WHO WE ARE & WHAT WE DO

PHARMACY SERVICES & SUPPLY CHAIN MANAGEMENT
Pharmacy Services & Supply Chain Management

Aurum’s work spans the cascade of health care from innovation to implementation, as illustrated below:

Our Model: Bridging the worlds of research, policy and implementation for impact

A multidisciplinary team of pharmacists, logisticians and related supply chain specialists support projects that require expertise in:

1. Health care pharmacy services and supply chain strengthening
2. Research pharmacy and supply chain services
3. Pharmacy regulatory systems strengthening

Clinical Research
Testing the safety and efficacy of new medical products:
- TB / LTBI treatment, vaccines, diagnostics
- HIV vaccines, PrEP, treatment, diagnostics
- COVID vaccines

Implementation & Translational Research
Designing, testing and bringing to market new health interventions that inform national and international policy and practice in TB, HIV and other diseases

Health Systems Strengthening
Specialities include:
- Health information
- Quality Improvement
- Human Resources for Health: Training & development

Health Service Delivery
- COVID testing
- HIV testing
- TB & STI screening
- Medical male circumcision
- Key Population services
- ART initiation and adherence support
A. Our Technical Expertise

1. Health Care Pharmacy Services & Supply Chain Strengthening

Aurum specialises in strengthening pharmacy operations and information systems in health care facilities, community service providers and retailers; and ensuring compliance with regulated pharmacy practices. Health services in low and middle-income countries often have limited pharmacy capacity, relying on professional nurses to manage drug supplies in smaller facilities. With little training or time to grasp complex stock management practices this can be a major cause of critical stock outs.

Aurum also has extensive experience and resources to support and strengthen the last mile of supply chain systems, even directly to the patient using novel delivery methods.

The primary objective of this programme therefore, is to ensure a reliable and effective supply of essential medicines. This is achieved mainly through technical assistance, which aims to capacitate a range of role players in pharmacy services as will be described below.

Where ‘hands on’, direct service delivery support is critical (and funding allows), Aurum does have the capacity to deploy Pharmacists’ Assistants to do stock management, and to escalate and assist in managing urgent stock-outs.

1.1. Regional & Facility-level Pharmacy Operations and Supply Chain Strengthening

PROGRAMME 1: Good Pharmacy Practice (GPP) & Good Warehouse Practice (GWP) compliance

Target Group: Pharmacists and Pharmacists’ Assistants employed in the public sector

Together with resident pharmacy staff, Aurum Pharmacy Advisors conduct integrated GPP and GWP audits in dispensaries and pharmacy depots, and develop appropriate improvement plans. This is followed by in-service corrective training and coaching of the pharmacy staff using Aurum’s modular curriculum and template set of 93 policies and standard operating procedures (SOPs). The main topics covered are:

- SOP development
- Receiving stock
- Operational planning
- Inventory management
- Regulatory & legal compliance
- Manufacturing
- Storage facilities & equipment
- Picking dispatch & delivery
- Budgeting & expenditure control
- Safety, Health and Environment
- Human Resources
- Quality Assurance & Pharmacovigilance
- Medicine sourcing
- Information Management and Use
- Procurement
- Dispensing (including chronic dispensing)
PROGRAMME 2: Stock Management, Pharmacovigilance and Patient Safety training

**Target Group:** Operational Managers of primary health clinics and hospital units who are required to manage pharmacy stock as part of their duties

Aurum offers a customised Management Development Programme that teaches general management and leadership skills, as well as national policy-aligned stock management practices, pharmacovigilance procedures, and patient safety reporting of adverse drug reactions and product quality problems.

PROGRAMME 3: Centralised Chronic Medicine Dispensing and Distribution (CCMDD) support

**Target Group:** Pharmacists, Clinic Operational Managers and staff, Community service providers

The CCMDD programme is a direct distribution service managed by the South African National Department of Health, which aims to decongest public health facilities by providing alternative drug collection points for patients that are stable on chronic medication and do not require clinical review. Bypassing intermediary depots and pharmacy stores, drugs are delivered directly to pick-up points (PUP) selected by the patient, thereby making pill collection more accessible. PUPs may be located in community centres, post offices, retail pharmacies, private medical practices etc. Aurum assists to

- Identify, assess and sign-up community entities to serve as PUPs
- Train PUP staff on CCMDD procedures, and monitor their compliance
- Optimise communication between the many parties that operationalise CCMDD services

CCMDD Innovations

Aurum introduced the innovative Pelebox\(^1\), a smart locker placed outside clinics or other PUPs to automate dispensing of chronic medicines. It reduces average collection time in clinics from 3½ hours to 2 minutes, and enables patients to collect their medicine at a convenient location and time.

With the advent of COVID, Aurum piloted a **home delivery** initiative to accelerate the decongestion of facilities, while ensuring adherence to treatment. Within 6 months, 46,000 patients had enrolled in the project (65% of those offered the service), and 97% of parcels were being delivered successfully. Aurum is now investigating the feasibility of **drone technology** for home delivery.

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\(^1\)Pelebox is designed by Technovera. It won the Africa Prize for Engineering Innovation from Britain’s Royal Academy of Engineering and was voted one of TIME’s 100 best inventions in 2019
PROGRAMME 4: Pharmacy Information Systems support

Target Group: Pharmacists and Operational Managers

Aurum’s team has the technical skill to install, maintain and provide end-user training and support for

- RxSolution, the backbone of public sector supply chain systems from central procurement services, to regional depots and distribution systems, facility stock control and dispensing
- Stock Visibility Systems, a central database that draws on real-time RxSolution data to assess drug availability, allowing rapid identification, reporting and remediation of stock shortages
- SyNCH, which automates and digitizes CCMDD processes

PROGRAMME 5: Antimicrobial Resistance (AMR) training

Target Group: Prescribers, pharmacists, others that influence procurement and prescribing practices

Aurum has the capability and experience to design, coordinate and/or implement key interventions for preventing and managing AMR. Working with local regulators, health providers, laboratory networks, and interest groups such as the South African Antibiotic Stewardship Programme, Aurum supplements established AMR programmes, or initiates such programmes, focusing on:

1. Consumer awareness and education
2. Strengthening infection prevention and control
3. Optimising antimicrobial use
4. Monitoring and reporting AMR distribution and trends

See Annexure 1 for Core Activities in Preventing and Managing Antimicrobial Resistance

1.2. National Pharmacy Services and Supply Chain Management

Aurum specialists provide the following technical assistance to ensure availability of product for the duration of projects and sustainably beyond project periods:

- Advising national pharmacy services on a range of matters, such as regulatory processes, importation licensing, clearances, development of policies and procedures, and establishment of pharmacovigilance structures and procedures.
- Working with national pharmacy sites and medical stores to strengthen stock forecasting and financial management, warehousing practices, and stock movement down to the last mile

1.3. Global Product Innovation, Supply Chain Services and AMR Strengthening

Aurum leads the innovative IMPAACT4TB project to launch new short-course TB prevention treatments and study the impact in 12 countries across the globe: South Africa, Brazil, India, Indonesia, Kenya, Ghana, Tanzania, Mozambique, Ethiopia, Cambodia, Zimbabwe, and Malawi. Key supply chain activities include:

- Procuring quality-controlled treatment for the project at an affordable cost and delivering the product to a projected 400,000 - 1.5 million patients over 5 years

\textsuperscript{IMPAACT4TB – Increasing Market and Public health outcomes through scaling up Affordable Access models of short Course preventive therapy for TB: a four-year project in 12 countries representing 50% of the global TB burden, which introduces new, shorter treatment options for people with latent TB infection in order to slow and ultimately stop the flood of new TB cases.}
• Laying the foundation for TB/HIV joint product management and strengthening in-country supply chain systems to forecast, procure and deliver TB preventive therapy into the future
• Launching the Global Fund WAMBO platform for TB products and GDF ordering systems, in close coordination with USAID-PSM.
• Investment planning with Ministries of Health and donor programmes to further reduce drug prices and scale up programmes beyond the project countries.
• Aggregating and analysing market intelligence data for scale-up planning at both global and country level. SCM and data teams are assisted in visualization of aggregated data and generation of production forecasts to plan for launch and roll-out of new products, diagnostics and therapeutics.

In Ghana, Fleming Funds support the development of AMR and AMU surveillance systems in human and animal health. Aurum is contracted to refurbish reference and surveillance laboratories with essential equipment, procure consumables and reagents, and build the capacity of Ghana Health Service laboratory teams to perform surveillance duties, maintain equipment and sustain consumable supply chains.

2. Research Pharmacy & Supply Chain Services

Aurum’s Clinical Research Division conducts research ranging from large-scale public health studies that evaluate novel TB prevention and treatment strategies, to highly regulated clinical trials of new HIV and TB medicines, vaccines and diagnostics, and most recently SARS-CoV-2 vaccines. Each of Aurum’s four main Clinical Research Sites has a dedicated pharmacy designed and equipped in compliance with national pharmacy regulations and with international trial standards. The fifteen research pharmacists and pharmacists’ assistants are cross-trained on research protocols, and have both blinded and open-label trial experience in administering investigational products to participants.

The Research Pharmacy service adheres to a comprehensive set of standard operating procedures, maintains impeccable quality control, conducts internal audits between research sites, and shares best practices for improvement. It has been rigorously audited in the past by SAHPRA, DAIDS, and various sponsor-contracted clinical research audit firms.

“To seek, to find, to share, to care.”
In Aurum’s role as lead investigator and study sponsor for *large multi-centre trials*, the Research Pharmacy service also coordinates the procurement and distribution of investigational products that are either being used for their registered purpose, or being repurposed for new indications. Aurum’s preferred logistics contractor Pharma Logistics SA, in partnership with the SMO Group, offers a global capability in:

- Procurement and comparator sourcing
- Import/export facilitation
- Storage and distribution at +15-25°C, +2-8°C, -20°C, -80°C and cryogenic temperatures
- Labelling/relabelling in compliance with Good Manufacturing Practice (GMP)
- Returns and destruction

### 3. Pharmacy Regulatory Systems Strengthening

Aurum is host to the South African Health Technologies Advocacy Coalition (SAHTAC) secretariat. SAHTAC was established after a landscape analysis by the South African Council on Health Research, which identified four key challenges impacting on health research and development (R&D):

1. Governance and commitment to R&D
2. Investment in and incentives for R&D
3. R&D technical skills and capacity
4. Regulatory environment: to adjudicate clinical trials, as well as the registered use of medicines and medical devices, Parliament had replaced the problematic Medicines Control Council with SAHPRA, a new independent public regulator. However, analysis showed that engagement with the national regulator needed to be strengthened, particularly interactions with civil society.

To respond to these issues, SAHTAC aims to create an enabling environment for research, development, and access to life-saving health technologies and innovation. Notable outcomes are to ensure that SAHPRA transparently reports the progress of products as they move through the regulatory process; and promote the capacity of policymakers, regulators, civil society and media among member states of the Southern African Development Community (SADC) to harmonise product regulatory processes across the region.
B. OUR EXPERTS

Niël Van Rooyen, Head of Department: Pharmacy Services, has a B.Pharm Honours and is responsible for the operational management of Aurum’s public sector Pharmacy support team. He directly oversees novel Aurum innovations such as the Home Delivery Project and the Pelebox locker solution for chronic dispensing. Before joining Aurum, he worked for the City of Tshwane Metropolitan Health Services for 12 years as Regional Pharmacist and then as Head of IT & Drug Supply Management. He has been involved with RxSolution development and implementation since 2003.

Renier Botha, Senior Pharmacy Advisor, has a B.Pharm and an encyclopaedic knowledge of Good Pharmacy Practice (GPP), notably on implementing pharmacovigilance and antimicrobial resistance programmes. Mr Botha began his career working in and managing public sector hospital pharmacy services and depots, including the design and commissioning of over 33 warehouses, repacking units, hospital pharmacies and clinics. He then focused on developing hospital and pharmacy information systems and implementing them across 300 public and private health facilities. Since joining Aurum in 2014, he has used his deep knowledge of GPP to design improvement programmes for public sector pharmacy operations, develop training curricula, and oversee their implementation by the Pharmacy Technical Advisory team.

Karin Kanewske Turner, Director: Global Programmes and Supply Chain systems advisor, has a Master in Public Health from Johns Hopkins University. She has 20 years’ experience in establishing and managing development programmes across Africa, having led multi-country USAID portfolios of up to $35m per annum across 14 countries. She ran four USAID-funded Supply Chain projects in Mozambique (SCMS JSI, Deloitte SCM, Project Last Mile and Village Reach), and a contract from the Misau Medical Stores to refurbish the national reference laboratory and build three regional warehouses. At BroadReach Healthcare she collaborated with Accenture on the Global Technical project for VAN Control Towers, funded by Gates and the Global Fund. Ms Turner joined Aurum in 2017 where her skills in health policy development and multi-lateral stakeholder management ensure collaboration on multi-national projects.
B. OUR EXPERTS

**Tracey Brett**, Supply Chain and Regulatory Consultant for Aurum’s Global Programmes, is a certified member of the UK Chartered Institute of Procurement and Supply. She has held a number of management and consulting positions with Marie Stopes International, FHI 360, DKT International, DKT WomanCare and the Palladium Group.

**Tanya Nielson**, Managing Director: Clinical Research Division, is a qualified pharmacist with a Master of Science in Pharmaceutics and 13 years’ clinical trials experience. She was appointed at Aurum as research pharmacist in 2005 to set up and register a DAIDS-compliant research pharmacy for HIV vaccine trials, and her pharmacy SOPs are still used to this day. Within two years, she progressed to operational management of the Klerksdorp Clinical Research Site, and then to overseeing all Aurum CRS’s. Her current responsibilities include management of facilities and infrastructure, HR management, procurement and budget control in addition to pharmacy management.

**Trevor Beattie**, Head of Department: Clinical Research Division, has a Master of Science in Clinical Trials from the London School of Hygiene and Tropical Medicine. He started at Aurum as a Project Coordinator in 2011, and rapidly progressed to Programme Manager of TB Vaccines and Adjunctive Host Directed Therapies before taking up his current role in 2018. He is responsible for the effective delivery of all clinical trials conducted by Aurum, including site development and staff training; study set-up, budgeting, data quality and progress monitoring; sponsor communication and reporting; and supply chain management.
C. OUR PROJECT EXPERIENCE

The projects listed below include only the most recent ones that illustrate this capability.

<table>
<thead>
<tr>
<th>Project name</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>The South African Health Technologies Advocacy Coalition</strong></td>
<td>Project Goal: SAHTAC aims to create an enabling regulatory environment for research, development, and access to life-saving health technologies and innovations, by:</td>
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|                                                                              | • Supporting the adoption and implementation of evidence-based policies  
|                                                                              | • Improving coordination of health R&D funding mechanisms  
|                                                                              | • Coordinating advocacy, particularly civil society engagement in health R&D and regulation  
| **Programmatic Implementation and Technical Assistance for HIV/AIDS & TB Prevention, Care & Treatment Services throughout the Health System in South Africa under PEPFAR** | Overall Project Goal: To contribute directly to HIV and TB/HIV epidemic control by providing technical assistance (TA) on HIV prevention, care and treatment; and in select programs, direct service delivery (DSD) for targeted, priority, and key populations at facility and community levels.  
|                                                                              | Pharmacy-related Scope of Work: The main objective of the pharmacy programme is to ensure a reliable and effective supply of essential medicines, particularly ART. At its peak, the programme has deployed 23 TA and 43 DSD staff to implement the following activities:  
|                                                                              | District & Facility level activities:  
|                                                                              | • Facility Pharmacy Operations TA & DSD, including  
|                                                                              | o Good Pharmacy Practice (GPP) audits and improvement plans in 162 high-burden facilities, followed by in-service corrective training and coaching where appropriate  
|                                                                              | o Direct deployment of Pharmacists’ Assistants in 21 critical facilities and 2 medicine depots to do stock management and dispensing, and to escalate and assist in managing urgent stock-outs  
|                                                                              | o A customised Management Development Programme (MDP) that trained 285 Operational Managers on core stock management, pharmacovigilance and patient safety practices  
|                                                                              | • Central Chronic Medicine Dispensing and Distribution (CCMDD)  
|                                                                              | o Identified, assessed and signed-up 257 community entities to serve as medicine pick-up points (PUPs); trained their staff on CCMDD procedures; and monitored compliance  
|                                                                              | o Procured and installed 36 Pelebox units for automated dispensing of chronic medicines  
|                                                                              | o Enrolled 46,000 patients on chronic medicines in a home delivery project to decongest facilities in the face of COVID, while ensuring continued adherence to treatment  
|                                                                              | • Pharmacy Information Systems: Support installation, maintenance, end-user training and support for RxSolution (installed and/or supported in 101 facilities), Stock Visibility System, and SyNCH (installed and supported in 324 facilities)  
| **PEPFAR-CDC**                                                               | **Funder ref. no.** NU2GGH001981  
| **Funding period**                                                           | Oct 2016 – Sep 2021  
| **Funding amount**                                                           | $ 227,363,170 (at Sep 2020)  
| **Bill & Melinda Gates Foundation**                                         | **Funder ref. no.** INV-022416  
| **Funding period**                                                           | Nov 2020 – Oct 2023  
| **Funding amount**                                                           | $ 999,986  

"To seek, to find, to share, to care."
C. OUR PROJECT EXPERIENCE

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Overall Project Goal: To reduce TB incidence and deaths among PLHIV and child contacts <5 in low and middle income countries by scaling up 3HP, a short-course TB preventive regimen of high-dose INH and rifapentine weekly for 3 months. The current 6-month INH regimen has not significantly decreased the pool of latent TB due to poor uptake. 3HP’s lesser toxicity and shorter regimen may address some barriers to adherence, and has lower risk of generating resistance, with similar efficacy.

Pharmacy-related Scope of Work: See Section 1.3 for detail.

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<tr>
<td>Comprehensive HIV &amp; TB Prevention, Care and Treatment Systems Strengthening in Facilities of South Africa’s Department of Correctional Services (DCS)</td>
<td>PEPFAR-CDC</td>
<td>1U2GGH001175</td>
<td>Apr 2014 – Mar 2019</td>
<td>$ 26,463,946</td>
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Overall Project Goal: To support and build capacity of health services in Correctional centres throughout South Africa to provide comprehensive HIV and TB prevention, care and treatment services to incarcerated persons.

Pharmacy-related Scope of Work: The main objective of the pharmacy TA programme was to improve the availability of essential medicines in DCS facilities by improving the efficiency and reliability of DCS pharmacy services. TA was undertaken across 238 centres and focused on strengthening:

- Structure i.e. supplementing staffing, installing equipment, reorganising stock storage facilities
- Process i.e. training and mentoring DCS health providers on supply chain management (from procurement to stock management to dispensing); and information management
- Governance i.e. guiding national DCS Pharmacy strategy and leadership, monitoring and quality control of services, and quality improvement of pharmacy systems

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<tr>
<td>Concept: Continuous Professional Development training on Antibiotic Stewardship</td>
<td>Ascendis Health Corporate Social Investment</td>
<td>Terminated during project implementation planning due to corporate restructuring</td>
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Project Goal: Using sensitivity reports from South African laboratory services and the National Institute for Communicable Diseases (NICD), the objective was to educate and update health care providers on drug sensitivity patterns in South Africa to foster responsible procurement and prescribing practices.

Proposed approach: Six-month pilot in 3 major urban hubs (Johannesburg, Cape Town and Durban) to evaluate reach and impact, and assess resource requirements for national roll out. Target audiences:

- Public sector provincial, district and hospital management teams, focusing on clinical programme managers and pharmacists who influence procurement and prescribing practices in the public sector
- Private sector health practitioners, accessed through hospital networks, large private practices, medical associations and other clinical forums

See Annexure 2 for Aurum’s project experience in managing investigational products for clinical trials.
Annexure 1: Core Activities in Preventing and Managing Antimicrobial Resistance

Aurum has the capability and experience to design, coordinate and/or implement the following key interventions for managing and preventing the spread of antimicrobial resistance (AMR):

1. **Consumer awareness and education**
   a) Analyse and map sectors whose catchment populations drive consumer demand for inappropriate antimicrobial use
   b) Train IPC champions in high-burden facilities in these sectors to educate patients on AMR
   c) Random monitoring and quality control of implementation through “mystery customer” method

2. **Strengthening infection prevention and control**
   a) Work with laboratories to map regions with high rates of AMR
   b) Work with health authorities to identify regions with high rates of morbidity and mortality caused by hospital-acquired infections
   c) Train operational managers and IPC champions in high-burden facilities in these regions to implement rigorous IPC programmes
   d) Random monitoring and quality control of IPC implementation through “mystery customer” method

3. **Optimising antimicrobial use**: In regions with high rates of AMR and/or morbidity and mortality related to hospital-acquired infections
   a) Offer accredited training and education of prescribers, pharmacists, and other personnel that influence procurement and prescribing practices. Topics would cover (1) the AMR problem, (2) local resistance and sensitivity trends, and (3) strategies to change procurement and prescribing practices, and overcoming barrier’s to change
   b) Lobby, develop and/or implement systems for controlling antimicrobial use, doing prescription audits, and giving corrective feedback

4. **Monitoring and reporting AMR**
   a) Work with laboratories and infectious disease specialists to collate resistance and sensitivity data (antibiograms) which may vary across regions and even across facilities
   b) Report trends to health providers to promote responsible procurement and prescribing practices

While Aurum works mainly in the public sector, it also has experience working with private sector health providers and employer health services. This affords the opportunity to reach a wide range of health providers where AMR may emerge. Through its HIV and TB research, it also has strong relations with national health laboratory services and infectious disease specialists, who would play a critical role in managing AMR.


Hospital-acquired infections are caused by a small group of bacteria with increasing resistance to currently available antimicrobial agents. The acronym ESCAPE can be used to remember these pathogens that have a high likelihood of “escaping” treatment: Enterococcus faecium, Staphylococcus aureus, Clostridium difficile, Acinetobacter baumannii, Pseudomonas aeruginosa, Enterobacteriaceae (includes Enterobacter species, Klebsiella pneumoniae, Escherichia coli)
Annexure 2: Project experience in managing investigational products for clinical trials

Aurum has the following experience in managing investigational products for clinical trials,

1. Phase II double-blind, randomized, placebo-controlled study to evaluate safety and immunogenicity of H1/Ic31® in HIV-infected adults with CD4+ lymphocyte counts greater than 350 cells/mm³
   Aurum coordinated the receipt, import, cold chain and distribution of 96 vaccine doses of the H1/Ic31® adjuvant TB subunit vaccine for 48 subjects at the Aurum Tembisa Clinical Research Site (CRS), South Africa and the Ifakara Health Institute, Tanzania.

2. Phase II, randomized, open-label trial to evaluate safety, preliminary efficacy, and biomarker response of host directed therapies added to Rifabutin-modified standard antimicrobial therapy in adult patients with drug-sensitive, smear-positive pulmonary TB (TB HDT)
   Aurum procured and repackaged study arm-specific Rifabutin-substituted standard TB therapy with adjunctive TB Host Directed Therapies into daily doses in polytops using a GMP certified drug distribution and repackaging facility. Drug procurement, packaging and distribution were complicated by:
   • Trial design, multi-arm multi centre, where 200 adult HIV negative DS-TB positive with moderate to far advanced TB disease graded by radiographic assessment were enrolled across three South African research sites, across the following 5 arms stratified by site and extent of disease:
     o Rifabutin substituted standard TB therapy alone (control)
     o Rifabutin substituted standard TB therapy plus AMG-634, formerly CC11050 200mg BID
     o Rifabutin substituted standard TB therapy plus everolimus 0.5mg QD
     o Rifabutin substituted standard TB therapy plus auranofin 3mg QD for 1 week, then 6mg QD
     o Rifabutin substituted standard TB therapy plus Vitamin D2, a total of 3 doses: 5mg initially (day 0), then 2.5mg Q month for 2 doses, days 28 and 56
   • Lack of availability of registered drug stocks with favourable shelf-life / early expiring stock
   • Ceased production of Auranofin by Astellas, Italy mid-trial whilst sourcing new Sebela product at triple the cost. This forced the Aurum drug management group to issue the instruction to repackage later visit doses into earlier doses for newly enrolled participants and to temporarily halt enrolment into the Auranofin arm until new stocks arrived. No Auranofin doses were missed during this time.

3. Phase I/II trial to evaluate safety, tolerability, and drug-drug interactions of short-course treatment of latent TB infection with high-dose rifapentine and isoniazid vs. standard isoniazid preventative therapy among HIV-infected patients taking dolutegravir-based antiretroviral treatment (DolPHIn)
   Twelve doses of once weekly isoniazid and rifapentine were dispensed to 75 participants across 3 arms.
Annexure 2: Project experience in managing investigational products for clinical trials

4. Phase IIb, open-label, randomized controlled dose multi-centre trial to evaluate the safety, tolerability, pharmacokinetics and exposure response relationship of different doses of Sutezolid in combination with Bedaquiline, Delamanid and Moxifloxacin in adult subjects with newly diagnosed, uncomplicated, smear-positive, drug-sensitive pulmonary TB

Starting in 2021, this Sudocu TB treatment trial will enrol 75 participants in South Africa and Tanzania, and will require the procurement, labelling and distribution of moxifloxacin, bedaquiline and sutezolid.

5. Pan-TB HM and DRTB-HDT: funded by the EDCTP and the European Commission Horizon 2020 call respectively, these two large Aurum investigator-initiated trials are commencing in 2021

• Pan-TB HM: Drugs will be procured (Delaminid, Bedaquilline, and N-acetylcysteine) and manufactured (Sutezolid), repackaged at a GMP facility into daily dose arm specific dosages and distributed to Wits CHRU, Tembisa CRS and the Aurum Mozambique CRS.

• DRTB-HDT project will source standard of care Rif-R TB treatment from country specific local TB programmes, and adjunctive HDTs, metformin and AMG-634 will be repackaged at a GMP facility into daily dose arm specific dosages. Drugs destined for EU sites in Georgia, Moldova, Romania, Belgium and Germany will be shipped by Pharma Logistics to a central drug distribution and storage centre in Hungary. Similarly, Aurum sites in Southern Africa and Mozambique will have drugs shipped centrally from Pharma Logistics’ centre in Centurion, South Africa.
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