C19RM Health Product Segmentation Framework

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This document describes the Health Product Segmentation Framework relevant for the COVID-19 Response Mechanism (C19RM). It provides guidance which is subject to change over time in response to rapidly evolving supply and demand dynamics of health products needed to control and contain COVID-19.

Additional information is available in the COVID-19 Response Mechanism Technical Information Note, the COVID-19 Response Mechanism Guidelines and the COVID-19 Response Mechanism Funding Request Instructions.

The C19RM Health Product Segmentation Framework classifies health products eligible for funding through C19RM based on the following considerations:

- Product use, whether "optimal" or "limited use/specialized";
- Recommended procurement channel; and
- Whether reportable through the C19RM Procurement Progress Reporting Template.

Product Use

The product use classification reflected within this framework is aligned with the C19RM Fast-track and Full Funding Request options designated within the funding request application guidance and templates. Specifically, the **products designated here as "Optimal" are eligible under both the Fast-track and Full Funding Request options**, along with the costs associated with their effective deployment. Procurement of "**Limited use/specialized" products** is expected to remain restrictive and **requires sufficient justification**. Products designated as "limited use/specialized" are not eligible for approval through a C19RM Fast-track Funding Request, although they can be submitted for consideration through a C19RM Full Funding Request.

Recommended Procurement Channel

Health and non-health products needed for the COVID-19 response include a diverse set of products with different market characteristics, which require deliberate approaches to secure better market outcomes (such as lower prices or improved lead times). A three-category framework for health products has been developed to articulate this:

- **Strategic:** products that are scarce on the global market. For such products, pooling of demand or coordination of order placement is needed to be able to secure volume that, if not done in a coordinated and timely way, may be lost to high income country markets. This may include very close and timely coordination for an ACT-A partner volume agreement that had to be made to secure volumes for low- and middle-income countries;
- **Mainstream**: products where supply may be tight or fragile and/or require enhanced visibility of progress on volumes secured and delivered is needed; and

- **Local sourcing advised**: products which are generally low value bulky and/or hazardous products, such as alcohol and bleach, or those for which contracting of a local contractor or supplier may be the only option, for example, for supply of some oxygen interventions.

For strategic products, as described in Section 2 of the Guide to Global Fund Policies on the Procurement and Supply Management of Health Products,[1] countries may be required to use PPM/wambo.org for as long as the supply dynamics and constraints remain as described above.

For mainstream products, countries are generally expected to use the Global Fund's PPM/wambo.org. This will allow for countries to benefit from negotiated terms and pricing while simplifying orders, especially for those products currently scarce on the global market. Where a competitive and comprehensive product offering is available, however, some of the more complex health and laboratory equipment in the HPMT, may be optimally procured at the national level to ensure rapid deployment, installation, training, and continuous aftersales support requiring established in-country presence of the manufacturer's representative or authorized agent. In line with the Guide to Global Fund Policies on Procurement and Supply Management of Health Products a competitive procurement taking a total cost of ownership approach should be applied with benchmarking to international benchmarks, where available. See Section 2.5.2 Procurement of Health Products of the COVID-19 Response Mechanism Guidelines for more information on recommended procurement channels.

Reportable through the C19RM Procurement Progress Reporting Template

For Strategic and Mainstream Health Products outside of the PPM/wambo.org procurement channel and Local Sourcing Advised Health Products with Enhanced Reporting, transaction-level data is needed at product level for key procurement and supply chain milestones, as described in the COVID-19 Response Mechanism Guidelines (see Section 2.5.3 for Principal Recipient reporting requirements, including the required frequency of reporting, which differs by portfolio). The C19RM Procurement Progress Reporting Template includes instruction guidance and the product scope for reporting. The tables below also clarify which health products procured outside of PPM/wambo.org are reportable.

The tables below, by product category and COVID-19 intervention, provide the classification of eligible health products for C19RM by product use, procurement channel categories and whether reportable through the C19RM Procurement Progress Reporting Template for procurement outside of PPM/wambo.org. There are seven tables:

Note: The 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.

[1] https://www.theglobalfund.org/media/5873/psm_procurementsupplymanagement_guidelines_en.pdf

Table 1: Diagnosis and Testing[2]

Health Product	Product use category	Procurement channel category	C19RM Procurement Progress Reporting Template
COVID-19 Diagnostic Reagents and Consumables			
RAPID DIAGNOSTIC TESTS			
SARS-CoV-2 Rapid Antigen Diagnostic Test Kit	Optimal	Strategic	Reportable
AUTOMATED PCR TESTS			
Abbott RealTime SARS-CoV-2 RT-PCR Kit	Optimal	Mainstream*	Reportable
Cepheid Xpert® Xpress SARS-CoV-2	Optimal	Strategic	Reportable
Hologic Aptima SARS-CoV-2 assay	Optimal	Mainstream*	Reportable
Roche Cobas SARS-CoV-2 RT-PCR Kit	Optimal	Mainstream*	Reportable
Other automated PCR kits eligible for procurement[3]	Optimal	Mainstream*	Reportable
MANUAL PCR TESTS			
BGI Real-time fluorescent RT-PCR kit for detecting 2019- nCoV with corresponding extraction kits[2]	Optimal	Mainstream*	Reportable
Thermo Fisher TaqPath COVID-19 CE-IVD RT-PCR Kit 911109 with corresponding extraction kits[2]	Optimal	Mainstream*	Reportable
Other manual amplification tests with corresponding extraction kits[2,3]	Optimal	Mainstream*	Reportable
SAMPLE COLLECTION			
Sample collection kit: swab and viral transport medium	Optimal	Mainstream	Reportable
Sample collection: triple packaging boxes for transport	Optimal	Mainstream	Reportable
Cepheid Xpert Nasopharyngeal swab collection kit 100	Optimal	Mainstream	Reportable
OTHER CONSUMABLES			
Extraction consumables (e.g. deep-well plate, microplate)	Optimal	Mainstream	Reportable
Filtered Pipette Tips Sterile	Optimal	Mainstream	Reportable
Other consumables	Optimal	Mainstream	Reportable

** Where contractual arrangements are already in place for PCR testing and supply of COVID-19 reagents, continued Local Sourcing is advised (as opposed to Mainstream).*

[2] 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 thermocyler is requested, details of the SARS-CoV-2 PCR assay to be used with the instrument should be indicated in the C19RM Funding Request.

[3] See Global Fund's list of SARS-CoV-2 Diagnostic test kits and equipment eligible for procurement: https://www.theglobalfund.org/en/covid-19/health-product-supply/#products

Health Product	Product use category	Procurement channel category	C19RM Procurement Progress Reporting Template
COVID-19 Molecular Test Equipment			
AUTOMATED EXTRACTORS			
BioMerieux EMAG (easyMAG) Equipment	Limited use/ Specialized	Mainstream*	Reportable
KingFisher™ Flex Purification System	Limited use/ Specialized	Mainstream*	Reportable
Qiagen QIAsymphony SP Equipment	Limited use/ Specialized	Mainstream*	Reportable
Roche MagNA pure Equipment	Limited use/ Specialized	Mainstream*	Reportable
Other automated extractors eligible for procurement[3]	Limited use/ Specialized	Mainstream*	Reportable
THERMOCYCLERS, INCLUDING RT-PCR ANALYZERS			
Applied Biosystems™ 7500 Real-Time, Fast Real-Time and Fast Dx Real-Time PCR Instrument Systems	Limited use/ Specialized	Mainstream*	Reportable
BioRad CFX96 PCR system	Limited use/ Specialized	Mainstream*	Reportable
Qiagen Rotor-Gene 5 Plex PCR system	Limited use/ Specialized	Mainstream*	Reportable
QuantStudio™ 5 Real-Time PCR System 96-well and 384-well	Limited use/ Specialized	Mainstream*	Reportable
Roche LightCycler 480 PCR system	Limited use/ Specialized	Mainstream*	Reportable
SLAN-96P PCR system	Limited use/ Specialized	Mainstream*	Reportable
Other eligible thermocyclers selected according to Instructions for Use provided by suppliers of SARS-CoV-2 manual PCR assays	Limited use/ Specialized	Mainstream*	Reportable
OTHER			
GeneXpert equipment (I, II, IV-2, IV-4, XVI-16, tablet/ desktop computer, barcode reader and aux. batteries)	Limited use/ Specialized	Mainstream*	Reportable
Magnetic stand: Manual extraction	Limited use/ Specialized	Mainstream*	Reportable
Tabletop PCR workstation with UV light	Limited use/ Specialized	Mainstream*	Reportable
UV cross linker	Limited use/ Specialized	Mainstream*	Reportable
UV transilluminator	Limited use/ Specialized	Mainstream*	Reportable
Other NEAR Point of Care equipment	Limited use/ Specialized	Mainstream*	Reportable
Spare parts, accessories, software; warranty, maintenance and service	Optimal	Local sourcing advised	Reportable

** Where contractual arrangements are already in place for PCR testing and supply of COVID-19 reagents, continued Local Sourcing is advised (as opposed to Mainstream).*

[3] See the Global Fund's list of SARS-CoV-2 Diagnostic test kits and equipment eligible for procurement: https://www.theglobalfund.org/en/covid-19/health-product-supply/#products

Table 2: Surveillance (Genomic Sequencing) and Epidemiological Investigation

Health Product	Product use category	Procurement channel category	C19RM Procurement Progress Reporting Template
SARS-CoV-2 Rapid Antibody Test kit	Limited Use/ Specialized	Mainstream	Reportable
Container, sharps	Limited Use/ Specialized	Mainstream	Reportable
Needles and syringes	Limited Use/ Specialized	Mainstream	Reportable
Reagents for sequencing (including Library Quantification kits)	Limited Use/ Specialized	Mainstream	Reportable
Sample collection kits for epidemiological investigation	Limited Use/ Specialized	Mainstream	Reportable
Equipment and ancillary equipment for Sequencing activities (i.e., centrifuge, thermoblock, Qubit, Nanodrop, etc.)[4]	Limited Use/ Specialized	Mainstream	Reportable
Triple packaging boxes for transport	Limited Use/ Specialized	Mainstream	Reportable
Spare parts, accessories, software; warranty, maintenance and service	Limited Use/ Specialized	Mainstream	Reportable

[4] Requests for sequencing equipment are not eligible for award unless the national testing strategy is adequate and the country demonstrates a minimum diagnostic capacity of 10 tests per 10,000 per week (see the C19RM Technical Information Note, including Annex 2).

Table 3: Infection Prevention and Control[5,6]

Health Product	Product use category	Procurement channel category	C19RM Procurement Progress Reporting Template
Core Personal Protective Equipment (PPE)			
Apron	Optimal	Mainstream	Reportable
Face shield	Optimal	Mainstream	Reportable
Gloves, examination (non-sterile)	Optimal	Mainstream	Reportable
Gloves, surgical (sterile)	Limited use/Specialized	Mainstream	Reportable
Goggles	Optimal	Mainstream	Reportable
Gowns, non-sterile	Optimal	Mainstream	Reportable
Gowns, sterile	Limited use/Specialized	Mainstream	Reportable
Masks, Medical/Surgical[7]	Optimal	Mainstream	Reportable
Respirator, FPP2/N95 and airflow test set	Optimal	Mainstream	Reportable
Non-Core PPE			
Boot cover	Limited use/ Specialized	Mainstream	Reportable
Boots	Limited use/ Specialized	Mainstream	Reportable
Coverall	Limited use/ Specialized	Mainstream	Reportable
Heavy-duty apron	Limited use/ Specialized	Mainstream	Reportable
Heavy-duty gloves	Limited use/ Specialized	Mainstream	Reportable
Scrubs	Optimal	Local sourcing advised	Not reportable
Surgical cap	Limited use/ Specialized	Mainstream	Reportable
Disinfectants			
Alcohol-based hand rub	Optimal	Local sourcing advised	Not reportable
Chlorine	Optimal	Local sourcing advised	Not reportable
Chlorohexidine	Optimal	Local sourcing advised	Not reportable
Hand wash (liquid)	Optimal	Local sourcing advised	Not reportable
Soap	Optimal	Local sourcing advised	Not reportable

[5] The “core” and “non-core” designation for PPE relates to the definition in the Guide to Global Fund Policies on Procurement and Supply Management of Health Products, where Quality Assurance Requirements are specified, applicable from 1 July 2021. The Guide is available from this site: https://www.theglobalfund.org/en/sourcing-management/.

[6] COVID-specific PPE is considered Optimal, while non-COVID PPE is designated as Limited Use/Specialized and requires justification. The latter is primarily for PPE use (e.g., coveralls) 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 limited use/specialized 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 on the basis of specific needs linked to sterile procedures (e.g. intubation, surgery).

[7] 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 taken into account during C19RM Funding Request quantification and development.

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

Health Product	Product use category	Procurement channel category	C19RM Procurement Progress Reporting Template
Medical oxygen – consumables			
Airway: Oropharyngeal airway, Guedel	Optimal	Mainstream	Reportable
Airway: Nasopharyngeal airway	Optimal	Local sourcing advised	Reportable
Colorimetric end tidal CO2 detector	Optimal	Local sourcing advised	Reportable
Cricothyrotomy set	Optimal	Local sourcing advised	Reportable
Endotracheal tube	Optimal	Mainstream	Reportable
Flow splitter (for oxygen concentrator)	Optimal	Mainstream	Reportable
Flowmeter (medical oxygen)	Optimal	Mainstream	Reportable
Humidifier (non-heated, reusable)	Optimal	Mainstream	Reportable
Infusion giving set	Optimal	Mainstream	Reportable
Laryngoscope (adult/child, neonate)	Optimal	Mainstream	Reportable
Nasal Cannula (high flow)	Optimal	Local sourcing advised	Reportable
Nasal Catheter (high flow)	Optimal	Local sourcing advised	Reportable
Nasal prongs (adult, child, neonate, single use)	Optimal	Mainstream	Reportable
Oxygen mask	Optimal	Mainstream	Reportable
Pulse oximeter probes (tabletop, handheld)	Optimal	Mainstream	Reportable
Resuscitator (adult, child)	Optimal	Mainstream	Reportable
Suction devices (electrical)	Optimal	Mainstream	Reportable
Tubing (suction, oxygen administration)	Optimal	Mainstream	Reportable
Medical Oxygen – equipment			
Mechanical ventilation for critical/intensive care	Optimal	Mainstream	Reportable
Mechanical ventilation for transport	Optimal	Local sourcing advised	Reportable
Non-invasive ventilation (HFNC, BiPAP and CPAP with tubing and patient interfaces)	Optimal	Local Sourcing advised	Reportable
Oxygen analyzer (electrochemical, battery-powered, handheld)	Optimal	Mainstream	Reportable
Oxygen analyzer (ultrasonic, battery-powered)	Optimal	Mainstream	Reportable
Oxygen concentrator (stationary/bedside or portable, with accessories)	Optimal	Mainstream	Reportable
Pulse oximeter	Optimal	Mainstream	Reportable
Spare parts, accessories; warranty, maintenance and service	Optimal	Local sourcing advised	Reportable
Surge suppressor	Optimal	Local sourcing advised	Reportable
Voltage stabilizer	Optimal	Local sourcing advised	Reportable

Health Product	Product use category	Procurement channel category	C19RM Procurement Progress Reporting Template
Medical Oxygen – liquid oxygen and PSA plants			
Medical gas cylinder, portable (compressed oxygen or compressed medical air, with valves and regulators)	Optimal	Local sourcing advised	Reportable
Pressure swing adsorption oxygen generator plants (incl. spare parts/accessories, warranty/ maintenance/service)*	Optimal (except for the instances below)	Local sourcing advised	Reportable
• New bulk liquid storage and piping	Limited use/Specialized	Local sourcing advised	Reportable
• Containerized or skid-mounted PSA plant(s) for cylinder filling or for piped supply	Limited use/Specialized	Local sourcing advised	Reportable
Other Health Equipment			
Blood gas analyzer	Limited use/Specialized	Mainstream	Reportable
Electrocardiogram (ECG) digital monitor and recorder	Limited use/Specialized	Mainstream	Reportable
Electronic drop counter, IV fluids	Limited use/Specialized	Mainstream	Reportable
Infusion pump	Optimal	Mainstream	Reportable
Patient monitor with ECG	Optimal	Mainstream	Reportable
Patient monitor with EKG	Optimal	Local sourcing advised	Reportable
Thermometer, non-contact	Limited use/Specialized	Mainstream	Reportable
Ultrasound	Limited use/Specialized	Mainstream	Reportable
X-ray equipment	Limited use/Specialized	Mainstream	Reportable
Spare parts, accessories; warranty, maintenance and service	Limited use/ Specialized	Mainstream	Reportable

** See Annex 4 of the C19RM Technical Information Note for more information.*

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

Health Product	Product use category	Procurement channel category	C19RM Procurement Progress Reporting Template
Dexamethasone and other steroids*	Optimal	Local sourcing advised	Not reportable
Low dose heparin sodium solution and low molecular weight heparins for injection*	Optimal	Local sourcing advised	Not reportable
Compound sodium lactate solution	Optimal	Local sourcing advised	Not reportable
Paracetamol	Optimal	Local sourcing advised	Not reportable
Other pharmaceuticals for the critical care of COVID-19 patients	Limited use/Specialized	Local sourcing advised	Not reportable

Table 6: Laboratory Systems

Health Product	Product use category	Procurement channel category	C19RM Procurement Progress Reporting Template
Laboratory equipment			
Autoclave for laboratory	Limited Use/ Specialized	Mainstream	Reportable
Biological Safety Cabinet BSL II	Limited Use/ Specialized	Mainstream	Reportable
Centrifuges	Limited Use/ Specialized	Mainstream	Reportable
Glove box	Limited Use/ Specialized	Mainstream	Reportable
Incubator	Limited Use/ Specialized	Mainstream	Reportable
Laboratory freezer	Limited Use/ Specialized	Mainstream	Reportable
Laboratory refrigerator	Limited Use/ Specialized	Mainstream	Reportable
Microcentrifuge	Limited Use/ Specialized	Mainstream	Reportable
Thermoblock	Limited Use/ Specialized	Mainstream	Reportable
Refrigerated bench top centrifuge	Limited Use/ Specialized	Mainstream	Reportable
Vortex	Limited Use/ Specialized	Mainstream	Reportable
Spare parts, accessories; warranty, maintenance and service	Limited Use/ Specialized	Mainstream	Reportable

Table 7: Health Product and Waste Management Systems[8]

Health Product	Product use category	Procurement channel category	C19RM Procurement Progress Reporting Template
Cold Chain Consumables			
Cold box	Limited Use/ Specialized	Mainstream	Reportable
Data logger	Limited Use/ Specialized	Mainstream	Reportable
Ice pack	Limited Use/ Specialized	Mainstream	Reportable
Remote temperature monitoring system	Limited Use/ Specialized	Mainstream	Reportable
~~Vaccine carrier~~	~~Limited Use/ Specialized~~	~~Mainstream~~	~~Reportable~~
~~**Cold Chain Equipment**~~			
~~Vaccine freezer~~	~~Limited Use/ Specialized~~	~~Mainstream~~	~~Reportable~~
~~Vaccine refrigerator~~	~~Limited Use/ Specialized~~	~~Mainstream~~	~~Reportable~~
~~Vaccine combined refrigerator and freezer~~	~~Limited Use/ Specialized~~	~~Mainstream~~	~~Reportable~~
Waste Management			
Autoclave	Limited Use/ Specialized	Mainstream	Reportable
Biohazard bags	Limited Use/ Specialized	Mainstream	Reportable
Container, sharps	Limited Use/ Specialized	Mainstream	Reportable
Incinerator, medical/general waste	Limited Use/ Specialized	Mainstream	Reportable
Reagents	Limited Use/ Specialized	Mainstream	Reportable
Spare parts, accessories; warranty, maintenance and service	Limited Use/ Specialized	Mainstream	Reportable

[8] The strikethrough indicates that not every health product listed in the Health Product Segmentation Framework is eligible for funding. For specific activities which can be supported, please refer to the C19RM Technical Information Note. In particular, see Systems Support Contributing to Vaccine Delivery Services (Pillar 10) (pages 26-27), Health Product Management Systems (Pillar 6) (pages 27-28) and Medical Waste Management Systems (Pillar 6) (page 29).