General

The Secretary-General has the honour to transmit to the General Assembly the report of the Special Rapporteur on the elimination of discrimination against persons affected by leprosy (Hansen's disease) and their family members, Beatriz Miranda-Galarza, in accordance with Human Rights Council resolution 53/8.

\* A/80/150.





# Report of the Special Rapporteur on the elimination of discrimination against persons affected by leprosy (Hansen's disease) and their family members

Access delayed, rights denied: bottlenecks in the leprosy drug supply chain and their daily impact on affected persons

# Summary

In the present report, the Special Rapporteur on the elimination of discrimination against persons affected by leprosy (Hansen's disease) and their family members, Beatriz Miranda-Galarza, examines challenges in accessing medicines and treatment as a key human rights issue. She highlights how failures in the drug supply chain affect individuals, families and communities, identifying bottlenecks based on input from States, grass-roots groups and experts. She calls for inclusive, rights-based health systems, meaningful engagement with affected communities and continued support for the mandate until the rights and contributions of persons affected by leprosy are fully recognized.

# I. Introduction

- 1. The present report is submitted in accordance with Human Rights Council resolution 53/8, in which the Council renewed the mandate of the Special Rapporteur on the elimination of discrimination against persons affected by leprosy (Hansen's disease) and their family members, Beatriz Miranda-Galarza. In the report, the Special Rapporteur explores how delays in the distribution of leprosy medicines have an impact on the physical, mental, social and economic well-being of those affected. She outlines the various underlying causes of these delays and highlights the strategies developed by affected individuals and organizations to overcome them. Through personal testimonies, she illustrates the urgent need to approach access to treatment and medicines as a human rights issue.
- 2. The discussion about access to medicines as a right has been addressed at various moments by the United Nations. In September 2016, the Secretary-General established a high-level panel to discuss and propose solutions for addressing the gaps between the right to health, the technological and scientific progress made in the field of health, and the unjust and inequitable circumstances in which most of the population in the world lives.
- 3. In July 2019, the Human Rights Council, in resolution 41/10 on access to medicines and vaccines, affirmed that availability, accessibility, acceptability and affordability are essential to the right to the highest attainable standard of physical and mental health. Based on the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights and other core international treaties, the resolution stresses the responsibility of States to ensure access for all, without discrimination, to medicines and vaccines, in particular essential medicines, that are affordable, safe, effective and of quality.
- 4. In 1981, the World Health Organization (WHO) recommended multidrug therapy a combination of dapsone, rifampicin and clofazimine as the standard cure for leprosy. Despite its effectiveness, access remains unequal, especially in remote or conflict-affected areas. Recent challenges include supply chain delays, logistical bottlenecks and reliance on a single manufacturer of multidrug therapy blister packs. While efforts are under way to develop new drugs and improve distribution, multidrug therapy remains the cornerstone of treatment. Leprosy reactions (type 1 and type 2) are major causes of nerve damage and disability, often requiring long-term corticosteroids or immunosuppressive drugs with significant side effects. Access to these treatments is limited by cost, supply issues and a lack of trained health workers, leading to delays and poorer outcomes.
- 5. In early 2024, organizations in Nigeria reported a year-long shortage of WHO-provided multidrug therapy due to new domestic testing rules and bureaucratic delays, affecting around 3,000 patients, including 800 children. A shipment from India arrived in March 2025, allowing treatment to resume, but challenges in reaching patients in remote areas persist, leading to growing concerns about the impact on affected individuals, their families and communities.
- 6. Persons affected by leprosy in various countries, particularly those experiencing conflict, political instability or the effects of climate change, have also expressed concern about recurring delays in access to medication. While none have reported delays as prolonged as those in Nigeria, their testimonies reveal significant challenges within national supply systems. In many cases, medicines are available at the national level but fail to reach marginalized or hard-to-reach areas due to distribution bottlenecks and weak internal logistics.

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- 7. The consequences of delays can be irreversible and sometimes fatal, not only for persons affected by leprosy but also for families, communities and States. Individuals may suffer from health deterioration, disabilities and economic hardship. At the State level, consequences include public health setbacks as the patient stops transmitting the disease upon initiation of treatment, increased costs, human rights violations and growing demands for accountability and reform.
- 8. In the present report, the Special Rapporteur urges Member States and international and local actors to recognize access to leprosy drugs as a human rights issue requiring shared responsibility. Violations of this right must lead to accountability and redress for affected individuals.
- 9. The Special Rapporteur offers recommendations to States and international actors to develop leprosy-inclusive policies, partnerships and initiatives to improve access to medicines. These actions should support the broader goal of eliminating leprosy, backed by an efficient, rights-based drug distribution system.
- 10. In preparing the report, the Special Rapporteur analysed responses from Member States and interviews with experts and stakeholders, including international organizations, pharmaceutical companies, human rights institutions, civil society and grass-roots representatives. Due to a lack of funding, it was not possible to hold an expert consultation, which would have enriched the report.
- 11. As the renewal of the mandate approaches, the Special Rapporteur emphasizes the importance of its independence and continuity. The rights of persons affected by leprosy remain at risk, and the mandate provides their only platform within the United Nations system. The Special Rapporteur urges Member States to uphold the mandate in recognition of the centuries of neglect and exclusion that persons affected by leprosy have endured. Their rights remain at risk, as evidenced by this and previous reports.
- 12. In this context, the Special Rapporteur welcomes discussions on country visits, as they offer opportunities to better understand the situation of affected persons and the progress made by States in protecting their rights.

# II. From chaulmoogra oil to multidrug therapy and post-exposure prophylaxis with a single dose of rifampicin: a road towards cure and rights

- 13. The introduction of multidrug therapy marked a major turning point in leprosy treatment. Before its development, treatments were largely based on traditional or spiritual beliefs, ranging from herbal remedies such as chaulmoogra oil and bloodletting to pilgrimages. Many individuals treated may not have had leprosy at all, due to frequent confusion with other conditions such as psoriasis or syphilis. <sup>1</sup>
- 14. The first breakthrough in leprosy treatment came with Alice Ball's method to make chaulmoogra oil injectable,<sup>2</sup> and in the 1940s sulfone antibiotics such as promin and dapsone were introduced. However, decades of monotherapy led to widespread resistance. In the 1960s and 1970s, new drugs such as rifampicin and clofazimine were tested, and by 1982 WHO had officially recommended multidrug therapy, a combination of these three drugs, to prevent resistance and improve cure rates.

<sup>1</sup> Hubert Sansarricq, "Multidrug therapy against leprosy: development and implementation over the past 25 years" (World Health Organization (WHO), 2004).

<sup>&</sup>lt;sup>2</sup> Suji Udayakumar, "Alice Augusta Ball: the unrecognized chemist behind a breakthrough leprosy treatment", 29 February 2024. Available at https://epic.utoronto.ca/alice-augusta-ball-the-unrecognized-chemist-behind-a-breakthrough-leprosy-treatment.

Although various multidrug regimens had been in use before, their inconsistency highlighted the need for standardized global protocols.

- 15. The roll-out of multidrug therapy was supported by WHO and key partners such as the International Federation of Anti-Leprosy Associations, the Nippon Foundation and Novartis, which has donated over 70 million multidrug therapy blister packs since 2000, contributing, together with other factors, to a 95 per cent reduction in global leprosy prevalence.<sup>3</sup> By the early 2000s, more than 12 million people had been cured.<sup>4</sup> WHO defined leprosy elimination as a public health problem, with fewer than 1 case per 10,000 people,<sup>5</sup> and promoted colour-coded multidrug therapy blister packs, available free of charge, for standardized treatment. These must always be used in combination to avoid drug resistance.
- 16. Isolated resistance to dapsone and rifampicin has been reported, especially in patients receiving irregular treatment. Rifampicin resistance is a major concern due to its key bactericidal role, with cases reported in Bangladesh, Brazil, India, Indonesia and Myanmar. No significant resistance to clofazimine has emerged, though it is less bactericidal and not routinely tested.
- 17. A major advance came with the Contact Transmission and Chemoprophylaxis in Leprosy (COLEP) study in Bangladesh (2003–2012), which showed that a single dose of rifampicin reduced the risk of leprosy by 57 per cent in contacts. The Leprosy Post-exposure Prophylaxis (LPEP) study (2015–2019) confirmed the safety and feasibility of post-exposure prophylaxis with a single dose of rifampicin in several countries. Based on these findings, WHO endorsed such treatment in 2018 and included it in its 2021–2030 strategy. Countries such as India, Indonesia, Nepal and Nigeria have since integrated it into their leprosy control programmes, often with support from the International Federation of Anti-Leprosy Associations and the Global Partnership for Zero Leprosy.
- 18. Concerns remain about stigma, rifampicin resistance in tuberculosis-endemic areas, limited effectiveness of post-exposure prophylaxis for household contacts of multibacillary cases and ethical issues surrounding mass prophylaxis potentially diverting focus from early diagnosis, multidrug access and community empowerment. 7 Some studies, however, show that the implementation of post-exposure prophylaxis has strengthened leprosy control by boosting screening, training and awareness, as seen in LPEP, READY4PEP, PEP4LEP and blanket campaigns in Indonesia. 8

Novartis, "Novartis renews WHO medicine donation pledge with aim of ending leprosy", 29 January 2021. Available at www.novartis.com/news/media-releases/novartis-renews-who-medicine-donation-pledge-aim-ending-leprosy.

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<sup>&</sup>lt;sup>4</sup> WHO, leprosy fact sheet. Available at www.who.int/news-room/fact-sheets/detail/leprosy.

<sup>&</sup>lt;sup>5</sup> The term "elimination" has often been confused with "eradication", leading to misunderstanding. Under the WHO 2021–2030 strategy, it now means "interruption of transmission" (no new local cases). However, the outdated definition still misleads many, contributing to a reduction in funding, political attention, health worker training and care for those affected.

<sup>&</sup>lt;sup>6</sup> Jan Hendrik Richardus and others, "Leprosy post-exposure prophylaxis with single-dose rifampicin (LPEP): an international feasibility programme", *The Lancet Global Health*, vol. 9, No. 1 (2021), pp. e81–e90. Available at www.thelancet.com/journals/langlo/article/PIIS2214-109X(20)30396-X/fulltext.

David G. Addiss, "Evidence, opportunity, ethics, and the allure of zero leprosy", *Leprosy Review*, vol. 89, No. 2 (2018), pp. 90–101.

<sup>&</sup>lt;sup>8</sup> Fleur ter Ellen and others, "Implementation approaches for leprosy prevention with single-dose rifampicin: a support tool for decision making", *PLoS Neglected Tropical Diseases*, vol. 16, No. 10, p. e0010792. Available at https://doi.org/10.1371/journal.pntd.0010792.

- 19. The Special Rapporteur notes that rising drug resistance is a serious concern, especially with disrupted supplies of multidrug therapy and poor adherence. Ethical issues also persist from the historical testing of leprosy drugs, such as sulfone trials in the 1940s, often conducted on institutionalized patients with limited autonomy and without proper informed consent, particularly in Africa, Asia and Latin America.
- 20. Until very recently, persons affected by leprosy were rarely included in the design or decision-making processes related to clinical trials or treatment strategies. Similar concerns have been raised about the use of post-exposure prophylaxis with a single dose of rifampicin, particularly when it is offered to healthy contacts, including children. Questions persist about the level of informed consent, the potential for misunderstanding and the risk of exposing families to discrimination or even social exclusion.
- 21. Leprosy research holds a dual legacy. It has led to major scientific advances, including effective treatments and the hope for shorter, stronger regimens using antibiotics developed for tuberculosis, which have fewer side effects. However, it is also marked by human rights violations, such as drug testing on affected persons, often without consent or proper information, particularly in institutional settings in the past.
- 22. The Special Rapporteur also emphasizes the need to frame the leprosy drug supply chain as a process that extends beyond mere access to medicines and medical treatment. The full complexity of what "access to medicines" entails is often overlooked in the design, implementation and evaluation of programmes and projects, limiting their effectiveness and their alignment with human rights principles.

# III. Framing access to leprosy drugs within a human rights approach

- 23. The Special Rapporteur calls for recognition of access to medicines and treatment as a fundamental human right also embedded in the practice of care and support (see A/HRC/56/59). This perspective shifts the discourse from one of charity or goodwill to one of legal entitlement. Persons affected by leprosy have both a legal and an ethical right to timely and adequate treatment. A human rights-based approach links access to medicines with broader State obligations to eliminate discrimination, marginalization and health inequities. It promotes sustainable and long-term commitments, including domestic resource allocation, integration into national health plans and prioritization in procurement systems, moving away from emergency responses or donor-dependent models.
- 24. This human rights-based approach is consistent with global health standards. WHO includes multidrug therapy for leprosy on its Model List of Essential Medicines for adults and children, recognizing it as a priority treatment based on public health relevance, safety, efficacy and cost-effectiveness. The Model List, updated every two years, guides national procurement and prioritization of essential drugs.
- 25. Access to essential medicines, according to WHO, requires continuous availability, affordability, appropriate dosage, quality assurance and rational use, principles that align with the framework of availability, accessibility, acceptability and quality endorsed by United Nations human rights bodies to ensure accountability under the right to health.
- 26. International frameworks, including International Labour Organization Convention No. 169, also stress the importance of culturally appropriate care,

recognizing traditional and Indigenous medical practices as part of comprehensive, inclusive health systems.

# A. International legal obligations

- 27. States must guarantee access to leprosy medicines in line with international health and human rights standards. The Alma-Ata Declaration and the Declaration of Lisbon on the Rights of the Patient affirm health as a fundamental right and emphasize State responsibility, especially for marginalized populations.
- 28. General comment No. 14 on the Committee on Economic, Social and Cultural Rights requires States to apply the availability, accessibility, acceptability and quality framework to essential medicines and fulfil core obligations, such as access to treatment, immediately, regardless of resource constraints. International cooperation is also recognized as essential to realizing the right to health.
- 29. National laws must align with global human rights instruments. Article 25 of the Universal Declaration of Human Rights affirms the right to medical care, making delays in leprosy treatment a violation requiring accountability.
- 30. The Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health further reinforces access to medicines as a human right, offering legal tools for States to challenge patent barriers and ensure affordability in the public interest.
- 31. At the regional level, the European Social Charter, the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (Protocol of San Salvador) and the additional protocol to the African Charter on Human and Peoples' Rights (Banjul Charter) all address health rights. Regional treaties also address related issues, such as violence against women, which is perhaps the representative example of social structures and relations steering health impacts.<sup>9</sup>

## B. Intersectional and group-specific obligations

- 32. Since delays in leprosy medicine supply disproportionately affect marginalized populations, particularly those who develop disabilities, access must be reinforced through binding frameworks such as the Convention on the Rights of Persons with Disabilities, which obligates States to ensure equality, healthcare and dignified living conditions for persons with disabilities, including those affected by leprosy.
- 33. Past reports have highlighted the gendered and generational impacts of access failures. The Convention on the Elimination of All Forms of Discrimination against Women and the Convention on the Rights of the Child affirm the right to health for women and children, requiring States to address the specific needs of these groups. The lack of paediatric or adapted formulations violates principles of non-discrimination and the right to age-appropriate care.

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Organization of American States, Inter-American Convention on the Prevention, Punishment and Eradication of Violence against Women (Convention of Belem do Para), 9 June 1994; and Council of Europe, Council of Europe Convention on Preventing and Combating Violence against Women and Domestic Violence (Istanbul Convention), November 2014.

# C. Global frameworks and specific guidelines

- 34. The Sustainable Development Goals, particularly Goals 3 and 10, promote health and equality for all. However, the exclusion of leprosy from universal health coverage undermines these Goals, reinforcing discrimination and inequality instead of addressing them.
- 35. The principles and guidelines for the elimination of discrimination against persons affected by leprosy and their family members affirm the right to health (principle 9) and participation in decision-making (principle 10). They call on States and international actors to remove structural barriers and ensure the inclusion of affected communities in shaping policies that have an impact on their lives.

# D. Access to medicines in international and domestic jurisprudence: making Governments accountable

- 36. Courts in many countries have interpreted access to medicines as an enforceable human right, often grounded in constitutional provisions on health, life or dignity. In India, the Supreme Court has ruled that the right to life (art. 21 of the Constitution) includes access to health services and medicines. Similarly, in *Paschim Banga Khet Mazdoor Samity v. State of West Bengal* (1996), the Court held that the Government must provide adequate medical services, including essential drugs. Indian courts have also upheld the use of compulsory licences to make medicines more affordable, especially for life-saving treatments.<sup>10</sup>
- 37. In South Africa, in *Minister of Health v. Treatment Action Campaign* (2002), the Constitutional Court ordered the Government to provide the antiretroviral drug nevirapine to prevent mother-to-child HIV transmission, affirming that the right to health includes access to medicines.<sup>11</sup>
- 38. The Constitutional Court of Colombia has recognized access to essential medicines as part of the right to health and life and regularly issues *tutelas* <sup>12</sup> (legal protection orders) compelling the Government to provide medicines to individuals in need. <sup>13</sup>
- 39. In Brazil, the courts have frequently ruled in favour of individuals seeking access to high-cost or unavailable medicines, considering it part of the constitutional right to health and dignity (arts. 6 and 196 of the Constitution). 14
- 40. However, experts recommend being cautious about examining whether a legal right to access medicines reinforces inequities in health systems by allowing wealthier persons to access expensive medicines, for instance, or whether the health system can universalize such access for all.<sup>15</sup>

<sup>&</sup>lt;sup>10</sup> Paschim Banga Khet Mazdoor Samity v. State of West Bengal, (1996) 4 SCC 37; Novartis AG v. Union of India & Others (2013), Civil Appeal No. 2706-2716; and Natco Pharma Ltd. v. Bayer Corporation (2011), CL No. 1.

<sup>&</sup>lt;sup>11</sup> Minister of Health v. Treatment Action Campaign, (2002) ZACC 15; 2002 (5) SA 721 (CC).

<sup>&</sup>lt;sup>12</sup> Rodrigo Uprimny and Laura Durán, "La tutela y el derecho a la salud: impacto y tensiones", *DeJusticia* (2007).

<sup>&</sup>lt;sup>13</sup> Constitutional Court of Colombia (2008), T-760/2008 (sentence T-760).

<sup>&</sup>lt;sup>14</sup> João Biehl and Adriana Petryna, When People Come First: Critical Studies in Global Health (Princeton University Press, 2013).

Alicia Ely Yamin, "Access to medicines and the right to health: a brief introduction for students and advocates", *Journal du droit de la santé et de l'assurance-maladie*, vol. 35, No. 5 (2022), pp. 10–14. Available at https://doi.org/10.3917/jdsam.225.0010.

# IV. Overview of the leprosy drug supply chain and the bottlenecks at every stage<sup>16</sup>

- 41. Before multidrug therapy reaches patients, it undergoes a multi-stage and complex process involving various social and political actors and systems. Each stage follows its own procedures and logic, yet the entire process and most obstacles remain largely unknown to most persons affected by the disease and even to the actors involved at the local level (health workers, care providers and local health authorities). When asked how he perceived the leprosy drug supply chain, a gentleman from India offered a powerful analogy: "Thinking about treatment reaching our hands is like believing in God. We can't see him, but at some point, we know we will meet him. It's the same with treatment, we don't see the process it follows, we don't even know how it's made, how it gets to us, or who are involved in the production, but we try to believe it will arrive eventually". <sup>17</sup>
- 42. As multidrug therapy is an essential medicine not commercially available like other drugs, it is crucial for national and local authorities, as well as persons affected by leprosy, to understand the stages of its supply chain and the barriers involved. This awareness is key to better understanding the reasons behind supply delays and to effectively demanding accountability and identifying responsible actors.

# A. Manufacturing and production

- 43. Each drug in multidrug therapy contains active pharmaceutical ingredients, now outsourced by Novartis to manufacturers in China and India. The ingredients are formulated into blister packs for adults and children and for both paucibacillary and multibacillary cases. Recently, packs have become standardized, differing only in treatment duration (6 or 12 months), which would simplify supply and distribution.
- 44. Multidrug therapy must meet WHO pre-qualification and comply with good manufacturing practices. However, some countries add national import requirements such as product registration (e.g. the National Agency for Food and Drugs Administration and Control of Nigeria, or the Central Drugs Standard Control Organization of India), import licences and stability testing. Producers pre-qualified by WHO include Sandoz, Lupin and Olon, while clofazimine is mainly produced in India by Novartis and Sangrose, though in limited quantities.
- 45. Good manufacturing practice standards cover training, hygiene, equipment, documentation, quality control and traceability. WHO pre-qualification involves dossier reviews, good manufacturing practice inspections and independent quality testing, as well as assessments of active pharmaceutical ingredient consistency, impurity profiles and synthesis methods. WHO also promotes good distribution practices to ensure safe storage and transport.
- 46. Import requirements from some countries may include local language labelling, temperature trackers, batch numbers and specific packaging standards such as child-proof containers or colour-coding. Countries may also require batch testing, quality certificates, pre-shipment inspections and extensive documentation such as a certificate of pharmaceutical product, certificate of analysis, certificate of origin,

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<sup>&</sup>lt;sup>16</sup> For each of the stages described in the present section, the bottlenecks reported are based on group interviews with persons affected by leprosy from different countries between January and April 2025, and information from the field is based on responses submitted by 20 countries to a call for inputs made by the Special Rapporteur (see www.ohchr.org/en/calls-for-input/2025/call-inputs-thematic-report-80th-session-general-assembly-2025).

<sup>&</sup>lt;sup>17</sup> Person interviewed from India, January 2025.

invoices and legalized papers. Some also demand ethical clearance for new formulations, emergency permissions or coordination with local partners, especially in decentralized systems.

#### 1. Bottlenecks reported

#### Single-source dependency

47. Since the 1980s, Novartis has been the sole global supplier of multidrug therapy packs, which are provided by donation and not sold commercially. This eliminates market incentives for other manufacturers, especially as leprosy primarily affects low-income, marginalized populations and demand remains low and unpredictable. Few companies can meet the technical and regulatory standards for multidrug therapy production, particularly for clofazimine. National leprosy control programmes do not procure multidrug therapy packs independently, and most endemic countries lack the resources to do so. As a neglected tropical disease, leprosy receives little investment in research and development or supply reform, leaving the multidrug therapy supply chain fragile and donor-dependent.

## **Production disruptions**

48. Production disruptions often result from shortages of active pharmaceutical ingredients, especially rifampicin and clofazimine, which are difficult to produce and are sourced from few suppliers. Additional delays arise from factory shutdowns, capacity limits or good manufacturing practice issues, particularly in facilities also producing high-demand drugs such as those for tuberculosis or the coronavirus disease (COVID-19). Increased outsourcing by Novartis to subcontractors in China and India adds further complexity and vulnerability to the supply chain. In addition, changes in contract partners or delays in coordination between active pharmaceutical ingredient and finished product suppliers may occur. Registering loose rifampicin (i.e. tablets that are not part of a multidrug therapy blister pack) for leprosy prevention at the national level can ease import and scale-up but often faces bureaucratic delays.

#### Limited paediatric formulations

49. Child-friendly multidrug therapy is often unavailable or inconsistently supplied due to low global demand, which makes production less attractive for manufacturers. The small market size, combined with the technical challenges of producing age-appropriate doses, leads to irregular manufacturing schedules. In addition, limited funding and a lack of prioritization for paediatric leprosy treatment in procurement plans further contribute to inconsistent availability.

#### 2. From the field

- 50. Some countries have reported that multidrug therapy blister packs have been rejected or delayed because labelling did not match local language requirements or lacked specific regulatory identifiers. Delays in Congo and the Sudan have occurred when local laboratories lacked the capacity to test drug batches or when shipment documents were incomplete or not compliant with import standards.
- 51. In 2023–2024, delays in drug shipments to Nigeria and Togo stemmed from manufacturer-side issues, including production and export complications.
- 52. Ironically, in some cases free donations face more scrutiny than commercial imports. Some countries have delayed clearance due to the lack of customs value declarations or suspicion of unregistered products. This could be because some customs authorities fail to classify multidrug therapy as an essential medicine for neglected tropical diseases and label it as a general pharmaceutical product, or due to

problems with the application of import duties or taxes. Similarly, countries have faced difficulties due to holding shipments under non-priority clearance procedures.

- 53. Indonesia reports that it has faced issues with small batches and non-blister drug availability, reflecting inconsistencies in production formats.
- 54. Countries have reported that product registration with national regulatory authorities such as the National Agency for Food and Drugs Administration and Control of Nigeria or the Central Drugs Standard Control Organization of India can take weeks to months. Batch testing by national laboratories before clearance can result in long delays, especially in countries with limited laboratory capacity. The legalization of documents such as invoices and certificates of origin may lead to short to moderate delays, depending on embassy or consulate processing times. Customs coding issues, such as misclassifying multidrug therapy medicines, can cause long delays in release and clearance. Ethical or political clearances, particularly for paediatric multidrug therapy or emergency use, can introduce additional delays, often undefined but potentially significant.

# B. Forecasting and procurement planning

- 55. Forecasting and procurement planning for multidrug therapy is a centralized, donation-based process led by WHO and dependent on timely, accurate inputs from national health authorities. Countries estimate their needs 12–24 months in advance based on case projections or previous years' data, treatment plans, stock levels and outreach activities, though weak surveillance often leads to overestimation or underestimation. Emergency requests can be made, but it could take months before new multidrug therapy packs arrive at the health centre.
- 56. National leprosy control programmes submit annual forecasts and requisition forms to WHO, detailing quantities, formulations and stock status. These are reviewed with ministries of health and donors using standardized tools. Once validated, WHO consolidates global requests and coordinates with Novartis to initiate production, which can take 6–12 months, especially for paediatric multidrug therapy and rifampicin.

#### 1. Bottlenecks reported

#### Weak surveillance systems

57. Outdated or inaccurate case detection data also suggest that countries' planning systems may lack real-time stock monitoring tools or have weak coordination between national and subnational levels and inadequate digital systems for inventory control. Furthermore, passive surveillance, limited laboratory confirmation and underreporting, especially in remote or conflict-affected areas, result in unreliable data that form the basis for forecasting. This can distort national estimates and affect global planning, often leading to reactive rather than proactive supply management.

#### **Poor forecasting**

58. Poor forecasting leads to overstocking, understocking or misaligned shipment schedules. When countries overestimate their needs, drugs may expire in storage due to low turnover or limited shelf life. Conversely, underestimation creates shortages that disrupt treatment continuity and increase the risk of disability or relapse. Poorly aligned shipment schedules caused by unrealistic assumptions or late submissions can also delay deliveries, especially when customs clearance or in-country logistics are weak.

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#### Limited country capacity

59. Staff turnover and a lack of training reduce understanding of WHO ordering mechanisms. Some health staff lack familiarity with WHO ordering tools and procedures, which can be complex and not always suited to local literacy levels or digital access. WHO has received feedback that its forecasting tools and guidelines require simplification or adaptation to varying levels of education and experience among programme staff, particularly in countries where leprosy programmes are underfunded or integrated into broader health systems with limited support.

#### Long lead times

60. The duration of four-to-six months required for international drug orders is often underestimated. This includes manufacturing time (especially for paediatric multidrug therapy and rifampicin), quality assurance, international shipping and customs clearance. When countries delay submitting their requests or fail to account for this lead time in planning, medicines may arrive late, causing treatment interruptions or stockouts.

#### 2. From the field

- 61. Countries engaged in active case-finding often underestimate drug needs or fail to update data, resulting in delayed or inadequate shipments. For instance, Nigeria cited poor forecasting and reporting gaps as a reason for a long delay. This has also been reported by Mozambique and Myanmar, where poor forecasting led to undersupply or oversupply.
- 62. Despite having relatively strong health infrastructure and being high-burden countries, Brazil and India reported gaps in their stock data, such as missing information on current stock balances at the national or regional levels, stock expiration dates or incomplete distribution tracking from central to local health units.
- 63. No countries other than Brazil reported the routine use of robust forecasting tools or real-time inventory management.
- 64. Customs and import planning were flagged in Ecuador or Indonesia, where shipment in small batches complicated forecasts.

# C. Donor coordination and international procurement

65. Once countries submit their validated forecasts, WHO consolidates global needs and coordinates with Novartis to plan production, prioritize supply and align delivery schedules. Acting as the intermediary, WHO also manages logistics, oversees shipments, addresses delays or emergency requests and ensures quality control. It regularly reports to Novartis on stock levels, country feedback and overall system performance.

# 1. Bottlenecks reported

#### **Burdensome procedures**

66. Ordering multidrug therapy involves multiple layers of documentation, coordination and approval. The need for multiple legal and regulatory documents often delays shipments, especially in countries with strict import rules or inefficient customs systems.

#### Slow communication

67. Delays in official letters or request forms can postpone shipping. In some cases, missing signatures, slow internal clearances or a lack of digital communication systems cause avoidable hold-ups in initiating production, shipping or entering countries.

# Lack of contingency plans

68. No back-up procurement options exist due to exclusive reliance on donations. There is limited or no emergency buffer stock at the global level, making it difficult to respond quickly to urgent or unexpected needs.

# No legal obligation

69. Multidrug therapy donation is voluntary, with no binding international agreement ensuring continuous supply. Since the system is donation-based and centrally managed, countries have little control over timelines and must fully depend on coordination between WHO and Novartis.

#### Insufficient country follow-up capacity

70. Many countries lack dedicated staff to track shipment progress or respond to documentation issues, which can lead to delays in customs clearance and last-mile delivery.

#### 2. From the field

- 71. During the COVID-19 pandemic, international disruptions halted the delivery of multidrug therapy. Many countries had no stockpiles or emergency plans to maintain treatment access.
- 72. No emergency procurement buffers were in place outside Brazil, exposing countries to severe disruption risks. The Democratic Republic of the Congo, India and Indonesia, among other countries, reported having no contingency plans and limited stock monitoring systems, which are either manual, outdated or non-existent. This weakens the ability to detect shortages early or to respond quickly.
- 73. All countries reported requiring external support to deal with supply chain management, showing frail domestic control and structural weaknesses in health governance, particularly in integrating leprosy treatment into broader national health systems. Delays due to documentation and customs clearance were highlighted in Ecuador, Indonesia and Mozambique.
- 74. The Democratic Republic of the Congo, Ethiopia and the Niger, among other countries, lack sufficient legal frameworks to streamline donor-supported procurement, which also weakens accountability.

#### D. International shipping and customs clearance

75. Once production is complete, WHO prepares the shipment by gathering the required documentation, including the invoice, packing list, certificate of analysis, certificate of pharmaceutical product, customs codes and authorization letters, if required. Medicines are dispatched from Novartis warehouses to the receiving country, usually by air freight, coordinated by WHO logistics partners. National customs authorities and WHO logistics teams are the main actors.

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76. Upon arrival at the destination airport or port, the national health authority or designated agent clears the shipment through customs. Customs officials review the documents for compliance with local regulations, including product registration, labelling and documentation authenticity. Delays occur if documents are missing or incorrect or if special permissions such as political or ethical clearance are required. Once cleared, the shipment is transported to the national warehouse or central medical store, where it is logged, stored and prepared for national distribution.

#### 1. Bottlenecks reported

#### Customs delays

77. Multidrug therapy shipments are often misclassified as general or non-essential goods, delaying clearance, as essential medicines usually qualify for fast-track processing. In some cases, customs officials are unaware of leprosy-specific drugs or the WHO donation programme, leading to low prioritization or extra inspections. Some countries report weak coordination or decentralized customs systems, as well as unofficial payments being required or additional charges applied for the warehouse when medication is kept at customs.

#### Regulatory bottlenecks

78. It is reported that some countries impose additional regulatory hurdles such as pre-shipment approval, product registration or local batch testing, even for WHO-approved medicines. These requirements are time-consuming and costly and may not be adapted to donation-based models. In some cases, delays have occurred simply because health authorities are unfamiliar with the necessary documentation.

#### Geopolitical instability

79. Conflict zones or fragile States struggle with inaccessible or unsafe entry points. The Sudan and South Sudan, for example, and parts of the Democratic Republic of the Congo and Ethiopia, as well as airports, seaports or roads, may be inaccessible or unsafe, making it difficult to deliver multidrug therapy packs. Even when shipments arrive in-country, ongoing violence, shifting control of territories or collapsed infrastructure can prevent safe and timely transport to treatment centres. Humanitarian exemptions or diplomatic negotiations may be required, but these take time and require coordination.

#### Climate change factors

80. Extreme weather events, such as floods, droughts and cyclones, lead to population displacement, reduced access to healthcare, poor sanitation and undernutrition, all of which heighten vulnerability to diseases and disrupt supply chains. Climate-induced migration as in Australia, Bangladesh, Brazil, Mozambique or India may force movement into overcrowded areas with limited logistics, complicating consistent medicine distribution.

#### High freight costs and rerouting

81. Political or economic disruptions inflate costs and slow delivery. Political unrest, fuel price spikes or trade restrictions often lead to increased freight costs and the rerouting of shipments. For example, a disrupted trade route or the closure of key ports as during the COVID-19 pandemic or the Red Sea crisis have forced WHO and logistics providers to use longer or more expensive routes, delaying deliveries by weeks or even months. Since multidrug therapy is donated, these cost increases can strain limited logistical budgets and may lead to postponed shipments. It has also been reported that,

due to high shipping costs, sometimes exceeding the value of the medicines themselves, multidrug therapy shipments have remained stuck in customs storage.

#### 2. From the field

- 82. In 2022, multidrug therapy shipped to Brazil was held in customs for over a month because it was not properly labelled as an essential medicine.
- 83. Customs delays are a major bottleneck in Indonesia, Mozambique and Nigeria, often caused by misclassification or limited clearance capacity. Brazil and India also report customs and international shipping issues as key disruptions. In Trinidad and Tobago, rifampicin stock remains in customs due to unusually complex import requirements and paperwork, possibly linked to laboratory report demands.
- 84. Somalia relies heavily on mobile outreach (skin camps) due to infrastructure collapse and restricted access, leading to significant challenges in delivering multidrug therapy to affected populations.
- 85. Customs facilitation was specifically requested as an international support need in Ecuador and Indonesia.

# E. National warehousing and internal distribution

- 86. Once multidrug therapy shipments clear customs, they are transferred to national central medical stores or designated warehouses managed by the ministry of health or the national leprosy control programme. This marks the beginning of the incountry supply chain, which includes storage, handling and last-mile delivery to treatment centres. The main actors involved in this stage are ministries of health, national disease control programmes and central medical stores.
- 87. Multidrug therapy is received, logged and stored under controlled conditions to ensure quality and track expiry dates. Proper storage infrastructure is essential, especially in hot or humid climates, where poor facilities can lead to spoilage or degradation. Inventory management systems may be manual, paper-based or semi-digital, depending on the country's resources.
- 88. Effective systems are needed to monitor current stock levels, expiry dates and regional distribution needs. In many countries, tracking is inconsistent, leading to stock imbalances, with overstocking in some areas and shortages in others.
- 89. From the central warehouse, multidrug therapy is distributed to regional and local health centres through public or donor-supported supply chains, either on a regular schedule or based on demand. Health facilities need proper storage and trained staff, but many lack systems for stock tracking, patient monitoring and managing unused or expired medicines.

## 1. Bottlenecks reported

#### Poor infrastructure

90. Many endemic countries reported problems regarding road access, transport mechanisms or adequate storage, including limited or non-functional storage facilities that lack proper shelving, ventilation or temperature control. Rural or remote clinics may be difficult to reach due to poor road conditions, a lack of bridges, seasonal flooding or mountainous terrain. In addition, many health systems lack reliable transport mechanisms, such as dedicated vehicles or fuel budgets, for timely medicine delivery from central to peripheral levels.

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#### Weak logistics systems

91. Most national leprosy programmes operate with very low administrative budgets and without real-time inventory tracking, relying instead on manual or paper-based records that are prone to error or delay. This hampers the visibility of stock levels across regions, making it difficult to detect shortages or redistribute medicines effectively. In some cases, delayed reporting and slow internal communication lead to inefficient resupply or stockouts at the point of care.

#### Centralized stock

92. Multidrug therapy shipments often remain in national warehouses without being delivered to rural clinics due to weak distribution systems or unclear allocation procedures. Without strong last-mile logistics, medicines may fail to reach rural or peripheral clinics, especially those in high-burden areas. As a result, patients in remote communities may be unable to access treatment, even when national stocks are sufficient. This undermines disease control efforts and increases the risk of disability or continued transmission.

#### 2. From the field

- 93. In northern India, multidrug therapy shipments were available in district warehouses, but remote clinics reported stockouts due to a lack of transport and poor coordination. Last-mile delivery is a recurrent gap despite decentralized planning. Losses and expiry due to poor warehousing were reported in Myanmar and Nigeria.
- 94. The Democratic Republic of the Congo, Mozambique and Nigeria reported that drugs remained in central or provincial stores due to a lack of partners in marginal or rural areas as well as weak infrastructure at subnational levels.
- 95. El Salvador and Nepal faced geographic and security-related barriers such as remote terrain and post-disaster road access, which make the distribution of medicines difficult. Some countries report disparities in internal distribution, disproportionately affecting rural, Indigenous and poor communities.
- 96. No real-time digital stock tracking systems are reported except in Brazil; most countries relied on manual or partial methods.

# F. Last-mile delivery and patient access

- 97. Last-mile delivery refers to the final step in the supply chain, transporting multidrug therapy medicines from regional or local warehouses to health facilities, outreach workers and ultimately to persons affected by leprosy. This stage is critical because, even if medicines are available at the national or regional levels, failures directly prevent patients from receiving timely treatment. The main actors in this stage are local clinics, community health workers, grass-roots organizations, international leprosy organizations and persons affected by leprosy.
- 98. Local clinics must be equipped to store and dispense multidrug therapy packs safely, which requires basic infrastructure (dry, secure, ventilated space), trained staff and supply management tools. Many affected persons live in remote, rural or hard-to-reach communities; in some regions community health workers or mobile outreach teams are therefore used to bring multidrug therapy directly to patients. In most cases, these services depend on external funding.
- 99. Regular follow-up is essential to ensure treatment adherence and completion, especially for multibacillary leprosy, which requires a longer treatment course.

#### 1. Bottlenecks reported

#### Lack of transport and staff

100. Clinics in remote areas often lack vehicles, fuel or trained personnel. Poor road infrastructure and a lack of dedicated transport vehicles often delay or block the delivery of multidrug therapy medicines to local clinics, and personnel are not always reliable or consistent. In many cases, staff are not adequately trained in handling leprosy medications, documenting patient progress or managing stock levels. This can lead to mismanagement, expired drugs or interrupted treatment.

# War and conflict disruptions

101. Health workers may flee or be unable to reach rural areas, leading to invisible epidemics. Facilities may be destroyed or underresourced, which result in supply chains often being rerouted or blocked entirely.

#### Climate change and environmental disruption

102. Natural disasters, seasonal weather disruptions and infrastructure collapse due to floods, landslides and droughts can disrupt roads and warehouses, delaying drug shipments and access to care.

# Displacement and loss of continuity of care

103. Climate, violence or economic-induced migration may sever access to regular health services, especially for nomadic, fishing or rural farming communities. The lack of patient tracking systems makes it difficult to continue treatment for people who are displaced.

#### **Neglect and discrimination**

104. Leprosy is deprioritized in some areas, limiting follow-up care and adherence. Persons affected by leprosy may avoid seeking treatment due to stigma, fear or misinformation, particularly in areas where community awareness is low.

#### No decentralized care model

105. Multidrug therapy is not consistently available at the primary healthcare level. However, many health systems lack the human resources or information systems needed to track patient outcomes, provide reminders or manage side effects, resulting in treatment dropouts and an increased risk of resistance or relapse.

#### Poor communication

106. Affected communities are often uninformed about delays or alternatives. Language barriers, cultural beliefs and past negative experiences with healthcare services can further discourage patients from accessing available treatment.

#### Barriers for groups in vulnerable situations

107. Women, children, older persons and persons with disabilities often face additional access barriers, such as the absence of paediatric multidrug therapy, limited mobility or gender-based discrimination, that further hinder treatment access. A similar situation is faced by persons living in remote areas without financial support for transportation or access to health services.

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#### 2. From the field

- 108. Last-mile challenges were reported as being widespread, especially in El Salvador, India, Nepal and the Niger, where distance, security and transport issues prevent consistent supply to clinics.
- 109. In several countries in Africa and South-east Asia, grass-roots groups only learned of stockouts when treatment stopped months after delays had begun. Seasonal flooding in South Asia or tropical cyclones in East Africa have left entire regions cut off, which also affects communication and access to care.
- 110. Most of the countries report that affected persons do not participate in the process of local distribution. The Governments assume that it is due to a high level of stigma and a lack of community health worker integration.
- 111. Countries including the Democratic Republic of the Congo and the Niger report a lack of partners in remote regions, compounding the issue. In addition, Ethiopia and the Niger admitted limited attention to delivery gaps at the patient level.

# V. Impact on the daily life of persons affected by leprosy

# A. Health consequences and disability

- 112. Leprosy affects the peripheral nerves, leading to a loss of sensation in the hands, feet and face. Without timely treatment, repeated unnoticed injuries cause ulcers, infections and deformities such as foot drop, blindness and hand and facial paralysis. Chronic wounds may become hard to heal, and once disability sets in it is often irreversible, even if treatment begins later.
- 113. Leprosy reactions affect 30 to 50 per cent of patients and can cause lasting nerve damage if untreated. Type 1 reactions involve nerve inflammation; type 2 reactions (erythema nodosum leprosum), common in multibacillary cases, cause systemic symptoms and often recur. Treatment requires steroids, thalidomide (restricted in many countries) and advanced immunosuppressants often unavailable in endemic areas. These drugs are poorly prioritized, excluded from essential medicine lists and face regulatory, funding, storage and distribution challenges. Limited data and a lack of trained health workers further hinder effective diagnosis and treatment.
- 114. Women face unique challenges in accessing leprosy medication. Limited autonomy and access to healthcare further hinder adherence, increasing the risk of disability and exclusion. Concerns are raised about pregnancy, breastfeeding and side effects such as skin discolouration, which lead to delayed or interrupted treatment.
- 115. In children, early nerve damage can interfere with growth and development, leading to lifelong impairment. Delays heighten the risk of leprosy reactions (acute immune responses) that can cause rapid deterioration if not managed promptly.
- 116. Older persons may already have comorbidities such as diabetes, arthritis or high blood pressure, making them more vulnerable to the compounded effects of untreated leprosy, such as poor wound healing, limited mobility or increased dependency. They depend more on public services, and the experience of mobility and sensory limitations could make it harder to travel long distances in search of available drugs.

# B. Mental health and emotional impact

117. Delays prolong visible symptoms, deepening shame and self-isolation, particularly in women. Anxiety, depression and suicidal ideation are common among

persons facing uncertainty about treatment or living with worsening disability. For older persons, this may mean abandonment or institutionalization. Patients in Nigeria reported signs of depression and even suicidal thoughts due to uncertainty about the arrival of medicines.

- 118. Women have less access to information, transport and medical decision-making power, which amplifies the harm of supply disruptions. They may be divorced or abandoned by their spouses if symptoms become visible, especially in communities where leprosy is still viewed as a curse or punishment. Disability can also lead to social exclusion, rejection as potential brides and loss of educational and employment opportunities.
- 119. Men also report facing cultural burdens, particularly in conservative societies where they are expected to be providers. Visible symptoms and impairments can lead to job loss, rejection as potential grooms and even abandonment by their wives. These issues often trigger episodes of anxiety and distress, which are rarely discussed openly due to gender-related taboos.
- 120. Families also suffer. Children and siblings of persons affected by leprosy report being discriminated against in social and extended family life. Furthermore, in most of the endemic countries, family members, especially women and children, carry out the role of caregivers. Children may internalize fear or shame if a parent or sibling shows visible symptoms.

#### C. Economic and livelihood effects

- 121. Loss of income from delayed treatment can push entire families into poverty. Persons with disabilities due to untreated leprosy are often excluded from labour markets.
- 122. Women and older caregivers may be forced to reduce economic activity to support affected family members, worsening intergenerational poverty.
- 123. Affected families often face loss of income, especially if the main breadwinner is ill, high out-of-pocket expenses for transport, wound care, assistive devices or private treatment, and interruption of children's education if they are needed at home to help.

# D. Impact in conflict zones and humanitarian crises

- 124. In areas such as Ethiopia and the Sudan, or parts of the Democratic Republic of the Congo, insecurity limits transportation, makes health services inaccessible and obstructs the delivery of multidrug therapy. Individuals also experience deep distress, as they report facing an uncertain future with no clear solutions in sight.
- 125. People in camps or displacement settings often lack access to diagnosis, and treatment starts late or never.

## E. Public, social and health systems-level consequences

- 126. Delays in treatment allow infectious individuals to continue spreading the bacterium, especially in crowded or poor settings. This undermines leprosy control efforts and puts vulnerable groups such as children at greater risk.
- 127. Without timely treatment, leprosy progresses to disability, requiring surgery, assistive devices and long-term care. This increases health system costs and burdens

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- already limited services, especially in low-resource settings. More people require surgery, assistive devices or long-term care, which burdens the system.
- 128. When essential medicines are unavailable, communities lose confidence in public health systems. This reduces care-seeking, fuels misinformation and weakens participation in leprosy programmes and other health services.
- 129. Delays lead to more advanced cases needing surgery, rehabilitation and long-term care, which are far costlier than early treatment with multidrug therapy. States may therefore face greater demand for disability benefits, welfare support and rehabilitation services.
- 130. Disability from untreated leprosy reduces the ability to work, while family members, often women or children, miss work or school to provide care.
- 131. Medicine shortages erode trust in health systems, requiring costly public campaigns to restore confidence and re-engage affected communities.
- 132. Ongoing transmission and disability undermine efforts towards poverty reduction, universal healthcare and Sustainable Development Goal targets.

# VI. Good practices<sup>18</sup>

- 133. Brazil reports the implementation of digital tracking systems and peer networks within a decentralized model, which has improved logistics. In addition, the Movement for the Reintegration of Persons Affected by Hansen's Disease has established an observatory managed by persons affected by leprosy aimed at monitoring patients' access to leprosy medicines across the country.
- 134. India and Indonesia have implemented phone counselling and established agreements with non-governmental organizations to help the authorities to improve logistics. India has also implemented the use of mobile clinics to reach marginal sectors.
- 135. Ecuador reports implementing telementoring for health workers and doctors who live in hard-to-reach areas.
- 136. The Democratic Republic of the Congo reports implementing an *accompagnée* model, albeit with minimal infrastructure, partnering with local organizations, peer networks and health workers to integrate medical treatment with psychosocial support and rehabilitation across endemic districts. Indonesia, meanwhile, has been organizing peer-reviewed stock checks.

# VII. Conclusions and recommendations

- 137. Access to leprosy medicines is a relevant component of the broader and complex process of care. It should therefore be fully integrated into discussions on care and support systems.
- 138. Access to leprosy treatment is a human rights issue. Delays in drug supply violate the right to health and dignity. Access to medicines must be seen as a legal and ethical obligation of States and international actors.
- 139. The drug supply chain is fragile and donor-dependent, creating structural vulnerability, especially in crisis situations.

<sup>18</sup> Responses submitted by 20 countries to a call for inputs made by the Special Rapporteur.

- 140. Bottlenecks exist at every stage, from production and import regulations to national warehousing and last-mile delivery, and delays occur due to weak infrastructure, limited forecasting, poor coordination and rigid bureaucracy.
- 141. Delays have life-altering consequences. Individuals suffer irreversible disability, discrimination and mental health impacts. Families experience economic hardship, social exclusion and disrupted education or caregiving burdens.
- 142. Conflict, climate change and marginalization worsen access. Persons in conflict-affected, climate-vulnerable or remote areas face the greatest barriers, with limited delivery capacity, health worker shortages and inadequate emergency planning.
- 143. Women, children and older persons are disproportionately affected. Gender, age and disability intersect with discrimination, limiting access to treatment, information and support. The absence of paediatric multidrug therapy is a major gap.
- 144. States lack control and preparedness. Most endemic countries depend on coordination by WHO, lack emergency stocks and have a limited ability to forecast, procure or track medicines independently.
- 145. Public trust is eroding. Repeated shortages and poor communication undermine trust in public health systems, leading to reduced care-seeking and weakened disease control efforts.
- 146. Good practices exist but remain fragmented. Initiatives in Brazil, India, Indonesia and Nigeria show promise but require greater support, scale-up and integration.
- 147. The Special Rapporteur's mandate remains essential as it is the only dedicated United Nations mechanism addressing the rights of persons affected by leprosy. Its renewal is critical to continue promoting accountability, visibility and reform.
- 148. Based on these conclusions, the Special Rapporteur makes the following recommendations to Member States, local authorities, international organizations and grass-roots organizations:
  - (a) Ensure predictable and timely supply of leprosy medicines by:
  - (i) Establishing long-term procurement agreements with manufacturers to avoid supply disruptions;
  - (ii) Maintaining emergency buffer stocks at the national and regional levels to absorb temporary shocks;
  - (iii) Supporting the regional production or licensing of essential medicines, including paediatric multidrug therapy;
  - (b) Strengthen forecasting and procurement systems by:
  - (i) Improving data collection and analysis to ensure accurate forecasting based on real-time consumption;
  - (ii) Integrating leprosy medicine forecasting into national essential medicines systems to avoid parallel, siloed processes;
  - (iii) Involving persons affected by leprosy and front-line workers in forecasting and reporting to reflect actual local needs;

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- (iv) Ensuring that WHO provides regular training to national authorities on forecasting tools, ordering procedures and supply chain coordination, using creative and people-centred tools;
- (v) Promoting innovative tools such as www.ntdeliver.com, as well as making information and education materials on the existence and usage of these tools available in the field of leprosy;
- (vi) Learning from and collaborating with other disease programmes (e.g. other neglected tropical diseases, tuberculosis and HIV/AIDS);
- (c) Address regulatory and customs delays by:
- (i) Simplifying and fast-tracking registration, labelling, batch testing and customs procedures for essential leprosy medicines;
- (ii) Building regulatory capacity in countries with weak national regulatory agencies and providing technical support through South-South cooperation;
- (iii) Encouraging regional harmonization of import standards for multidrug therapy and related supplies;
- (d) Improve last-mile delivery and storage by:
- (i) Investing in infrastructure, transport and storage systems, particularly in underserved and remote areas;
- (ii) Training health workers in drug handling, record-keeping and patient tracking to reduce wastage and stockouts;
- (iii) Using digital tools to monitor stock levels in real time and enable rapid redistribution;
- (e) Integrate human rights perspectives by:
- (i) Guaranteeing equitable access to treatment for women, children, older persons and displaced populations;
- (ii) Including mental health support in leprosy services, especially in communities experiencing delays or conflict;
- (iii) Promoting training on the implementation of the principles and guidelines for the elimination of discrimination against persons affected by leprosy and their family members, as well as other key human rights instruments;
- (f) Protect access in conflict and climate-affected settings by:
- (i) Including multidrug therapy in emergency health kits and pre-positioning supplies in high-risk or disaster-prone zones;
- (ii) Supporting mobile clinics, community health workers and crossborder partnerships in fragile contexts;
- (iii) Integrating leprosy services into disaster risk reduction and climate adaptation strategies;
- (g) Strengthen participation and accountability by:
- (i) Involving persons affected by leprosy and their representative organizations in planning, monitoring and evaluating supply chains;
- (ii) Creating community-level complaint and feedback mechanisms to report shortages and raise concerns without fear of reprisal;

- (iii) Promoting transparency and public reporting of procurement processes, budgets and delivery timelines;
- (h) Provide redress and compensation by:
- (i) Ensuring that States develop mechanisms to provide compensation, support or remedial measures for persons affected when treatment is delayed or interrupted due to systemic failures;
- (ii) Ensuring that compensation is guided by principles of reparative justice, particularly for those who develop avoidable disabilities or suffer long-term impacts from drug delays;
- (i) Reduce donor dependency and promote sustainable national ownership by:
  - (i) Encouraging domestic resource allocation for leprosy programmes to reduce reliance on external donors;
  - (ii) Integrating leprosy medicines into national essential drug lists and health insurance schemes where available:
  - (iii) Developing transition plans for countries phasing out donor aid, ensuring continuity of supply through public procurement;
  - (iv) Advocating for shared international responsibility, where donor support complements, not replaces, State obligations;
  - (j) Advocate for sustained global commitment by:
  - (i) Calling on donors, WHO and international partners to maintain strong funding and technical support for multidrug therapy access and logistics;
  - (ii) Including leprosy explicitly in universal health coverage, neglected tropical disease strategies and Sustainable Development Goal 3 frameworks;
  - (iii) Advocating for the renewal and strengthening of the Special Rapporteur's mandate as the only dedicated mechanism to uphold the rights of persons affected by leprosy.

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