Building sustainable pathways to new medicines: The DNDi-GARDP CMC platform as a model for collaborative global health innovation

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Introduction

- Scientific discoveries alone do not deliver medicines to patients. **Chemistry, Manufacturing and Controls (CMC)** transforms promising research into quality-assured products that can be tested, approved, manufactured, and supplied sustainably.
- **CMC** covers the technical activities required to design, develop, manufacture, register & supply quality medicines consistently.
- Global health innovation faces pressure from funding constraints, geopolitical uncertainty, supply chain risks, and changing pharma industry priorities, while demand for new treatments for neglected diseases and drug-resistant infections continues to grow.
- The **DNDi-GARDP CMC Platform** is responding to this challenge by **combining people, expertise and systems** across pharmaceutical development, manufacturing, quality, technology transfer, and regulatory CMC in a shared model that strengthens efficiency, resilience, and impact across diseases and partners.
- The **CMC Platform's capabilities** and **four case studies** are presented below**, showing how new collaborative approaches can connect emerging innovators with critical CMC expertise, and accelerate access to new medicines for underserved populations.**

DNDi-GARDP CMC platform: Integrated product development capabilities



Accelerating access to a new hepatitis C treatment

- Working with pharmaceutical partners in Egypt and Malaysia, the CMC Platform supported the development of ravidasvir, a direct-acting antiviral for hepatitis C.
- The CMC Platform led and coordinated development, Phase 3 IMP supply, manufacturing, and regulatory CMC activities.
- Ravidasvir was launched in Malaysia in 2022 and later included in the WHO Essential Medicines List.

PHARCO PHARMACEUTICALS pharmaniaga®

Bringing a new class of antibiotic to patients

- In partnership with Innoviva Specialty Therapeutics Inc., the CMC Platform played a pivotal role in developing zoliflodacin, a new antibiotic for drug-resistant gonorrhoea.
- The Platform led new formulation development, Phase 3 IMP supply, manufacturing and registration-enabling activities with an Indian partner, delivering regulatory approvals in the USA (December 2025) and Thailand (July 2026).

NUZOLVENCE® (zoliflodacin)

Expanding access through technology transfer

- Following a voluntary licence and technology transfer agreement between Shionogi and GARDP in 2022, the CMC Platform is partnering with CHAI and Orchid Pharma to support manufacture of cefiderocol in India.
- Combining expertise across development, technology transfer, quality, scale-up, and regulatory activities, the project aims to enable sustainable access to this Reserve antibiotic.

OrchidPharma — A Dhanuka Group Company — CLINTON HEALTH ACCESS INITIATIVE

New treatment options through drug repurposing

- Through a partnership with the Helminth Elimination Platform (HELP), the CMC Platform advanced a veterinary drug (oxantel pamoate) as a potential treatment for soil-transmitted helminth infections in humans.
- The CMC Platform developed a child-friendly chewable tablet formulation, manufactured and supplied IMP for clinical trials in Tanzania in 2025.

HELP Helminth Elimination Platform

Conclusions & next steps

- The DNDi-GARDP CMC platform demonstrates how shared technical capabilities can become a strategic resource for the wider global health ecosystem. The case studies show that combining CMC expertise and networks can improve efficiency, reduce duplication, support regional manufacturing, and accelerate impact.
- The next phase is to expand this collaborative model by providing CMC expertise to product development partnerships, academic institutions, public organisations, and non-profit partners addressing unmet global health needs.

LET'S BUILD THE NEXT GENERATION OF GLOBAL HEALTH PRODUCTS TOGETHER!
We welcome conversations with organisations seeking CMC expertise to accelerate product development, manufacturing, and patient access.

DNDi Best Science for the Most Neglected
GARDP Global Antibiotic Research & Development Partnership

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