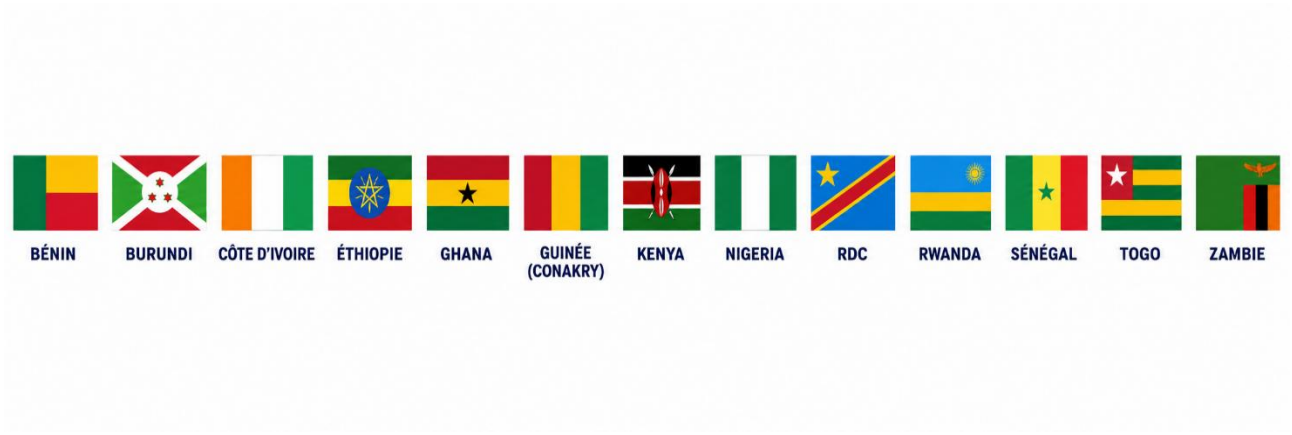

MEDISAFE 2

TERMS OF REFERENCE

Mobilisation of Individual and Organisation-Supported Consultants Providing Pharmaceutical Technical Assistance

Pharmaceutical Component (Specific Objective 3)
Combating substandard and falsified medical products (SFMP)
13 countries in West and East Africa

Reference framework

- Contracting authority: Expertise France (implementation) with European Union funding (NDICI).
- Reporting line: Pharmaceutical Component Lead (Technical Expert, Pharmaceutical Regulation and Supply Chain Security), Nairobi, in liaison with the PMU and the Expertise France liaison (Paris).
- Contracting modality: selection and contracting on an individual basis; contracts are concluded individually with each expert, on a man-day basis (see sections 2 and 3).

1. Context

Substandard and falsified medical products (SFMP) constitute a major health, economic and security threat in Africa. The World Health Organization estimates that one in ten medical products circulating in low- and middle-income countries is substandard or falsified, causing more than 250 000 preventable deaths per year. In response to this challenge, the European Union and Expertise France are implementing the MEDISAFE programme.

MEDISAFE Phase 1 (2018-2023) covered 11 countries in East and Central Africa (Burundi, DRC, Ghana, Ethiopia, Seychelles, Kenya, Uganda, Tanzania, Malawi, Rwanda and Zambia). It produced the Reference Manual on SFMP legislation (African perspective), guides and strategies on supply chain security, legislation and communication, as well as the regional roadmap against SFMP adopted by the partner countries in Nairobi in April 2022. It brought together more than 300 participants across 14 regional and national events, in partnership with the European Union (CBRN network), UNODC, INTERPOL, the Council of Europe and AUDA-NEPAD.

MEDISAFE 2.0 extends and broadens this first phase: a four-year project, funded by the European Union (NDICI) for a total amount of EUR 9 000 000, implemented by Expertise France under indirect management via a contribution agreement with the European Union Delegation in Nigeria. It covers 13 countries organised into two regional clusters.

Cluster A (West Africa): Benin, Côte d'Ivoire, Ghana, Guinea (Conakry), Nigeria, Senegal, Togo.

Cluster B (East and Southern Africa): Burundi, Democratic Republic of the Congo, Ethiopia, Kenya, Rwanda, Zambia.

In line with the action document's approach, the project distinguishes the countries that benefited from MEDISAFE Phase 1, seven of the 13: Ghana, Burundi, DRC, Ethiopia, Kenya, Rwanda and Zambia, from the newly added countries. It combines activities tailored to the maturity level of the new countries, capitalisation and consolidation on activities for the former, and cross-cutting regional activities bringing the two groups together (peer mentoring, experience-sharing, operational coordination).

Overall objective: Mitigate the health, economic and security threats posed by substandard and falsified medical products (SFMP) in West and East Africa.

The project pursues this objective through three complementary specific objectives, linked within a single theory of change and all embodying an inclusive and gender-sensitive approach:

- SO1 - National and regional legal capacities to combat SFMP are strengthened through an inclusive and gender-sensitive harmonisation of legal frameworks and the implementation of key regulations.
- SO2 - The capacity of national and regional law enforcement actors to detect, investigate and combat SFMP is strengthened through the optimisation of inclusive operational procedures, improved intelligence and the development of transnational cooperation responding to the specific needs of the most vulnerable, in particular women and children.
- SO3 - The supply chain is strengthened and secured, and public awareness of SFMP is increased, through inclusive and gender-sensitive approaches, by promoting the active role of women health professionals, women-led and caregivers organisations, in order to ensure people's safety and equitable access to safe and effective medical products.

These terms of reference fall under the pharmaceutical component (SO3), to which two outputs contribute:

- Output 3.1 - Civil society actors have raised their level of awareness and strengthened their knowledge, risk perception and preventive behaviours regarding SFMP, pharmaceutical crime and digitally enabled forms of trafficking.
- Output 3.2 - Partner countries establish and operationalise risk-based systems for traceability, post-market surveillance and regulatory control of medical products, in order to prevent, detect and respond to the circulation of SFMP in national and cross-border supply chains.

The project is entering its four-month inception phase, the culmination of which is the MEDISAFE 2 Action Plan validated by the countries and Expertise France, to be submitted to the European Union Delegation. Gender-sensitive approaches, in particular accounting for the differentiated exposure of women, men and vulnerable populations, and promoting the role of women health professionals and women-led organisations, are integrated in a cross-cutting manner.

2. Purpose and principle of mobilisation

To complement the project's core pharmaceutical expertise (the Lead Pharmaceutical Expert and the communication and awareness specialist, each recruited under separate terms of reference), MEDISAFE 2 mobilises a pool of specialised international consultants. This document describes the seven profiles sought. It serves as a call for expressions of interest: candidates apply individually, in their own name, for one or more profiles. Several experts may be retained under the same profile, according to needs.

Selection and contracting are carried out on an individual basis. Contracts are concluded individually with each expert (man-day framework contracts, activated by purchase orders according to needs), and not with consulting firms. Experts affiliated with a firm, an institute or a network may apply in their own name and are assessed on their individual CV and references. An expert invoicing through his or her own legal structure (single-person company, sole proprietorship or equivalent) applies under the same conditions: the individual is assessed and the contract designates the expert by name. An expert who does not have a structure for invoicing purposes may be administratively hosted by an organisation of his or her choice (hosting/portage arrangement): in that case, the contract and the purchase orders still designate the expert by name, the expert remains personally responsible for the deliverables, and no substitution is permitted without the prior written approval of Expertise France.

3. Common arrangements

Form of mobilisation	Individual consultant. Contracts are concluded individually with each expert, on a man-day basis, and not with firms. An expert without an invoicing structure may be administratively hosted by an organisation (hosting/portage arrangement); the contract still designates the expert by name.
Procedure	Selection of individual experts through this call for expressions of interest, in accordance with Expertise France's procurement rules (assessment of CVs, references and fee proposals); possible application for one or more profiles;

	contracting lead time to be anticipated from inception where the service supports Year 1 activities.
Reporting line	Pharmaceutical Component Lead (Technical Expert, Pharmaceutical Regulation and Supply Chain Security)
Working languages	French and English depending on the countries of intervention. Working proficiency in both languages is an asset for all profiles, as is the ability to work from reference material available in English only (WHO GBT, WHO Toolkit, GS1); language coverage across the two clusters is ensured at pool level, several experts being retainable per profile
Application	CV of the expert (individual application) + references of comparable assignments + short methodological note + proposed daily fee rate + where applicable, identification of the hosting organisation (portage)

4. Profiles sought

Each profile below specifies the purpose of the support, the expected competencies and the indicative volume. Profiles 4.3 and 4.4 may be covered by the same expertise; profiles 4.2, 4.5, 4.6 and 4.7 fall under targeted mobilisation according to the needs validated by country. For all profiles, familiarity with the WHO Global Benchmarking Tool (GBT) sub-indicators relevant to the profile is an asset.

4.1 - Supply chain security and traceability expert

Purpose of the support: Support the supply chain security assessments (based on the MEDISAFE National Pharmaceutical Supply Chain Security Guide, EU CBRN CoE Project 66, March 2024, available at https://global-threats.europa.eu/publications/national-pharmaceutical-supply-chain-security-guide_en) of at least the eight countries prioritised in Year 1 (Kenya, DRC, Côte d'Ivoire, Benin, Guinea; self-assessment for Zambia, Burundi, Nigeria), whose findings will be considered in the work plan for Medisafe 2 and will be integrated in the National Action Plan (NAP); support the activities to improve traceability and the integration of traceability and verification solutions (TRVST experience in Nigeria, Rwanda).

Expected competencies:

- Higher degree and proven experience of the pharmaceutical supply chain (PSM).
- Knowledgeable on traceability and serialisation standards (GS1) and of verification solutions.
- Experience of supply chain security assessments and of correcting findings in an African context.
- Ability to support national actors in developing and revising their own procedures (SOPs), without substituting for them.

Indicative volume: ≈ 15 days over the inception phase, extensible according to the country's needs

4.2 - Good Manufacturing, Storage and Distribution Practices (GMP/GSDP) expert

Purpose of the support: Support the assessment and strengthening of good manufacturing practices among local manufacturers, in close collaboration with the national regulatory authorities (NRAs), only where this priority is identified and confirmed by the country. Under the same conditions, support the assessment and strengthening of quality assurance systems (WHO MQAS type) and of good storage and distribution practices among targeted supply chain actors (importers, wholesalers, distributors, procurement agencies).

Expected competencies:

- GMP and GSDP inspector/auditor qualification or recognised equivalent experience.
- Experience of supporting pharmaceutical production sites and distribution/storage facilities, to implement WHO guidelines and PIC/S reference manuals (GMP, GSDP, MQAS).
- Ability to train and transfer skills to national inspectors and others NRA actors.

Indicative volume: As required (targeted mobilisation)

4.3 - Market surveillance and control (MC) and/or vigilance expert

Purpose of the support: Support the development of market surveillance and vigilance functions in NRAs including reporting systems, control of importation, signal management, risk-based market surveillance plans (one per subregion) including sampling protocols and support for the use of the results

Expected competencies:

- Proven experience on market surveillance and control of medical products.
- Knowledge of systems for market surveillance and control as described in WHO Reference documents and of the detection technologies recommended by the WHO.
- Knowledge of vigilance systems for medical products (reporting, signal detection and risk communication).
- Experience on coordinated response to SFMP between NRA – quality control laboratory - field actors coordination.

Indicative volume: ≈ 15 days (shared with profile 4.4, extensible according to the country's needs)

4.4 - Quality control laboratory (QCL) expert

Purpose of the support: Support the strengthening of the national quality control laboratories: analytical practices, contribution to market surveillance and control activities, progression towards recognition and prequalification.

Expected competencies:

- Experience of a pharmaceutical quality control laboratory and of the WHO-GPQCL, ISO/IEC 17025 standards.
- Knowledge of detection technologies and of the WHO Global Benchmarking Tool (GBT).

- Ability to support national quality control laboratories in Africa.

Indicative volume: shared with profile 4.3 (extensible according to the country's needs)

4.5 - Online pharmacy regulation and pharmaceutical cybercrime expert

Purpose of the support: Support the regulatory oversight of online medicine sales (regulations, authorisation and control), in close interface with the Law Enforcement pillar and the cyber units.

Expected competencies:

- Experience of regulating e-commerce for health products.
- Familiarity with the constitution and preservation of digital evidence in the online sale of medical products (captures, logs, traceability of findings, chain of custody) and with the conditions of handover to law enforcement services.
- Ability to link the regulatory and law enforcement dimensions.

Indicative volume: ≈ 12 days (targeted mobilisation, extensible according to the country's needs)

4.6 - National SFMP action plan (NAP) development and multisectoral coordination expert

Purpose of the support: In countries where the development of a national action plan (NAP) against SFMP is prioritised, facilitate the multisectoral development of the NAP based on the WHO handbook, building on the findings of the supply chain security assessments, up to the national validation workshops and the articulation with the African Union continental plan on SFMP.

Expected competencies:

- Proven experience of facilitating the development of national health strategies or action plans, ideally NAPs against SFMP based on the WHO handbook.
- Strong multisectoral facilitation skills (health, justice, customs, law enforcement, public agencies, private sector, civil society).
- Knowledge of the African regulatory landscape (AMRH, AMA, Regional Economic Communities).

Indicative volume: As required (targeted mobilisation from Year 1, following the supply chain security assessments; extensible according to the country's needs)

4.7 - Regulatory systems strengthening (RSS), quality management system and WHO Global Benchmarking Tool (GBT) expert

Purpose of the support: Support the national regulatory authorities in strengthening their regulatory systems and their quality management system (ISO 9001-type QMS, continuous improvement culture), using the WHO Global Benchmarking Tool (GBT) as the common reference: knowledge of the Institutional Development Plans developed after the benchmarking of NRAs, mapping of country priorities onto the GBT sub-indicators most directly linked to preventing, detecting and responding to SFMP (regulatory system, market surveillance and control, vigilance, regulatory inspection, licensing of establishments, laboratory testing,), and preparation for (re)benchmarking so that project deliverables contribute to maturity level progression. This support does not substitute for formal WHO benchmarking, and an expert supporting a country under this profile may not act as a WHO assessor for that same country.

Expected competencies:

- Proven experience of regulatory systems strengthening with national regulatory authorities in Africa; GBT qualification (WHO-trained expert or assessor) or equivalent documented practice.
- Experience of implementing quality management systems and continuous improvement approaches within public institutions, ideally national regulatory authorities for medical products.
- Ability to link GBT sub-indicators, Institutional Development Plans and national action plans into operational priorities.

Indicative volume: As required (targeted mobilisation according to the priorities validated by country under the IDP/NAP pathway)