

C19RM Health Product Segmentation Framework

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Introduction

The Health Product Segmentation Framework was first issued in April 2021, to inform Principal Recipients (PRs) and other in-country partners about eligibility of health products under the COVID-19 Response Mechanism (C19RM), the procurement channels to be used and related reporting requirements.

The COVID-19 situation has since changed and C19RM funding has transitioned from supporting the emergency response to longer-term investments in resilient and sustainable systems for health. Programmatic priorities include surveillance system strengthening, laboratory and diagnostics, human resources for health and community systems strengthening, medical oxygen, respiratory care and therapeutics, and health product and waste management systems. The Health Product Segmentation Framework has now been updated to reflect this shift.

Important

Key changes include:

- Only two procurement channel categorizations remain in effect: (1) "Mainstream" and (2) "Local Procurement Advised/Possible." Based on the current context of the COVID-19 pandemic, no products are classified as "strategic products."
- The references to "product use" related to "optimal" and "limited use" have been removed, as no longer relevant in the current context.
- Categorization and lists of health products have been aligned with those of the Product Master
 in the <u>C19RM Health Product Management Template (HPMT)</u>, including additional guidance on
 how to reflect items not specifically available in the HPMT.
- As a result of the C19RM strategic shift, any requests for health products related to the following interventions are now subject to special approval on a case-by-case basis: (no.1) Diagnosis and Testing, (no.3) Infection Prevention and Control and Protection of the Health Workforce, and (no.5) Case Management, Clinical Operations and Therapeutics: Pharmaceuticals.

¹ See: COVID-19 Response Mechanism Information Note

The document remains relevant for: (1) any remaining investments through C19RM; and (2) any C19RM reinvestments in systems for health and pandemic preparedness, which complement Grant Cycle 7 grants. The guidance may change in response to evolving supply and demand dynamics of health products needed to control and contain COVID-19 and prepare for future pandemics.

Additional information is available in the COVID-19 Response Mechanism Guidelines.

This document classifies health products eligible for funding through C19RM based on the following considerations:

- Recommended procurement channel category.
- Whether reportable through the C19RM Procurement Progress Reporting Template.

Recommended Procurement Channel

To effectively respond to COVID-19 and prepare for future pandemics, health and non-health products should include a diverse set of products with different market characteristics, which require deliberate approaches to secure better market outcomes (such as lower prices and/or improved lead times). A three-category framework for health products has been developed to articulate this:

- For **Strategic Health Products:**² currently, no products are included under this category. The category is retained for potential future use.
- For Mainstream Health Products: countries are generally expected to use the Global Fund's Pooled Procurement Mechanism (PPM)/wambo.org. This enables countries to benefit from negotiated terms and pricing while simplifying orders. However, some of the more complex health and laboratory equipment in the Health Product Management Template (HPMT), may be procured at the national level or through existing pooled procurement channels (GDF, PAHO, UNICEF, and others) to ensure rapid deployment, installation, training and continuous aftersales support. In line with the Management of Health Products, a competitive procurement taking a total cost of ownership approach should be applied with benchmarking to international standards, where available. Additional requirements around procurement performance assurance and reporting apply in cases where the PR elects not to use PPM/wambo.org for the procurement of Mainstream Health Products. The PR is expected to provide monthly reporting for visibility from procurement to delivery.³
- For Local Sourcing Advised/Possible Health Products: these are generally low value, bulky and/or hazardous products (e.g., alcohol, bleach, disposable waste collection boxes, containers, and others), and freight costs are high compared to the product cost. More

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Page 2 of 13

² As described in Section 2 of the <u>Guide to Global Fund Policies on Procurement and Supply Management of Health Products</u>, countries may need to use PPM/wambo.org where supply dynamics and constraints require pooling of demand to attain better market outcomes, such as lower prices or improved lead times. If the PR is a United Nations (UN) entity, countries may procure through the existing UN entity procurement channel, provided the PR agrees to provide monthly reporting to the Global Fund on visibility from procurement to delivery.

³ For Focused portfolios, reporting can be provided on a quarterly or annual basis depending on the procurement channel. See this Update on C19RM Procurement Progress Reporting Template for more information.

complex diagnostic and/or health equipment where existing contractual agreements can be leveraged for acquisition, installation and maintenance are also included in this category.

More information on recommended procurement channels is available in the <u>COVID-19</u> <u>Response Mechanism Guidelines</u> (see Section 15.3 on Procurement of Health Products).

Reportable Health Products through the C19RM Procurement Progress Reporting Template

For **Strategic** and **Mainstream Health Products** procured outside of the PPM/wambo.org procurement channel and **Local Sourcing Advised/Possible Health Products** that are marked as reportable in the below tables, transaction-level data is needed at product level for key procurement and supply chain milestones.⁴ The reporting needs to be completed using the <u>C19RM Procurement Progress Reporting Template</u>. This template includes instruction, guidance and the product scope for reporting.

The tables below, by product category and intervention,⁵ provide the classification of eligible health products for C19RM by product use and procurement channel categories and identify products that can be reported through the C19RM Procurement Progress Reporting Template. There are seven tables:

- Table 1: Diagnosis and Testing
- Table 2: Surveillance, including Epidemiologic Investigation and Contact Tracing
- Table 3: Infection Prevention and Control and Protection of the Health Workforce
- <u>Table 4: Case Management, Clinical Operations and Therapeutics: Medical Oxygen</u> & Respiratory Care
- <u>Table 5: Case Management, Clinical Operations and Therapeutics:</u> Pharmaceuticals
- Table 6: Laboratory Systems
- Table 7: Health Products and Waste Management Systems

Note: Any branded products listed in the tables below match specific products pre-populated in the Health Product Management Template. However, additional products that conform to the Global Fund's quality assurance requirements may also be eligible under C19RM procurement.

⁵ Interventions are aligned to the modular framework.



Page 3 of 13

⁴ Section 15.3 in the <u>COVID-19 Response Mechanism Guidelines</u> details PR reporting requirements, including the required frequency of reporting, which differs by portfolio.

Table 1: Diagnosis and Testing⁶

(Note: As stated on page 1, request for health products listed in table 1 is subject to special approval, on a case-by-case basis)

Health Product	Procurement Channel Category	C19RM Procurement Progress Reporting Template
COVID-19 Tests / Antigen Rapid Diagnostic Test Ag-RDT		
SARS-CoV-2 Ag rapid test kit ⁷	Mainstream*	Reportable
COVID-19 Diagnostic Reagents and Consumables		
COVID-19 tests / diagnostic reagents and cartridges (automated/ manual PCR tests) ⁶	Mainstream*	Reportable
COVID-19 tests / diagnostic consumables (sample collection - swab, viral transport medium, triple packaging boxes; extraction consumables; pipette tips)	Local Sourcing Advised/Possible	Reportable
Molecular Test Equipment		
Automated extractors	Mainstream*	Reportable
Thermocyclers, including RT-PCR analyzers	Mainstream*	Reportable
Magnetic stand: Manual extraction	Mainstream*	Reportable
Tabletop PCR workstation with UV light	Mainstream*	Reportable
UV crosslinker spare parts and accessories	Mainstream*	Reportable
UV transilluminator spare parts and accessories	Mainstream*	Reportable
Spare parts, accessories, software; warranty, maintenance, and service	Local Sourcing Advised/Possible	Reportable
GeneXpert - Equipment		
GeneXpert equipment	Mainstream*	Reportable
Spare parts, accessories, software; warranty, maintenance, and service	Local Sourcing Advised/Possible	Reportable
Other Near Point of Care		
Equipment	Mainstream*	Reportable
Spare parts, accessories, software; warranty, maintenance, and service	Local Sourcing Advised/Possible	Reportable

⁶ Compatibility between SARS-CoV-2 PCR assays, extraction kits and amplification equipment (thermocycler) as described per the supplier's Instructions for Use should be carefully assessed. When an extraction kit is requested, details about the intended use of subsequent SARS-CoV-2 PCR assays should be indicated in the C19RM Funding Request. If a thermocycler is requested, details of the SARS-CoV-2 PCR assay to be used with the instrument should be indicated in the C19RM Funding Request.

7 See Global Fund's list of SARS-CoV-2 Diagnostic test kits and equipment eligible for procurement.

Health Product	Procurement Channel Category	C19RM Procurement Progress Reporting Template
TrueNat Equipment ⁸		
Truelab Uno Dx	Mainstream*	Reportable
Trueprep	Mainstream*	Reportable
Spare parts, accessories, software; warranty, maintenance, and service-	Local Sourcing Advised/Possible	Reportable
Bi-directional Testing ⁹		
GeneXpert MTB/RIF, MTB/RIF ULTRA, and MTB/XDR tests	Mainstream*	Reportable
Truenat MTB, MTB Plus and MTB-RIF tests	Mainstream*	Reportable

^{*} Where contractual arrangements are already in place and can be leveraged for diagnostic & health equipment and associated consumables, continued Local Sourcing is advised (as opposed to Mainstream).

⁸ Please note that this category will no longer be eligible for C19RM funding as of 1 January 2024. This is in line with the financing transition to resilient and sustainable systems for health and pandemic preparedness as indicated in the COVID-19 Response Mechanism Information Note.

⁹ Please note that this category will no longer be eligible for C19RM funding as of 1 January 2024. This is in line with the financing transition to resilient and sustainable systems for health and pandemic preparedness, as indicated in the COVID-19 Response Mechanism Information Note.

Table 2: Surveillance, including Epidemiological Investigation and Contact Tracing

Health Product	Procurement channel category	C19RM Procurement Progress Reporting Template
COVID-19 Tests / Antibody Rapid Diagnostic Test Ab-RDT		
SARS-CoV-2 Ab rapid test kit ¹⁰	Mainstream	Reportable
Lab/ELISA based antibody tests ¹¹	Mainstream	Reportable
Genomic Surveillance / Sequencing		
Sequencing analyzers,12	Mainstream	Reportable
Reagents for sequencing (including Library Quantification kits)	Mainstream	Reportable
Sequencing analyzers: Spare parts, accessories, software; warranty, maintenance, and service	Mainstream*	Reportable
Sample collection (needles, syringes, triple packaging boxes for transportation, sharps container)	Local Sourcing Advised/Possible	Reportable
Sample collection kits for epidemiological investigation ¹³	Mainstream	Reportable

^{*} Where contractual arrangements are already in place and can be leveraged for diagnostic & health equipment and associated consumables, continued Local Sourcing is advised (as opposed to Mainstream).

See Global Fund's list of <u>SARS-CoV-2 Diagnostic test kits and equipment eligible for procurement</u>.
 The Lab/ELISA based antibody tests are not specifically available in the HPMT, the PR is advised to select the SARS-CoV-2 Ab rapid test kit option, and specify in the comment section that this in fact concerns a procurement of Lab/ELISA based antibody tests.

¹² Ancillary equipment can be found in Table 1.

¹³ This entry is not available as such in the HPMT. The PR is advised to select "Sample Collection" under "Genomic Surveillance/Sequencing". Further detail can be provided in the comment section.

Table 3: Infection Prevention and Control and Protection of the Health Workforce^{14,15}

(Note: As stated on page 1, request for health products listed in table 3 is subject to special approval, on a case-by-case basis)

Health Product	Procurement channel category	C19RM Procurement Progress Reporting Template
Core Personal Protective Equipment (PPE)		
Apron (reusable)	Mainstream	Reportable
Face shield	Mainstream	Reportable
Gloves [examination (non-sterile), surgical (sterile)]	Mainstream	Reportable
Goggles	Mainstream	Reportable
Gowns (non-sterile, sterile)	Mainstream	Reportable
Masks, [medical/surgical] ¹⁶	Mainstream	Reportable
Respirator, FPP2/N95 and airflow test set	Mainstream	Reportable
Scrubs	Local Sourcing Advised/Possible	Not reportable
Non-Core PPE		
Apron (single use, disposable)	Local Sourcing Advised/Possible	Reportable
Boot cover	Local Sourcing Advised/Possible	Reportable
Boots	Local Sourcing Advised/Possible	Reportable
Coverall	Local Sourcing Advised/Possible	Reportable
Heavy-duty apron	Local Sourcing Advised/Possible	Reportable
Heavy-duty gloves	Local Sourcing Advised/Possible	Reportable
Surgical cap	Local Sourcing Advised/Possible	Reportable
Disinfectants		
Alcohol-based hand rub	Local Sourcing Advised/Possible	Not reportable
Chlorine	Local Sourcing Advised/Possible	Not reportable

¹⁴ The "core" and "non-core" designation for PPE relates to the definition in the <u>Guide to Global Fund Policies on Procurement and Supply Management of Health Products</u>, where quality assurance requirements are specified, applicable from 1 July 2021.

¹⁵ Non-core PPE (e.g., coveralls) is primarily for use in the context of Viral Hemorrhagic Fevers, such as Ebola. In addition to PPE for active Ebola outbreaks, PPE for Ebola preparedness needs, particularly where COVID-19 and Ebola cases may be treated within the same health facilities may be justified based on context-specific circumstances. Some non-core PPE may also be appropriate for laboratory procedures; please refer to the guidance from WHO which is updated over time; see https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-(covid-19). Sterile gloves and gowns should be justified based on specific needs linked to sterile procedures (e.g., intubation, surgery).

¹⁶ Medical/surgical masks come in two main categories, Type 1 and Type 2, where Type 2 masks have higher filtration efficacy and are advised for frontline health worker taking care of COVID-19 patients, while Type 1 masks are advised for patients. This distinction should be considered during C19RM Funding Request quantification and development.

Health Product	Procurement channel category	C19RM Procurement Progress Reporting Template
Chlorohexidine	Local Sourcing Advised/Possible	Not reportable
Hand wash (liquid)	Local Sourcing Advised/Possible	Not reportable
Soap	Local Sourcing Advised/Possible	Not reportable

Table 4: Case Management, Clinical Operations and Therapeutics: Medical Oxygen & Respiratory Care

Health Product	Procurement channel category	C19RM Procurement Progress Reporting Template
Medical Oxygen – Consumables		
Airway: Oropharyngeal airway, Guedel	Mainstream	Reportable
Airway: Nasopharyngeal airway	Mainstream	Reportable
Colorimetric end tidal CO2 detector	Mainstream	Reportable
Cricothyrotomy set	Mainstream	Reportable
Endotracheal tube	Mainstream	Reportable
Flow splitter (for oxygen concentrator)	Mainstream	Reportable
Flowmeter (medical oxygen)	Mainstream	Reportable
Humidifier (non-heated, reusable)	Mainstream	Reportable
Infusion giving set	Mainstream	Reportable
Laryngoscope (adult/child, neonate)	Mainstream	Reportable
Nasal Cannula (high flow)	Mainstream	Reportable
Nasal Catheter (high flow)	Mainstream	Reportable
Nasal prongs (adult, child, neonate, single use)	Mainstream	Reportable
Oxygen mask	Mainstream	Reportable
Pulse oximeter probes (tabletop, handheld)	Mainstream	Reportable
Resuscitator (adult, child)	Mainstream	Reportable
Suction devices (electrical)	Mainstream	Reportable
Tubing (suction, oxygen administration)	Mainstream	Reportable
Medical Oxygen – equipment		
Mechanical ventilation for critical/intensive care	Mainstream	Reportable
Mechanical ventilation for transport	Mainstream	Reportable
Non-invasive ventilation (HFNC, BiPAP and CPAP with tubing and patient interfaces)	Mainstream	Reportable
Oxygen analyzer (electrochemical, battery-powered, handheld)	Mainstream	Reportable
Oxygen analyzer (ultrasonic, battery-powered)	Mainstream	Reportable
Oxygen concentrator (stationary/bedside or portable, with accessories)	Mainstream	Reportable
Pulse oximeter (with or without alarm or cables & sensor)	Mainstream	Reportable

Health Product	Procurement channel category	C19RM Procurement Progress Reporting Template
Spare parts, accessories; warranty, maintenance, and service	Mainstream	Reportable
Surge suppressor	Local Sourcing Advised/Possible	Reportable
Voltage stabilizer	Local Sourcing Advised/Possible	Reportable
Medical Oxygen Liquid & Gas		
Medical gas cylinder, portable (compressed oxygen or compressed medical air, with valves and regulators)	Local Sourcing Advised/Possible	Reportable
Pressure swing adsorption oxygen generator plants (incl. spare parts/accessories, warranty/ maintenance/service)	Mainstream*	Reportable
New bulk liquid storage and piping ¹⁷	Local Sourcing Advised/Possible	Reportable
Other Health Equipment		
Blood gas analyzer	Mainstream*	Reportable
Critical care equipment ¹⁸ (e.g., defibrillators)	Mainstream*	Reportable (as "other health equipment")
CT Scanner ¹⁹	Local Sourcing Advised/Possible	Reportable (as "other health equipment")
Electrocardiogram (ECG) digital monitor and recorder	Mainstream*	Reportable
Electronic drop counter, IV fluids	Mainstream	Reportable
General Hospital Equipment (e.g., patient beds, screens, etc.). ²⁰	Local Sourcing Advised/Possible	Not reportable
Infusion pump	Mainstream*	Reportable
Patient monitor with/without ECG/EKG	Local Sourcing Advised/Possible	Reportable
Thermometer, non-contact	Local Sourcing Advised/Possible	Reportable
Ultrasound	Local Sourcing Advised/Possible	Reportable
UPS units	Local Sourcing Advised/Possible	Reportable
X-ray equipment with/without CAD/AI	Mainstream*	Reportable
X-ray protection (lead apron, lead collar etc.) ²¹	Local Sourcing Advised/Possible	Not reportable
Spare parts, accessories; warranty, maintenance, and service	Mainstream*	Reportable

^{*} Where contractual arrangements are already in place and can be leveraged for diagnostic & health equipment and associated consumables, continued Local Sourcing is advised (as opposed to Mainstream).

¹⁷ This entry is not available as such in the HPMT. The PR is advised to select "Pressure Swing Adsorption (PSA) Oxygen Generator Plants" under "Oxygen Pants" under "Medical Oxygen Liquid & Gas" and specify in the Comment Section.

¹⁸ This entry is not available as such in the HPMT. The PR is advised to select the most relevant "product detail" under "Other Health Equipment" and specify in the Comment Section.

¹⁹ This entry is not available as such in the HPMT. The PR is advised to select the "Other Type" under "X-Ray: Equipment" under "Other Health Equipment" and specify in the Comment Section.

²⁰ This entry is not available as such in the HPMT. The PR is advised to select the most relevant "product detail" under "Other Health Equipment" and specify in the Comment Section.

²¹ This entry is not available as such in the HPMT. The PR is advised to select the "Spare parts and accessories" under "X-Ray: Equipment" under "Other Health Equipment" and specify in the Comment Section.

Table 5: Case Management, Clinical Operations and Therapeutics: Pharmaceuticals

(Note: As stated on page 1, request for any pharmaceuticals listed in table 5 is subject to special approval, on a case-by-case basis, mostly in the context of ongoing Global Fund-supported "Test and Treat" projects.)

Health Product	Procurement channel category	C19RM Procurement Progress Reporting Template
COVID-19 Existing/Repurposed Medicines (anticoagulants and steroids)	Local Sourcing Advised/Possible	Not reportable
COVID-19 Novel Medicines (e.g.,molnupiravir, nirmatrelvir/ritonavir)	Mainstream	Reportable
COVID-19 Other Medicines (Ringer's lactate, paracetamol, other essential medicines)	Local Sourcing Advised/Possible	Not reportable

Table 6: Laboratory Systems

Health Product	Procurement channel category	C19RM Procurement Progress Reporting Template
Laboratory Equipment		
Autoclave for laboratory	Mainstream*	Reportable
Biological Safety Cabinet BSL II/III	Mainstream*	Reportable
Microplate/ELISA Reader and Washer ²²	Local Sourcing Advised/Possible	Reportable (as "Laboratory Equipment")
Centrifuges	Local Sourcing Advised/Possible	Reportable
Glove box	Local Sourcing Advised/Possible	Reportable
Incubator	Local Sourcing Advised/Possible	Reportable
Laboratory freezer	Local Sourcing Advised/Possible	Reportable
Laboratory freezer – ultra low	Local Sourcing Advised/Possible	Reportable
Laboratory refrigerator	Local Sourcing Advised/Possible	Reportable
Microcentrifuge	Local Sourcing Advised/Possible	Reportable
Thermoblock	Local Sourcing Advised/Possible	Reportable
Refrigerated bench top centrifuge	Local Sourcing Advised/Possible	Reportable
Vortex	Local Sourcing Advised/Possible	Reportable
Spare parts, accessories; warranty, maintenance, and service	Local Sourcing Advised/Possible	Reportable

^{*} Where contractual arrangements are already in place and can be leveraged for diagnostic & health equipment and associated consumables, continued Local Sourcing is advised (as opposed to Mainstream).

²² This entry is not available as such in the HPMT. The PR is advised to select the "Equipment" under "Equipment: Other" under "Laboratory Equipment" and specify in the Comment Section.

Table 7: Health Products and Waste Management Systems

Health Product	Procurement channel category	C19RM Procurement Progress Reporting Template
Cold Chain Equipment ²³		
Vaccine combined refrigerator & freezer	Mainstream-	Reportable-
Vaccine freezer	Mainstream-	Reportable-
Vaccine refrigerator	Mainstream-	Reportable-
Cold Chain Consumables		
Cold box	Mainstream	Reportable
Data logger	Mainstream	Reportable
Ice pack	Mainstream	Reportable
Remote temperature monitoring system	Mainstream	Reportable
Vaccine carrier ²³	Mainstream-	Reportable-
Waste Management		
Autoclave	Mainstream*	Reportable
Consumables (biohazard bags, sharps container)	Local Sourcing Advised/Possible	Reportable
Reagents	Local Sourcing Advised/Possible	Reportable
Waste Disposal Units (including incinerators, medical/general waste)	Mainstream**	Reportable
Spare parts, accessories; warranty, maintenance, and service	Local Sourcing Advised/Possible	Reportable

^{*} Where contractual arrangements are already in place and can be leveraged for diagnostic & health equipment and associated consumables, continued Local Sourcing is advised (as opposed to Mainstream).

^{**} Given the diversity of specifications as well as anticipated needs, local sourcing of waste disposal units is also possible.

²³ Cold chain equipment for vaccine delivery are not covered by the Global Fund nor eligible for funding through C19RM.