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ANNEX 3

to the Commission Implementing Decision on the financing of the multiannual action plan in favour of Sub-Saharan Africa for 2023-2025

Action Document for Improved access to Innovative and life-saving commodities for sexual and reproductive health in Africa

MULTIANNUAL PLAN
This document constitutes the multiannual work programme within the meaning of Article 110(2) of the Financial Regulation, within the meaning of Article 23 of the NDICI-Global Europe Regulation.

1 SYNOPSIS

1.1 Action Summary Table

1. Title **CRIS/OPSYS business reference** **Basic Act**	**Improved access to Innovative and life-saving commodities for sexual and reproductive health in Africa** OPSYS number: ACT-61830 Financed under the Neighbourhood, Development and International Cooperation Instrument (NDICI-Global Europe)
2. Team Europe Initiative	Yes: Regional Team Europe Initiative on Sexual and Reproductive Health and Rights (SRHR) in Sub-Saharan Africa
3. Zone benefiting from the action	The action shall be carried out in the Sub-Saharan Africa
4. Programming document	Multi-Annual Indicative Programme for Sub-Saharan Africa (SSA Regional MIP)[1]
5. Link with relevant MIP(s) objectives / expected results	The Action is contributing to the SSA Regional MIP **Priority area 1:** Human Development **Result 1.4:** The environment for SRHR is enabled **Expected Results:** Reduction in maternal and newborn morbidity and mortality through innovative partnerships that incorporate maternal health commodities into the health system including at primary health care level.
PRIORITY AREAS AND SECTOR INFORMATION	

[1] Commission Decision adopting a multiannual indicative programme for Sub-Saharan Africa for the period 2021-2027 C(2021) 9373 final of 15.12.2021

6. Priority Area(s), sectors	Priority Area 1: Human Development DAC Code 130: Reproductive Health DAC Code 120: Health			
7. Sustainable Development Goals (SDGs)	**Main SDG: SDG 3:** Ensure healthy lives and promote well-being for all at all ages. **Target 3.1** By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births. **Target 3.2** By 2030, end preventable deaths of newborns with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births. **Target 3.B:** Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all. **Target 3.7** Ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes. **Target 3.8** Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all. **Other significant SDGs**: **SDG 5**: Achieve gender equality and empower all women and girls. **Target 5.6** Ensure universal access to sexual and reproductive health and reproductive rights as agreed in accordance with the Programme of Action of the International Conference on Population and Development and the Beijing Platform for Action and the outcome documents of their review conferences. **SDG 10:** Reduced inequalities **SDG 16:** Peace, justice and strong institutions			
8 a) DAC code(s)	**DAC code 13020** – Reproductive health care – 70% **DAC code 13081** – Personnel development for population and reproductive health – 15% **DAC code 12110** – Health policy and administrative management – 15%			
8 b) Main Delivery Channel	**30010** – Unitaid **41119** – United Nations Population Fund			
9. Targets	☐ Migration ☐ Climate ☒ Social inclusion and Human Development ☒ Gender ☐ Biodiversity ☐ Education ☐ Human Rights, Democracy and Governance			
	General policy objective @	**Not targeted**	**Significant objective**	**Principal objective**

10. Markers (from DAC form)	Participation development/good governance	☒	☐	☐
	Aid to environment @	☒	☐	☐
	Gender equality and women's and girl's empowerment	☐	☒	☐
	Reproductive, maternal, newborn and child health	☐	☐	☒
	Disaster Risk Reduction @	☒	☐	☐
	Inclusion of persons with Disabilities @	☐	☒	☐
	Nutrition @	☒	☐	☐
	RIO Convention markers	**Not targeted**	**Significant objective**	**Principal objective**
	Biological diversity @	☒	☐	☐
	Combat desertification @	☒	☐	☐
	Climate change mitigation @	☒	☐	☐
	Climate change adaptation @	☒	☐	☐
11. Internal markers and Tags:	**Policy objectives**	**Not targeted**	**Significant objective**	**Principal objective**
	Digitalisation @	☒	☐	☐
	digital connectivity digital governance digital entrepreneurship digital skills/literacy digital services	YES ☐ ☐ ☐ ☐ ☐	NO ☐ ☐ ☐ ☐ ☐	
	Connectivity @	☒	☐	☐
	digital connectivity energy transport health	YES ☐ ☐ ☐ ☐	NO ☐ ☐ ☐ ☐	

	education and research			
	Migration @	☒	☐	☐
	Reduction of Inequalities @	☐	☒	☐
	Covid-19	☒	☐	☐
BUDGET INFORMATION				
12. Amounts concerned	Budget line(s) (article, item): • 14.020120: EUR 7 000 000 • 14.020121: EUR 7 000 000 • 14.020122: EUR 6 000 000 Total estimated cost: EUR 20 000 000 Total amount of EU budget contribution: EUR 20 000 000 Ten EU Member States are involved in the SRHR TEI in SSA including BE, CZ, DE, DK, FI, FR, IE, LU, NL, SE. The combined indicative financial contributions towards the TEI amount to EUR 1.786 billion, of which 12,4 % consists of Commission ongoing and planned contributions.			
MANAGEMENT AND IMPLEMENTATION				
13. Type of financing	**Indirect management** with the entity(ies) to be selected in accordance with the criteria set out in section 4.4.1			

1.2 Summary of the Action

This regional Action is proposed in the framework of the Global Gateway Health package presented at the EU-African Union (AU) Summit in 2022 and of the Team Europe Initiative on Sexual and reproductive health and rights (SRHR) in Africa, which currently involves the Commission and ten EU Member States with EUR 1.8 billion of financial commitments. The Action will contribute to the spending target of 20% of Official Development Assistance (ODA) on human development, in line with the new European Consensus on Development[2] and the newly adopted Neighbourhood, Development and International Cooperation Instrument (NDICI-Global Europe)[3], , SDGs 3 good health and well-being and SDG 5 gender equality, and it is principally aimed at sexual and reproductive health and health systems. Its secondary objective is gender and women's equality:

The EU, its Member States, African countries, and the AU have all made ambitious commitments to reduce maternal and newborn mortality[4] in the context of the advancement of sexual and reproductive health and rights (SRHR). Maternal and newborn mortality is almost entirely preventable with good maternal and delivery care[5] yet it continues to lag behind other health indicators. Although gradually declining in most contexts, progress on reducing maternal deaths (from all causes) in many African countries is advancing too slowly or is significantly

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:42017Y0630(01)

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R0947&qid=1692287281730

[4] The number of maternal deaths during a given period per 100,000 live births during the same period. The global maternal mortality target (to reduce maternal deaths to at least as low as 70 per 100,000 live births) was agreed in 2015 in a consensus paper on Ending Preventable Maternal Mortality (EPMM) and adopted as a SDG target (SDG indicator 3.1.1). Maternal mortality is usually estimated or measured less frequently than other basic health indicators (every 3 to 5 years) and evidence would be strengthened where country civil registries and vital statistics systems were strengthened. There is a tendency in many countries to underreport maternal deaths. and https://www.who.int/health-topics/maternal-health#tab=tab_1

[5] WHO, Maternal Mortality Factsheet, 19 September 2019, Geneva. https://www.who.int/news-room/fact-sheets/detail/maternal-mortality

off track to meet the SDG target[6]. Post-partum haemorrhage (PPH) causes 25-40 % of maternal deaths globally, the majority in Africa,[7] and is also directly linked to increased stillbirths and early neonatal deaths. The average annual rate of reduction in global maternal mortality was 2.9 per cent between 2000 and 2019,[8] far short of the 10.6 % annual reduction needed to achieve global goals[9].

Saving lives at birth requires a range of targeted and focused investments to ensure health services have the tools, the skills, and the resources needed to deliver the right care to women and girls during delivery. Women and their communities need to be empowered to seek affordable care in a timely way. This is particularly the case among the most vulnerable or marginalised women including those living in remote areas, in poverty or with a disability. While an array of health system factors hamper progress in individual countries (political and financial commitment, service delivery infrastructure, willingness to attend health facilities, the availability of skilled personnel to name but a few), the lack of a well-trained midwifery health workforce and a supportive and fully functional health system that has appropriate, accessible and acceptable commodities at the point of delivery are two significant contributing factors.

Affordable tools that can prevent/treat post-partum haemorrhage (PPH) are underused. In addition, PPH commodities are being adapted for reliable use at lower levels of the health system increasing accessibility to more women experiencing a risk of haemorrhage during birth.

The Action will support a range of interventions aimed at ensuring PPH can be prevented and treated across the health system including in remote areas. It will do this by (i) generating the evidence to enable the expansion of maternal care guidance and support countries to adopt WHO service delivery protocols that reflect updated guidance; (ii) working through regional partners, increasing country procurement and use of key PPH prevention and treatment commodities especially in remote areas to improve access by vulnerable women including those living with a disability, and (iii) supporting the expansion of Africa based manufacturing and production of PPH prevention and treatment commodities in order to increase accessibility and expand reliable distribution of quality assured PPH medicines at the same or lower cost.

Through its focus on equality, the realisation of SRH rights, and on saving maternal lives, **the action will contribute to the carrying out of the EU Gender Action Plan 2021-2025 (GAP III)**,[10] in particular to its thematic areas of engagement 'promoting sexual and reproductive health and rights' and 'promoting economic and social rights and empowering girls and women'. In addition, the Action dovetails neatly with - and complements - the UNFPA Supplies Partnership programme (supported by the EU) which supplies commodities to countries in proportion to their level of need and with the MAV+ TEI which is fully focused on manufacturing essential commodities in Africa.

2 RATIONALE

2.1 Context

Overarching context. This Action centres on the reduction of maternal mortality in Africa and is situated with a context of broad commitments by both Europe and Africa to reducing preventable maternal mortality. It is proposed in the context of the new EU Global Health Strategy adopted in November 2022 which reasserts EU commitment to tackle key global health challenges and health inequalities, and in the [11] Health Package presented at the EU-AU Summit in 2022. The regional TEI on Sexual and reproductive health and rights (SRHR),[12], has strong EU Member States support (BE, CZ, DK, FI, FR, DE, IE, LU, NL, SE are members of

[6] https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(14)70227-X/fulltext#sec1
[7] PPH is categorised as a blood loss of ≥ 500mls and severe PPH is a blood loss of ≥ 1000mls after childbirth.
[8] Ending Preventable Maternal Mortality, https://www.who.int/news/item/03-09-2020-ending-preventable-maternal-mortality-online-consultation-for-coverage-targets-for-ending-preventable-maternal-mortality
[9] WHO 2023 data presented to the Nigeria Ministry of Health, February 16 2023.
[10] The Gender Action Plan III is a Joint communication by the Commission and the High Representative of the Union for Foreign Affairs and Security Policy which was welcomed through EU Presidency Conclusions of 16 December 2020. Drafting was led by European Commission in close consultation with EU Member States, EEAS, civil society organisations, partner governments, and international organisations (UN entities, International Finance Institutions among others). The different parties contributed to the drafting of the document through meetings and through responses to a survey conducted during the process.
[11] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/stronger-europe-world/global-gateway_en
[12] 'The EU remains committed to the promotion, protection and fulfilment of all human rights and to the full and effective implementation of the Beijing Platform for Action and the Programme of Action of the International Conference on Populatio and Development (ICPD) and the outcomes of their review conferences and remains committed to sexual and reproductive health and rights (SRHR), in this context. Having that in mind, the EU reaffirms its commitment to the

the TEI). Access to SRHR is fundamental for the achievement of the SDGs and the Africa Union's Agenda 2063 and vital to health[13].

EU and Global Commitments to reducing maternal deaths. African and European country governments have committed to advancing SRHR for women and girls, individuals and couples across the world. These commitments have been laid out in the Sustainable Development Goals (Goals 3 and 5) and in the Programme of Action of the International Conference on Population and Development (ICPD)[14], updated most recently through the 2019 Nairobi Summit of the ICPD 25.[15] The new EU Global Health Strategy reaffirms a commitment to uphold SRHR which has been reiterated in several Council Conclusions and EP Resolutions, and stated in the **EU Consensus for Development**. Similarly, African political and economic leadership bodies including the African Union, the Regional Economic Communities (RECs), the Africa CDC, the newly established African Medicine Agency and others have long-standing commitments to advancing the realisation of SRHR including maternal mortality reduction for all women and girls in all contexts and these are unambiguous and well-documented[16] and operationalised in the **Maputo Plan of Action.** This emphasis is expressed through the **Campaign on Accelerated Reduction of Maternal Mortality in Africa** (CARMMA) that aims to expand quality health services that are critical for the reduction of maternal mortality. Progress is tracked through the CARMMA Scorecard. RECs are guided by regional strategic frameworks aligned to continental and global commitments monitored through peer accountability mechanisms or scorecards against which Member States report on periodically at the level of Ministers of Health[17].

Persistence of preventable maternal death in Africa. Although gradually declining in most contexts, **progress on reducing maternal deaths** (from all causes) in many African countries **is advancing too slowly or is even significantly off track to meet the SDG target**. For example, across the continent, although the percentage change in the maternal mortality ratio was 33.1 % between 2000 and 2020, the average annual rate of reduction in global maternal mortality was 2.9 percent,[18] this is far short of what is needed to achieve global goals. Indeed, according to the World Health Organisation, the annual rate of reduction in maternal deaths needed to achieve the SDG target by 2030 is 10.6 %[19]. Few countries are individually on track to achieve the reduction. In addition, this rate masks significant regional (and intra-regional) disparity ranging from 525 maternal deaths per 100,000 live births across Africa to 152 in Asia and 13 in Europe. In Sub-Saharan Africa, MMR is as high as 545 maternal deaths per 100 000 live births, corresponding to an estimated 202 000 maternal deaths in the region (out of a global 287 000 maternal deaths.) The health of newborns is closely related to the health of their mothers. Almost half of all under-five deaths globally occur in the first month of life (2.3 million out of an estimated five million child deaths),[20] with a significant proportion (one in six) occurring on the day of birth[21]. More than two million stillbirths[22] occur

promotion, protection and fulfilment of the right of every individual to have full control over, and decide freely and responsibly on matters related to their sexuality and sexual and reproductive health, free from discrimination, coercion and violence. The EU further stresses the need for universal access to quality and affordable comprehensive sexual and reproductive health information, education, including comprehensive sexuality education, and health-care services.' European Consensus on Development (2017)

[13] The United Nations defines SRHR to include contraceptive services, maternal and new-born care, prevention and control of STIs, including HIV, comprehensive sexuality education, safe abortion care, including post-abortion care, prevention, detection, and counselling for SGBV, prevention and treatment of infertility and cervical cancer, and counselling and care for sexual health and wellbeing. See for example the UNFPA summary here: https://www.unfpa.org/sites/default/files/pub-pdf/SRHR_an_essential_element_of_UHC_SupplementAndUniversalAccess_27-online.pdf and the WHO approved summary in 2018 published here: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30901-2/fulltext

[14] Explain the ICPD and hyperlink

[15] https://www.unfpa.org/icpd

[16] Commitments include the African Charter on Human and People's Rights, the Maputo Protocol and the African Children's Charter. Within the Southern African Development Community (SADC) there is the Protocol on Gender and Development, the Model Law for Ending Child Marriages (2016) and the SADC SRHR Strategy (2019 -2030) and Scorecard (2020). In the East African Community (EAC) there is the Gender Equity and Development Bill, and the EAC Child Policy. The EAC Community Sexual and Reproductive Health Bill is under development and the EAC is in the process of revising its Reproductive, Maternal, Newborn, Child and Adolescent Health Policy.. The Economic Community of West African States (ECOWAS) has a supplementary Act on Equality and Rights between Women and Men for Sustainable Development, and Common Standards to Protect and Care for Children on the Move.

[17] List and reference the EAC, SADC, ECOWAS and other scorecards

[18] Ending Preventable Maternal Mortality, https://www.who.int/news/item/03-09-2020-ending-preventable-maternal-mortality-online-consultation-for-coverage-targets-for-ending-preventable-maternal-mortality

[19] WHO 2023 data presented to the Nigeria Ministry of Health, February 16 2023.

[20] UNICEF (2020) Ending Preventable Newborn Deaths and Stillbirths 2020-2030: Moving faster towards high-quality universal health coverage in 2020-2025. UNICEF, New York, 2020.

[21] https://data.unicef.org/topic/child-survival/neonatal-mortality/

[22] Newborn health is closely linked to the health of mothers in pregnancy and delivery. About 75 per cent of neonatal deaths occur in the first seven days of life and a third of these on the day of birth. Neonatal deaths are primarily caused by birth injuries and asphyxia, preterm birth, post-partum infections and birth defects. A neonatal death is defined as the death of baby that has taken at least one breath after birth and has died within seven days. About 15% of neonatal deaths occur on the day of birth. A stillbirth is the death of a foetus in utero either before or during birth. A baby is stillborn when it does not take one breath, move, or show any reaction or sign of life as they are born or thereafter. https://www.who.int/health-topics/newborn-health#tab=tab_1

every year about half of which occur during labour.[23] The newborns of women experiencing PPH are at particularly high risk of stillbirth and have an increased risk of dying within their first day or two of life[24]. Stillbirths and neonatal deaths are largely preventable with quality antenatal, intrapartum and postpartum care.

The SRHR Team Europe Initiative (TEI) creates opportunities to accelerate progress. The Team Europe initiative was launched in Kigali, Rwanda on 14 December 2022[25] to advance the Global Gateway and concentrate international EU partnerships on accelerating growth, removing barriers to progress and strengthening alignment across the European development effort to maximise the impact of combined political and economic resources for development. The overarching objective of the SRHR TEI is to 'Improve sexual and reproductive health and rights in Africa, particularly among adolescent girls and young women'.

The TEI has strong support and commitment: ten EU Member States are involved in the TEI working group[26] and the combined indicative financial contributions towards the TEI amounts to EUR 1.8 billion as of February 2023, of which 12% consists of the Commission's on-going[27] and planned[28] contributions including actions planned in this AD. Harnessing alignment and unity of purpose, the combined funding commitment to SRHR TEI objectives creates potential to achieve ambitious results on addressing structural barriers to progress.

Global Gateway and Africa-EU Partnership: Focus on SRHR (maternal health) and gender. The EU Global Gateway strategy highlights health as one of five key areas of partnership particularly focused on supply chain security and the development of local production and distribution capacities as well as through strengthening health systems which includes the better use of health commodities in service delivery. **The Global Gateway mainstreams the EU's gender strategy** (the Global Action Plan III) which includes a comprehensive approach to enabling the realisation of SRHR in all development contexts. In addition, it will contribute to other important aims including to expand the EU's international partnerships on health based on co-ownership and co-responsibility among partners. Improving health sovereignty will ensure more resilience and autonomy, both critical to sustainability. The action is consistent with the new EU Global Health Strategy[29] (GHS 2023) contributing to two of its three overarching objectives: (i) Deliver better health and well-being of people across the life course; and (ii) Strengthen health systems and advance universal health coverage.

Three Regional Economic Communities (RECs) including the East African Community (EAC), the West African Health Organisation (WAHO) of the Economic Community of West African States (ECOWAS), and the Southern African Development Community (SADC) are engaged in the TEI[30] including the co-creation of TEI objectives and priorities. Developing these relationships further, the Commission has engaged regional partners and MS in the elaboration and refinement of the action proposed in this AD. As a result of this co-creation process, and reflecting the main barriers to SRHR progress, three specific objectives have been identified for the TEI Joint Intervention Logic (JIL). These are: (i) Increased implementation of continental and regional SRHR commitments in health and education sector; (ii) Improved availability, affordability, acceptability and use of quality assured SRH commodities for all, especially women and girls and (iii) Strengthened advocacy and accountability to ensure SRHR needs are met

Addressing inequities in SRHR including access to maternal and newborn care is critical to achieving universal health coverage, protecting human rights, advancing gender equality, combating discrimination and improving the social determinants of health. Pursuing these aims lies at the heart of the World Health Organisation (WHO) mandate to support countries to achieve SDG 3 and the ICPD targets.[31]

[23] See for example, the current framework for global action on newborns: the Every Newborn Action Plan 2015-2030: https://www.who.int/publications/i/item/9789241507448

[24] Hough, A., Shakur-Still, H., Roberts, I., Koukounari, A., Lawn, J.E. and (2021), Stillbirths and neonatal deaths among 18 942 women with postpartum hemorrhage: Analysis of perinatal outcomes in the WOMAN trial. Int J Gynecol Obstet, 153: 146-153. https://doi.org/10.1002/ijgo.13413

[25] EU and African partners launch flagship initiative (europa.eu) https://ec.europa.eu/commission/presscorner/detail/en/IP_22_7738

[26] Belgium, Czech Republic, Denmark, Finland, France, Germany, Ireland, Luxemburg, Netherlands, Sweden

[27] Spotlight Africa Regional Program and Spotlight Africa countries (€ 130 million) and multi country projects from CfP on vulnerable adolescents' SRHR (€ 32 million)

[28] €60 million from the Africa MIP

[29] https://health.ec.europa.eu/system/files/2023-02/international_ghs-report-2022_en.pdf

[30] SADC (Southern African Development Community), ECOWAS (Economic Community of West African States), WAHO (West African Health Organisation), EAC (East African Community).

[31] WHO Inequality monitoring in sexual reproductive, maternal, newborn, child and adolescent health. February 2022 file:///C:/Users/sara.sotillos/Downloads/9789240042438-eng.pdf

2.2 Problem Analysis

Africa has the highest rate of death from haemorrhage during and after birth in the world. While driven by a range of factors (including late presentation at health facilities, financial barriers, long distances, poor equipment and inadequate staff training), commodity access and its correct and timely use are significant contributors as clinical and pharmaceutical interventions at the right moment can slow or stop bleeding or prevent it altogether. On the whole, African countries underutilise quality-assured[32] medicines and devices for the prevention and treatment of haemorrhage, especially post-partum haemorrhage (PPH) at primary and community levels.

There are several new and/or underutilised WHO-recommended[33] maternal health products that have the potential to address some of the major commodity related gaps in PPH care. These include tranexamic acid (TXA), Heat Stable Carbetocin (HSC), and misoprostol. Although TXA has been shown to reduce PPH mortality by 30%, uptake by governments has been slow. While it has long been used for treating trauma, TXA is relatively new in the maternal health space and there is currently no WHO prequalified product available Misoprostol has recently been recommended to enable access to PPH prevention at the lowest levels of the health system, but the drug suffers similar access issues to oxytocin and demand barriers prevent uptake at both the policy and clinical levels. HSC has the potential to overcome oxytocin access barriers for PPH prevention, but again, the uptake of new WHO recommendations has been slow. The product is under patent (with a single manufacturer). Work is needed to ensure supply security through, among other means, enabling local production. With wider uptake, these commodities (together with appropriate use of quality-assured oxytocin) would enable more comprehensive preventive and therapeutic PPH care across all levels of the health care system.

Market failures affect the supply of locally manufactured recommended commodities. Post-partum haemorrhage (PPH) prevention and treatment has typically relied on oxytocin and ergometrine, effective and inexpensive drugs that have saved many women's lives. However, ergometrine has potentially serious side effects while oxytocin is often low quality and requires a cold chain right up to the point of use that can lead to further degradation, limiting its access in rural areas or in lower-level health facilities. These factors combine to reduce the clinical value of oxytocin. A recent study found that 48% of oxytocin samples tested contained insufficient active ingredient either as a result of poor manufacturing or inadequate storage conditions[34]. These factors weaken the clinical value of oxytocin, which is otherwise an inexpensive, effective drug with few side effects. High-quality oxytocin is generally not available in primary health or community settings where a significant number of births take place. In addition, some commodities – for example, heat stable carbetocin – are currently under patent and require negotiation and knowledge transfer for local production to begin. African manufacturers face a risk-reward imbalance.

Health systems capacity and health worker training limit the effective use of available commodities. Commodities on their own cannot bring about the intended outcomes without a well-trained and fully authorised health workforce in midwifery skills, able and empowered to identify complications, provide timely clinical interventions and initial stabilisation and referrals in case of emergencies. In many health systems, skilled personnel are not adequately trained or empowered to ensure drugs are stored at the right temperature and within expiration date and then used correctly, in the right dosage and at the right time. Medical equipment is also critical as administering some IV treatments to small babies is very challenging if there is no adequate equipment.

Women with disabilities are almost one-fifth of the world's population of women and they are just as likely to be sexually active as their peers without disabilities[35] despite inaccurate stereotypical views to the contrary. Hence, they have the same SRH needs, rights, and desires as other women and girls. Due to multiple and intersecting forms of discrimination on the basis of gender and disability, however, women and girls with disabilities face unique and pervasive barriers to the full realisation of their SRHR. For example, women and girls with disabilities are deeply affected by restrictions on access to SRH[36]. Limited access to SRHR contributes to and exacerbates other restrictions faced by women and girls with disabilities including around education, employment,

[32] Quality assured in this context refers to the finished pharmaceutical product and is taken to mean prequalified under the WHO RH Medicines schemes and/or certified by a Stringent Regulatory Authority. In this instance, what is meant by 'quality assured' refers solely to the FPP and does not extend to the in-county activities needed to ensure that the products reach the final beneficiary in the intended state to ensure safety and efficacy. These additional in-country activities are of critical importance but are not within this definition of quality assured.

[33] https://apps.who.int/iris/bitstream/handle/10665/277276/9789241550420-eng.pdf https://list.essentialmeds.org/

[34] Oxytocin study: https://obgyn.onlinelibrary.wiley.com/doi/full/10.1002/ijgo.14197

[35] WHO and United Nations Population Fund (UNFPA), Promoting Sexual and Reproductive Health for Persons with Disabilities: WHO/UNFPA Guidance Note 3 6-7 (2009), https://www.unfpa.org/publications/promoting-sexual-and-reproductivehealth-persons-disabilities.

[36] S. Hameed, A. Maddams, T. Shakespeare, et al, From words to actions: systematic review of interventions to promote sexual and reproductive health of persons with disabilities in low- and middle-income countries 2 (2020), https://gh.bmj.com/ content/5/10/e002903.

and participation in public life, undermining their health, well-being, and self-esteem, and often leading to isolation, disempowerment, and infantilisation. Hence, SRHR may be a prerequisite or corollary to fulfilling other human rights and, concurrently, its realisation depends on the realisation of other rights, such as universal access, non-discrimination, freedom from violence, privacy, and information. [37]

Addressing these problems. This action will focus on **improving access to new and underused quality assured life-saving maternal health commodities**[38] primarily specific objective 2 of the SRHR TEI JIL. The Action will strengthen country partnerships with regional actors in ways that are complementary to on-going global, regional and country-based efforts in this area.

In focusing on expanding access to new and underused SRH commodities, the action responds to critical EU priorities: Advancing empowerment and **the realisation of human rights** among women and girls, and expanding opportunities for women and girls in the context of the ICPD and the EU GAP III, investing in essential pharmaceutical capacity and access in the context of the emerging EU Global Health Strategy and Global Gateway, strengthening regional partnerships, and achieving the SDGs.

The Action could **reduce inequalities and improve health outcomes** across geographies and wealth quintiles, while also contributing to **climate change mitigation** through supplies solutions that consume less energy (e.g., conservation at room temperature, regional manufacturing reducing the environmental impact of transport. In fact, it is estimated that health systems emit 5% of greenhouse gas emissions. Transport, including the logistic chain, is one important factor. With adequate planning, shipments can be mainly done by sea, reducing the necessity of emergency orders that are normally shipped by air (more polluting). The packaging can also be environmentally friendly.

Components of this Action will advance the steps most needed to remove availability and access barriers at this time:

- **Take steps to ensure evidence** around new and underused commodities is fully available, clearly appraised and can be translated into practice
- **Generate demand** for new and underused PPH products through effective advocacy, health worker training, and local, national and regional level policy updates
- **Update maternal care service delivery guidelines** and protocols (including EmONC guidelines) integrating guidance around the use of new and underused maternal health commodities for PPH (and conduct related training for health managers, pharmacists, midwives and health personnel)
- **Address regulatory and procurement barriers** to integrating new and underused commodities into health systems (and develop associated policy/ conduct related training for procurement and supply chain managers in close collaboration with National Medicines Regulatory Authorities, RECs and AUDA-NEPAD, responsible to establish the African Medicines Agency)
- **Stimulate market investments** and private sector engagement in regional manufacturing of maternal health commodities in ways that address long term access issues.

Identification of main stakeholders and corresponding institutional and/or organisational issues (mandates, potential roles, and capacities) to be covered by the action:

Primary stakeholders
As duty-bearers:
The main stakeholders in this Action include **national health and finance authorities in African countries** (including Ministries of Health and Finance, national health planners and providers, gender focal points at Ministries and health workers especially midwives), **regional and continental partners** (the RECs, the AU), partners engaged in and accountable for maternal health in the **global health system** (including United Nations agencies and partnerships and the development banks), commodity **manufacturers** and producers, and **women and girls** across the continent.

The action will support innovative partnerships to increase the availability and use of commodities in the health system, particularly at primary and community levels where women in all their diversity and girls are most at risk

[37] See U.N. Committee on Economic, Social, and Cultural Rights (ESCR Committee), General Comment No. 22: The right to sexual and reproductive health, U.N. Doc. E/C.12/GC/22 (2016) [hereinafter ESCR Committee, Gen. Comment 22].
[38] This conceptualization is fully aligned to human rights-based principles and approaches and includes the principles of availability, acceptability, accessibility, quality, etc.

during pregnancy and delivery. This includes ensuring that these commodities are incorporated into national policies and essential medicines lists and that **health care providers** have the capacity to administer them appropriately. It will generate operational evidence, strengthen supply chains, and support implementation and adherence to evidence-based practices at primary and community levels through health service provider training. Other key stakeholders related to **health systems strengthening** include the RECs, through whom much of the action will be mediated, country governments and health authorities, responsible for ensuring life-saving services are delivered, skilled health personnel, and a wide range of other actors including civil society organisations, women's associations, private sector entities, academic institutions and other development partners.

Other important stakeholders include the TEI Member States, other related TEIs (MAV+) and partners working on maternal health in a range of ways. Although addressing the regulatory barriers for innovative SRH products will primarily be supported through the MAV+ TEI[39], there will be important **synergies between MAV+ and the SRHR TEI** at the point of defining interventions for strengthening regional production and/ or manufacturing. The supply chain in this context constitutes an end-to-end approach that extends from the production, verification, registration and procurement of commodities to regulatory management, distribution, and use, including – critically – access and availability at the point of delivery whenever needed. While the processes advanced through MAV+ could have important spillover effects on PPH commodities – especially if they are a focus of WHO attention – there are a range of complementary skills, regulatory changes, institutional shifts, capacities and knowledge that this Action will promote to ensure that PPH related commodities are available, in demand, used correctly, and ultimately save the lives of women and girls (and their newborns).

Global architecture to deliver maternal health commitments

At the global level, a coalition of partners focus on policy, technical and implementation challenges to build and maintain momentum for achieving global maternal death reduction goals and these partnerships have an important role in moving new regimens from the realm of innovation to becoming best practice. While not direct stakeholders, the programmes anticipated in this Action will seek effective coordination and engagement with these key partners at global or regional or country level in order to ensure that evidence and practice resulting from the Action is fully integrated into best practice guidelines. For example, the **Ending Preventable Maternal Mortality (EPMM) initiative**, co-convened by UNFPA and WHO, seeks to 'promote and track progress towards strategic priorities for maternal health and survival and to build the necessary momentum to end preventable maternal deaths within a generation.'[40] The Every Newborn Action Plan plays a similar role in relation to newborns (and averting stillbirths).[41] Together these two coalitions form the main global arenas monitoring MNH and supporting a live agenda. While WHO sets norms and standards, UNFPA leads on implementation especially in three areas highly relevant to this Action: (i) the integration of new commodities into supply chains and service delivery processes including the 'last meters/ last mile' approach, (ii) improving competency based clinical trainings of midwives, particularly in life-saving skills, including the appropriate use of commodities to save maternal and newborn lives, and (iii) health system strengthening through the identification of national maternity unit networks, service quality improvement packages, training of regulatory authorities, data quality and data monitoring and referral mechanisms. UNFPA also supports health system resilience strengthening to climate change impact on maternal and newborn health programmes and works closely with and through the Africa RECs across the continent through its three regional offices, provides technical support to governments. in every country through its country offices. The UN's combined Human Reproduction Programme (HRP) includes all relevant agencies and programmes[42]. UNFPA's global SRH commodities programme (the UNFPA Supplies Partnership) works with countries to increase their uptake and use of SRH commodities (mainly contraceptives) primarily through the distribution of quality-assured commodities that the poorest 50+ countries can access largely at no cost or at very low cost. The Supplies Partnership stocks PPH medicines but is not resourced or mandated to change

[39] MAV+ (Manufacturing and Access to Vaccines, Medicines and Health technology products in Africa)

[40] As the central global vehicle for maternal health policy and practice, the Ending Preventable Maternal Mortality includes leading maternal health actors: FCI Program of Management Sciences for Health (MSH), Jhpiego, the Maternal and Child Survival Program (MCSP), United Nations Population Fund (UNFPA), UNICEF, United States Agency for International Development (USAID), White Ribbon Alliance (WRA) and the World Health Organization (WHO) in addition to the MHTF (UNFPA). https://www.mhtf.org/projects/ending-preventable-maternal-mortality/

[41] Every Newborn Action Plan 2015-2030 was developed under the guidance of a thirteen-member steering group and a wide range of partners (p.56): https://www.who.int/publications/i/item/9789241507448

[42] HRP (the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction) is the main instrument within the United Nations system for research in human reproduction, bringing together policy-makers, scientists, health care providers, clinicians, consumers and community representatives to identify and address priorities for research to improve sexual and reproductive health. HRP is based at the WHO headquarters in Geneva, Switzerland. It supports and coordinates research on a global scale, synthesises research through systematic reviews of literature, builds research capacity in low-income countries and develops dissemination tools to make efficient use of ever-increasing research information. https://www.who.int/teams/sexual-and-reproductive-health-and-research-(srh)/human-reproduction-programme

their use-case based on improved knowledge (that is a WHO role). In addition, however, the EU Action could help boost demand for UNFPA resourced commodities while also stimulating wider availability and procurement through local manufacturers.

Partnerships

In relation to commodity production and regulatory management, **Africa CDC** and **AUDA-NEPAD**, as key agencies of the African Union, are partners with the designated mandate to strengthen disease surveillance and management, pharmaceutical manufacturing, and regulatory strengthening and harmonisation in Africa, working closely with regional economic commissions. In a complementary action, the **Reproductive Health Supplies Coalition (RHSC)** hosts a Maternal Health Caucus bringing together a wide network of more than 50 public and private sector partners engaged in maternal health commodity development and use. The Caucus shares information around discovery, development, regulatory, service delivery and other stages across the end-to-end process linked to the supply of commodities.

In terms of catalytic activities, **Unitaid** has initiated a maternal health portfolio of grants that includes a programme to (i) support adoption of new and underused PPH drugs at various level of the health care system in high-burden countries, (ii) generate evidence around feasibility and cost-effectiveness of delivery and models of care, and (iii) inform and actively support improvements on the supply-side.

As Right-holders

Direct beneficiaries and key stakeholders are women and girls in all their diversity throughout the reproductive life course as well as their families, especially newborns and young children.

Women's human rights associations, CSOs, ethnic and religious groups.

Media, including social media, plays critical role in changing social norms and behaviours among mass. With an aim to raise awareness and transformative changes in behaviour and social norms, the partnership with media will ensure reporting of sexual and reproductive health practices.

3 DESCRIPTION OF THE ACTION

3.1 Objectives and Expected Outputs

The **Overall Objective** of this action is to reduce preventable maternal and perinatal mortality in Africa.

The **Specific Objectives** of this action are to:

1. Generate evidence on impact, feasibility, acceptability, and cost-effectiveness of delivery models for priority PPH drugs to accelerate country uptake, informing both global policy guidelines and country operational arrangements.
2. Leverage regional platforms to increase the capacity of the national health systems to roll out the use of new and underused quality assured PPH commodities (medicines, medical supplies, devices and equipment) for the prevention and treatment of PPH especially within primary health care settings, building on country experience where relevant.
3. Improve access to affordable, recommended quality-assured commodities to prevent and treat PPH in Africa, especially through manufacturers in Africa.

The **Outputs** to be delivered by this action contributing to the corresponding Specific Objectives are:

Contributing to Specific Objective 1: Generate evidence on impact, feasibility, acceptability, and cost-effectiveness of delivery models for priority PPH drugs to accelerate country uptake, informing both global policy guidelines and country operational arrangements

1.1 Support the adoption of new and underused PPH drugs at various levels of the health system in two countries (Nigeria and Zambia)

1.2 Generate sufficiently strong evidence around the feasibility and cost-effectiveness of new and underused commodities to support an update to maternal care guidelines issued by WHO

Contributing to Specific Objective 2: Leverage regional platforms to increase the capacity of the national health systems to roll out the use of new and underused quality assured PPH commodities (medicines, medical supplies, devices and equipment) for the prevention and treatment of PPH especially within primary health care settings, building on country experience where relevant.

2.1 National-level documents updated to be concordant with WHO guidelines and harmonised so that national policy managers, supporting partners, providers as well as CSOs and community groups are receiving consistent and harmonised information.

2.2 Skilled health personnel trained to increase the practical use of new and underused commodities at primary and community levels including through self-care using gender transformative approaches and in line with WHO recommendations

2.3 Additional regionally supported activities to reinforce an integrated approach in countries to address access barriers depending on specific country needs.

1. **Contributing to Specific Objective 3:** Improve access to affordable, recommended quality-assured commodities to prevent and treat PPH in Africa, especially through manufacturers in Africa

3.1 Strengthened procurement management of PPH commodities in collaboration with regional procurement mechanisms of EAC[43], ECOWAS/WAHO[44], SADC and the UNFPA Supplies Partnership
3.2 Establishment of the Manufacturers for Maternal Health Initiative (AM4MH) to advance a market-based approach that aligns and balances intellectual property, technology transfer, quality, and regulatory systems for increased production of value-for-money PPH commodities in Africa.

3.2 Indicative Activities

Activities contributing to Output 1.1

- The Action will support a large-scale demonstration project with embedded operational research in two high maternal mortality burden countries (Nigeria and Zambia). Activities will include co-designing a learning agenda with key country stakeholders, evidence gathering, technical and policy analysis and implementation research.

Activities contributing to Output 1.2

- Technical, policy analysis and practical programmatic assistance to support the preparation and presentation of evidence, multi-country meetings, decision-making processes, and communication.

Activities contributing to Output 2.

- Support to countries to update maternal care service delivery guidelines and protocols to enable new and underused commodities to be incorporated into care during birth through technical assistance and support to meetings and regional leadership with gender base approach.
- Updated guidelines will be rolled out across country health systems to district and local facility levels including similar activities but within individual countries.

Activities relating to Output 2.2

- In-service training programmes for skilled health personnel in countries, especially midwives and supply chain personnel in primary and community settings, and where possible, training of community health workers in the use of new commodities for the prevention and treatment of PPH primarily through in-person and online training modules, supportive supervision and the preparation of written guidelines with gender transformative approaches where relevant.

[43] EAC Member States have agreed (September 2022) to establish a pooled procurement mechanism for reproductive health commodities, contributing to the regional supply value chain being promoted under AfCFTA
[44] Regional Financial Mechanism of Reproductive Health Commodities of ECOWAS, funded by DE (KFW), NL, FR (AFD) and Gates Foundation

- The guidance around integrating and using new and underused PPH commodities will also be incorporated into pre-service training and skill development programmes primarily through technical assistance for the preparation of written guidelines and practical training modules

Activities relating to Output 2.3

- Technical assistance, coordination, meetings and practical support to ensure the programme optimises compatibility with a health system strengthening approach in all targeted countries and to enable regional partners to identify and make adjustments in light of country specific needs beyond what is set out in 2.1 and 2.2.

Activities relating to Output 3.1

- Technical assistance with and through regional bodies will enable work with countries to align policies and incorporate PPH commodities into pooled procurement processes and to ensure other partners, notably the global UNFPA Supplies Partnership and other established procurement mechanisms, and provide technical support to increase uptake of new and underused commodities from regional manufacturers where possible
- Technical contributions to regulatory harmonisation initiatives within (and across) the RECs to ensure alignment on principles and prioritisation of PPH commodities in implementation of strengthened regional quality assurance mechanisms (in collaboration with WHO RPQ) in order to accelerate access to products from regional manufacturers. [45]

Activities related to Output 3.2

- Technical support, partnerships, awareness raising among women and girls in all their diversity, men, and traditional and religious leaders, practical assistance for the development of public-private engagement will facilitate and increase participation of regional manufacturers in competing for tenders, improving quality, and lowering prices.
- Technical, coordination and operational support to develop and implement funded action plans to advance the production capabilities of specific manufacturers for selected PPH products in objectively determined countries in South, East and West Africa including the deployment of relevant market shaping tools and secure access terms to ensure accelerated market entry and sustained availability of quality-assured products developed/commercialised through these interventions.

The commitment of the EU's contribution to the Team Europe Initiative to which this action refers, will be complemented by other contributions from partners following a Team Europe approach. It is subject to the formal confirmation of each respective member's meaningful contribution as early as possible. In the event that the TEI's and/or these contributions do not materialise, the EU action may continue outside a TEI framework.

3.3 Mainstreaming

Environmental Protection & Climate Change
Outcomes of the SEA screening. The Strategic Environmental Assessment (SEA) screening concluded that no further action was required.
Outcomes of the EIA (Environmental Impact Assessment) screening. The EIA (Environment Impact Assessment) screening classified the action as Category C (no need for further assessment).
Outcome of the CRA (Climate Risk Assessment) screening. The Climate Risk Assessment (CRA) screening concluded that this action is no or low risk (no need for further assessment)

Gender equality and empowerment of women and girls
As per the OECD Gender DAC codes identified in section 1.1, this action is labelled as G1. This implies that the programme will make a significant contribution to gender equality. It will do this through contributing to strengthening women's and girls' sexual and reproductive health and rights (SRHR) in the context of the SRHR TEI. The Action aims to build partnerships across Africa to support and increase safe delivery for women and girls, reducing the risk of death for mother and infant and improving prospects for a healthy life. Together with better access to contraceptive services, safe delivery enables women and girls to choose with confidence whether, when and how many children to have while improving maternal outcomes and enabling newborns to better thrive.

45 This area of work will be implemented in close collaboration with the MAV+ programme with WHO to ensure complementarity

Managing safe delivery is part of a package of care that enables women to control their lives, realise their rights and build their own futures.

Human Rights

The Action supports the realisation of human rights through its focus on the sexual and reproductive rights of women and girls. Specifically, the action will invest in broadening the tools available to avert preventable deaths in women and their newborns, strengthening services and expanding choices around both prevention and treatment of PPH, a leading cause of injury and death among women of reproductive age.

Disability

As per OECD Disability DAC codes identified in section 1.1, this action is labelled as D1. This implies that the action is relevant for inclusion of persons with disabilities in two ways. Firstly, the Action targets all women and girls in underserved and hard to reach areas including those women and girls living with a disability. The rights of women to expect quality of care during delivery extends to those who live with a disability. In addition, maternal health emergencies can lead to disabilities including through extreme blood loss, stroke, and obstetric fistula. Quality maternal care contributes to reducing some types of disability.

Reduction of inequalities

The inequalities in relation to maternal and newborn health are well documented and have been referenced. They are multidimensional in nature and compound in effect. Inequalities can begin before birth and include socioeconomic factors affecting health and nutrition, geographic and employment factors that affect access to essential services (health and social services) and others. Intergenerational effects can result in children failing to improve their life chances relative to their parents, a situation that is overwhelmingly determined by educational attainment.

Inequalities are horizontal as well as vertical and drivers of inequality reinforce structural barriers to progress. For example, women in the lower quintiles are more likely to be living in rural, underserved, overcrowded, poor or other marginal areas or to have less access in real terms to quality health information and services. Such services would empower women to avoid or time their pregnancies, the foundation of safe pregnancy and birth. In addition, access to quality information and services would enable and encourage women to seek out sufficient antenatal care (ANC) and deliver in a safe setting. Inequality makes it much harder for women and girls to access the health care they need in a timely way.

On a systems level, investment into health services across the national system is often uneven with more invested into doctor-led services delivered in referral hospitals in urban areas relative to primary care, nurse-delivered services, and areas that would be considered rural or peri-urban slums. Inequality in health systems investments also affects health staff and inadequate training leaves staff with insufficient knowledge to deliver quality care at birth. Indeed, in some cases, staff are documented as being hostile and abusive to women and girls in labour and the impact on demand for services is negative. This is an equity issue related to training, experience of supportive supervision, terms and conditions of service, deployment and retention and is one of the main determinants of quality of care (and thus equitable access to care).

Democracy

Government commitments to raising tax and using available resources for the delivery of quality services in support of health and well-being is a reasonable expectation of women and men in the context of modern democratic processes. In addition, accountability for quality of care, including accountability where women and infants have unnecessarily died during delivery is vital for a functioning democracy.

Conflict sensitivity, peace and resilience

Needs increase in conflict settings. The restoration of basic services of adequate quality can support and reinforce peace arrangements. The Minimum Initial Service Package (MISP) guides the delivery of SRHR services in the immediate response to a humanitarian and/or conflict setting. Quality maternal services are a critical element of this package. Typically, about 4% of a population will be pregnant and many women and girls may not have received sufficient ANC care if they have been internally displaced. More women and girls will be vulnerable to complications during birth and will need as much quality care – including new and underused maternal health commodities – as possible.

Disaster Risk Reduction
No specific or direct contribution to DDR. However, having coherent guidelines, trained health staff and practical, accessible tools and commodities to manage maternal health care including the prevention and treatment of maternal emergencies in the context of a resilient health system is relevant to reducing the impact of disasters and the risks to maternal and newborn health. Specifically, the Action aims to scale up the use of commodities for PPH prevention and treatment which do not need refrigeration and those that could be suitable for self-care, both of which will make maternal care and the prevention of maternal deaths easier during and after disasters, reducing impact and saving lives during periods of service disruption and difficult transport.

3.4 Risks and Lessons Learnt

Category	**Risks**	**Likelihood (High/ Medium/ Low)**	**Impact (High/ Medium/ Low)**	**Mitigating measures**
External environment	**Risk 1:** Country governments fail to increase their investments into health systems more broadly in ways that strengthen maternal and newborn health	**Medium**	**Medium**	On-going dialogue and advocacy by all partners around political and financial commitment to health especially by UN agencies and EUDs. To be effective, these efforts should focus on empirical evidence.
Planning, processes and systems	**Risk 2**: Available quality assured PPH medicines and medical equipment are not imported and/or distributed in sufficient quantities to impact overall maternal health outcomes related to PPH	**Medium**	**Medium**	Advocacy around the evidence of increased effectiveness, overall health cost savings, improved quality of life outcomes. Much stronger/more developed adverse event reporting and pharmacovigilance mechanisms to build evidence of causal links between product quality and health outcomes.
To people and the organisation	**Risk 3**: Health staff leave the health services after training, or they fail to apply their training in ways that support improved quality of maternal care	**High**	**Medium**	Support health staff to implement training; advocate for supportive supervision; include empowerment tools and skills in training to enable staff to use their new knowledge and skills, push for adequate recognition of relevant training in local healthcare systems
To people and the organisation	**Risk 4:** Quality of locally produced commodities remains sub-standard and/ or costs remain high or even increase	**Medium**	**High**	Focus on critical quality issues. Deploy supply side market interventions to ensure quality and cost barriers are addressed. Support national procurement processes and

				UNFPA Supplies Partnership to scale up orders and negotiate costs (where applicable). Use de-risking strategies to kickstart a virtuous cycle of quality improvement and cost reduction.
To legality and regulatory aspects	**Risk 5**: Insufficient numbers of African based pharma companies, partners and manufacturers are willing to take steps required to engage in the specialised production that improves quality of PPH commodities at reasonable cost	**Medium**	**Medium**	Active engagement of manufacturers through regional manufacturer associations. Present business case to encourage manufacturers to participate in AM4MH initiative. Align AM4MH activities with other manufacturing support initiatives by the implementing entity and other partners like GIZ, the Global Fund and USAID. Identify bespoke interventions where possible to encourage individual manufacturers to participate.

Lessons Learnt:

Lessons concerning maternal care and the prevention and treatment of maternal and newborn emergencies:

Saving lives at birth requires targeted and focused investments to ensure health services have the tools, the skills, and the resources needed to deliver the right care to women and girls during delivery. While an array of health system factors hamper progress in individual countries (political and financial commitment, service delivery infrastructure, willingness to attend health facilities, the availability of skilled personnel to name but a few), the lack of a well-trained midwifery health workforce and a supportive and fully functional health system that has appropriate, accessible and acceptable commodities at the point of delivery are two significant contributing factors. Affordable tools that can prevent/treat post-partum haemorrhage or save the suffering baby, like incubators, monitors, respiratory equipment (e.g., CPAP) are also life-saving investments. It is essential to identify those pregnant women on high risks and prevent rather than treat. This pivots on the availability of the right commodities, the acceptability of these commodities to women, and their correct use by trained skilled health personnel at the right time to save lives. It also relies on women feeling empowered to seek care early and to reach the right level of care when they need it. Working on commodity availability is a critical dimension of saving maternal and newborn lives; however, it needs to be embedded in a comprehensive approach to maternal care improvements and clearly linked to broader systems strengthening actions. This should be factored into the choice of partner and the role of key stakeholders.

Lessons concerning the use of commodities for the prevention and treatment of PPH:

The supply and use of, and the demand for new and underused commodities draws on lessons especially related to what has not worked including the barriers to using new/ underused commodities at primary health care level and in low resource settings. TXA, misoprostol and HSC, along with high-quality oxytocin all have a role to play in an essential package of PPH care. For PPH prevention, HSC offers an appropriate option when the quality of oxytocin cannot be guaranteed, as it can be stored at room temperature without cold chain – which is a common challenge in the African context. Misoprostol provides a valuable oral option that can be used at lower levels of the health system where injection is not possible, including community health worker or self-administration in circumstances where a

woman is likely to deliver outside of a formal health setting (e.g., at home). TXA has been proven to decrease PPH by 30% and is now considered as an essential component of PPH treatment standard of care although it is not widely used in resource constrained settings yet. Expanding access to and utilisation of these commodities – as well as implementing the integration of oxytocin in the cold chain that is very well developed for vaccines (and was heavily supported during COVID-19)[46] - has the potential to significantly reduce maternal deaths and stillbirths caused by PPH, especially at the peripheral end of the health system where getting assistance during a maternal health emergency can take too long. If fully deployed in African countries, these products could meaningfully improve the prevention and treatment of maternal health emergencies and significantly reduce maternal mortality[47].

Lessons concerning the active engagement of Africa based PPH-related commodity manufacturers:

A number of lessons emerge from past experience that shape understanding about identifying and overcoming barriers to manufacturing, procuring and distributing different commodities. Manufacturers respond to market forces unless they are incentivised in another direction. Maternal care commodities are technically challenging to produce at the required quality standard and may not be needed in sufficient quantities to interest manufacturers sufficiently. It may cost too much given the low number of orders for manufacturers to produce commodities at low enough prices to be competitive. Solutions include using volume guarantees and pooled procurement mechanisms to incentivise manufacturers while technology transfer and other interventions can support quality improvements. Various interventions in the past have helped scale up the production of cost-effective commodities for HIV treatment, increase manufacturer willingness to produce low volume specialised commodities for paediatric AIDS treatment, to expand production of anti-malarials locally in Africa and to make new classes of contraceptives economically accessible to poorer countries. Unitaid, through an ongoing investment in Kenya, has delivered the first WHO prequalified sulfadoxine pyrimethamine tablets in sub–Saharan Africa for the prevention of malaria in pregnancy. Additional work is ongoing with two manufacturers in Nigeria led to two submissions for WHO prequalification, which will deliver two additional regional sources of this product if approved.

3.5 The Intervention Logic

The underlying intervention logic for this action is that:
IF sufficient evidence is gathered to demonstrate operational feasibility and cost-effectiveness of new and underused maternal health commodities in both preventing and treating post-partum haemorrhage (PPH) **AND** that evidence is high quality and robust

IF WHO promotes and, where suitable, updates its operational guidance to reflect this evidence **AND** countries efficiently adapt their own maternal health guidance and any related or necessary regulatory and procurement systems, to reflect WHO recommendations, **AND** this transformed regulatory and supply environment leads to increased procurement and effective use of quality assured PPH commodities,

THEN in practical terms, it is reasonable to expect that there will be increased uptake of WHO PPH recommendations, including around new, underused and quality-assured commodities;

At the same time-

IF maternal health care protocols, including for EmONC, and service delivery guidance in countries are updated to incorporate new and underused quality assured PPH commodities **AND** that guidance is disseminated throughout the health system,

IF health workers are trained in the practical use of new PPH commodities especially at primary and community levels including through self-care **AND** every woman, including those living with disabilities or in other ways experiencing vulnerabilities, is able to benefit from the most appropriate PPH commodities during delivery,

46 Additional resource for this recommendation: https://apps.who.int/iris/bitstream/handle/10665/311524/WHO-RHR-19.5-eng.pdf
47 Unitaid modelling on impact of its current portfolio of PPH investments (using the MANDATE tool) estimated up to 22,000 [12,500–50,000] maternal lives saved in African and India by 2031 - an 11% [6%–24%] reduction in worldwide PPH maternal mortality.

THEN there is an increased possibility that new and underused PPH commodities will be used more systematically during delivery especially at primary level and in remote geographical areas where they can have the greatest impact; where correctly used PPH commodities can avert PPH and save the lives of mothers and newborns.

Furthermore-

IF the regional procurement mechanisms led by EAC, WAHO/ECOWAS, and SADC are strengthened such that countries procure and distribute increased supplies of new and underused PPH commodities **AND IF** beneficiary governments of the UNFPA Supplies Partnership prioritise the availability of already existing quality assured PPH medicines such that countries procure and distribute increased supplies of new and underused PPH commodities more systematically to increase the availability of quality assured PPH medicines especially to primary level **AND** supply chains are strengthened and managed better to ensure consistent supplies,

IF efforts to broaden private investment and strengthen local production of quality-assured PPH commodities increase - and increasingly satisfy - demand for better value, quality-assured PPH commodities **AND** these commodities are procured by countries and donors and systematically distributed across the health system to the last mile,

THEN an adequate quantification, (which pools country needs to take advantage of economies of scale), of quality assured products that are more reasonably priced will be available in more countries, in all geographies within countries, and at all levels of service delivery.

Thus-

IF all these outputs are achieved and, bearing assumptions, all outcomes are advanced, **THEN** fewer women and girls, including women and girls living with a disability or experiencing other vulnerabilities as well as those living in rural and difficult to access areas, will suffer from or die of post-partum haemorrhage. Deliveries will be safer, women will be healthier, have better birth experiences, and given the close relationship between the health of mother and infant, their babies will also be less likely to die during or shortly after birth as well.

Contribution to the SRHR TEI Joint Intervention Logic. As noted, the action responds to the TEI Joint Intervention Logic (JIL) primarily its 2nd Strategic Objective (*Improved availability, affordability and acceptability of quality assured SRH-commodities for all, especially women and girls*). In this action, attention will be focused on maternal health commodities thereby reducing preventable maternal and infant deaths and disabilities. The action will also contribute to its 1st Strategic Objective (*Increased implementation of continental and regional SRHR commitments in health and education sector*), particularly to support the achievement of the Maputo Plan of Action (for RMNCAH) and to enable governments to increasingly fund and deliver quality SRHR through primary health care within a UHC approach. And it will also contribute to its 3rd Strategic Objective (*Strengthened advocacy and accountability to ensure SRHR needs are met)*, especially to support the expansion of regional research programmes.

Aspects of this action complement the MAV+ TEI. For example, specific objective 3 includes the aim to expand the local production of PPH commodities with positive effects on quality and cost.

Criteria for determining geographic scope. The Action is regional in scope and will be delivered and/or mediated primarily through regional partners including Regional Economic Communities (RECs) and continent-wide partners, primarily the Africa Union (AU). Therefore, all countries in a region should be encouraged to engage with the programme and benefit from it. Some outputs will be delivered in specific countries, notably SO2, concerning health systems strengthening for improved prevention and treatment of PPH includes training of health care workers and the adoption of WHO guidelines by national health care authorities and so on. The countries where these activities will be undertaken are in the process of being selected (bearing in mind the available budget). While not finalised, the criteria to be taken into account for selection will include:

- **Geography**: all the African regions will be included in a balanced way.
- **Need**: high maternal mortality will be factored in.
- **Political will**: countries with manifest and proven political will to address PPH issues, as reflected in tangible efforts and concrete commitments
- **Future oriented**: priority given to countries with a track record of adopting innovations, absorbing and supporting reforms, leading and advocating for better use of tools and innovations to address health challenges especially for mortality reduction.
- **Feasibility**: feasibility of implementing priority PPH drugs in the local health system including adequate workforce and functioning supply chains

- **Politically stable environment**: countries with broad stability to enable effective engagement and activities to be undertaken
- **Gender focused**: actively engaged on expanding gender equality and increasing access to SRHR.
- **Active health sector coordination**: Health sector partners - including UN agencies, GHIs and bilateral partners - are engaged in a meaningful process that strengthens coordination, alignment and harmonisation of programmes to reduce duplication and boost efficiency

EUDs will be consulted, and weightings will be applied to the criteria in due course. While these are not finalised, weight will be given to countries that host one of the RECs, countries where EUDs express interest, and countries which are actively engaged in tackling gender equality and reducing maternal mortality.

3.6 Logical Framework Matrix

This indicative logframe constitutes the basis for the monitoring, reporting and evaluation of the intervention.
On the basis of this logframe matrix, a more detailed logframe (or several) may be developed at contracting stage. In case baselines and targets are not available for the action, they should be informed for each indicator at signature of the contract(s) linked to this AD, or in the first progress report at the latest.
New columns may be added to set intermediary targets (milestones) for the Output and Outcome indicators whenever it is relevant.

- At inception, the first progress report should include the complete logframe (e.g. including baselines/targets).
- Progress reports should provide an updated logframe with current values for each indicator.
- The final report should enclose the logframe with baseline and final values for each indicator.

The indicative logical framework matrix may evolve during the lifetime of the action depending on the different implementation modalities of this action.
The activities, the expected Outputs and related indicators, targets and baselines included in the logframe matrix may be updated during the implementation of the action, no amendment being required to the Financing Decision.

Results	Results chain (@): Main expected results (maximum 10)	Indicators (@): (at least one indicator per expected result)	Baselines (values and years)	Targets (values and years)	Sources of data	Assumptions
Impact[48]	To reduce preventable maternal and perinatal mortality in Africa	1 Maternal mortality ratio (Sub-Saharan Africa countries) SDG 3.1 2 Neonatal death rate (Sub-Saharan Africa countries) SDG 3.2 3 Number of countries with laws and regulations that guarantee full and equal access to women and men aged 15 years and older to sexual and reproductive health care, information and education (SDG 5.6.2).	1tbd 2 tbd	1 tbd 2 tbd	1 Interagency Committee estimates (WHO) 2 Interagency Committee estimates (WHO)	*Not applicable*
Outcome 1	Evidence on impact, feasibility, acceptability, and cost-effectiveness of delivery models for priority PPH drugs to inform global and national operational guidelines generated.	1.1 WHO PPH implementation guidelines revised, informed by target country data (Nigeria, Zambia) 1.2 Number of target countries with key strategic documents (national and sub-national) updated / developed in line with global (WHO) guidance 1.3 Number of target countries with registrations of new and underused PPH	1.1 tbd 1.2 tbd 1.3 tbd	1.1 tbd 1.2 tbd 1.3 tbd	1.1 WHO 1.2 UNITAID annual reporting/UNFPA annual reporting 1.3 Unitaid annual reporting/ RECs	

[48] Note that impact level indicators are aspirational, may not be seen within life of the project, and will not be considered as a marker of programmatic success

		products (HSC, TXA, misoprostol) authorised for the appropriate PPH indication				
Outcome 2	The capacity of the national health systems to better use the new and underused commodities (medicines, medical supplies and equipment) for the prevention and treatment of PPH especially within primary health care settings increased.	2.1 Number of countries implementing updated guidelines that reflect the availability of new and underused PPH commodities. 2.2 Percentage of population able to access services delivered by health workers trained in using newly approved or underused PPH commodities (disaggregated by country and health worker type). 2.3 Percentage of service delivery points with no stock outs of PPH commodities (disaggregated by commodity and level of care). 2.4 Number of countries with HMIS and/or LMIS that integrate PPH commodities.	2.1 tbd 2.2 tbd	2.1 tbd 2.2 tbd	2.1 UNFPA 2.2 UNFPA drawing on national health data 2.3 National health pharmaceutical data	
Outcome 3	Access to affordable quality-assured recommended commodities to prevent and treat PPH in Africa, especially through manufacturers in Africa improved.	3.1 Proportion of quality assured targeted PPH commodities sourced from local manufacturers compared to imported products 3.2 Number of African pharmaceutical companies with quality assured products bidding for PPH commodity tenders (either all or selected PPH commodities from the WHO essential pharma list, disaggregated by product)	tbd	tbd	3.1 Implementing entity 3.2 Implementing entity	
Output 1 relating to Outcome 1	1.1 Evidence generated to support updated implementation guidelines issued by WHO for the prevention and treatment of PPH	1.1.1 Number of women and girls reached with new and underused PPH commodities in study countries. 1.1.2 Number of commodities included in WHO guidance for PPH at primary level disaggregated by **prevention** and **treatment**	1.1.1 tbd 1.1.2 tbd	1.1.1 tbd 1.1.2 tbd	1.1.1 Unitaid from the AMPLI PHII study 1.1.2 Unitaid/ UNFPA	
Output 2 relating to Outcome 1	1.2 Regulatory and procurement guidance generated to support regional scale up of new or underused PPH commodities in countries	1.2.1 Number of regions hosting evidence appraisal events to support countries to consider new evidence and adapt national protocols	1.2.1 tbd	1.2.1 tbd	1.2.1 RECs/ Implementing entity	

		1.2.2 Number of countries participating in regional events to appraise evidence about new and underused PPH commodities	1.2.2 tbd	1.2.2 tbd	1.2.2 RECs/ Implementing entity	
Output 1 relating to Outcome 2	2.1 National-level documents updated to be concordant with WHO guidelines and harmonised so that national policy managers, supporting partners, providers as well as CSOs and community groups are receiving consistent and harmonised information.	2.1.1 Number of countries that have undertaken collaborative processes to update their maternal care protocols to harmonise them with WHO guidance 2.1.2 Number of countries that have updated their maternal care protocols to reflect additional or newly approved commodities for PPH prevention and/ or treatment	2.1.1 tbd 2.1.2 tbd	2.1.1 tbd 2.1.2 tbd	2.1.1 RECs and UNFPA 2.1.2 UNFPA	
Output 2 relating to Outcome 2	2.2 Skilled health workers trained in the practical use of new and underused commodities at primary and community levels including through self-care	2.2.1 Number of training events by region and by country 2.2.2 Total number of health workers trained (disaggregated by country and health worker type)	2.2.1 tbd 2.2.2 tbd	2.2.1 tbd 2.2.2 tbd	2.2.1 RECs/ UNFPA 2.2.2 UNFPA/ RECs	
Output 1 relating to Outcome 3	3.1 Strengthened procurement management of PPH commodities in collaboration with regional procurement mechanisms of EAC[49], ECOWAS/WAHO[50], SADC and the UNFPA Supplies Partnership are strengthened	3.1.1 Number of PPH commodities included in regional pooled procurement mechanisms 3.1.2 Volume of commodity ordered through pooled procurement arrangements (or volume guarantee mechanisms) disaggregated by country and commodity.	tbd	Tbd	3.1.1 RECs and UNFPA 3.1.2 Implementing entity	
Output 2 relating to Outcome 3	3.2 Establishment of the Manufacturers for Maternal Health Initiative (AM4MH) to advance a market-based approach that aligns/ balances intellectual property, technology, quality, and regulatory systems for increased production of value-for-money PPH commodities in Africa.	3.2.1 Number of commodity manufacturers producing one maternal health commodity from the WHO recommended essential list. 3.2.2 Quantity of maternal health commodity manufactured in Africa that is procured by (i) UNFPA Supplies Partnership for delivery to African countries and by (ii) an identified subset of countries where the programme is delivered.	tbd	tbd	3.2.1 Data from RHSC and Unitaid 3.2.2 UNFPA Supplies Partnership	

[49] EAC Member States have agreed (September 2022) to establish a pooled procurement mechanism for reproductive health commodities, contributing to the regional supply value chain being promoted under AfCFTA

[50] Regional Financial Mechanism of Reproductive Health Commodities of ECOWAS, funded by DE (KFW), NL, FR (AFD) and Gates Foundation

4. IMPLEMENTATION ARRANGEMENTS

4.1 Financing Agreement

In order to implement this action, it is not envisaged to conclude a financing agreement with partner countries.

4.2 Indicative Implementation Period

The indicative operational implementation period of this action, during which the activities described in section 3 will be carried out and the corresponding contracts and agreements implemented, is 60 months from the date of adoption by the Commission of this Financing Decision.

Extensions of the implementation period may be agreed by the Commission's responsible authorising officer by amending this Financing Decision and the relevant contracts and agreements.

4.3 Implementation of the Budget Support Component

Not applicable

4.4 Implementation Modalities

The Commission will ensure that the EU appropriate rules and procedures for providing financing to third parties are respected, including review procedures, where appropriate, and compliance of the action with EU restrictive measures[32].

4.4.1 Indirect Management with an entrusted entity

This action may be implemented in indirect management with an entity, which will be selected by the Commission services using the following criteria:

- Demonstrated track record in active engagement in the health sector with specific expertise in Sexual and Reproductive Health and Rights,
- established relationships with regional bodies including at continental and sub-continental levels.
- Operational capacity on the ground in targeted countries to carry out the envisaged activities, in-country presence across most countries.

This implementation by the entrusted entity entails the implementation of the three specific objectives of this action.

4.4.2 Changes from indirect to direct management mode (and vice versa) due to exceptional circumstances (one alternative second option)

In case the preferred implementation modality cannot be implemented due to circumstances outside of the Commission's control; a fall back option will be an alternative implementation modality in direct management- to sign a grant.

(a) Purpose of the grant

The grant will contribute to achieving the 3 Specific Objectives of the Action.

(b) Type of applicants targeted

International Organisations

4.5 Scope of geographical eligibility for procurement and grants

The geographical eligibility in terms of place of establishment for participating in procurement and grant award procedures and in terms of origin of supplies purchased as established in the basic act and set out in the relevant contractual documents shall apply, subject to the following provision.

The Commission's authorising officer responsible may extend the geographical eligibility on the basis of urgency or of unavailability of services in the markets of the countries or territories concerned, or in other duly substantiated cases where application of the eligibility rules would make the realisation of this action impossible or exceedingly difficult (*Article 28(10) NDICI-Global Europe Regulation*).

4.6 Indicative Budget

Indicative Budget components	**EU contribution (amount in EUR)**
Specific Objective 1 Generate evidence on impact, feasibility, acceptability, and cost-effectiveness of delivery models for priority PPH drugs to accelerate country uptake, informing both global policy guidelines and country operational arrangements composed of	
Indirect management with entrusted entities- cf. section 4.4.1	3 000 000
Specific Objective 2 Leverage regional platforms to increase the capacity of the national health systems to roll out the use of new and underused quality assured PPH commodities (medicines, medical supplies, devices and equipment) for the prevention and treatment of PPH especially within primary health care settings, building on country experience where relevan composed of	
Indirect management with entrusted entities - cf. section 4.4.1	9 000 000
Specific Objective 3 Improve access to affordable, recommended quality-assured commodities to prevent and treat PPH in Africa, especially through manufacturers in Africa composed of	
Indirect management with entrusted entities - cf. section 4.4.1	8 000 0000
Evaluation – cf. section 5.2 **Audit** – cf. section 5.3	may be covered by another Decision
Totals	**20 000 000**

4.6 Organisational Set-up and Responsibilities

This action is part of the regional Team Europe initiative on SRHR in Africa that is the general framework to which the three specific objectives of this action contribute, particularly to the 2nd Strategic Objective of the JIL, with a structured and coherent approach. The action as a whole will therefore be embedded in the overarching coordination and management structure of the SRHR TEI:

- The TEI Oversight and Coordination Committee (OCC) will be responsible to provide and adjust the longer-term vision of the TEI in consistency with relevant strategic orientations by TEI members and partners, and facilitate the policy dialogue with key African partners, including delivery of joint messages to support the TEI ambition, and ensure alignment of its priorities with those of the partner regions.
- TEI Regional Management Groups will be responsible of the operational management, implementation, monitoring and communication of the TEI at regional level.
- Above this particular TEI, a High-Level Steering Committee of the EU-AU Health Flagships is being established to provide high level political steer and strategic guidance of the health programmes pertaining to AU-EU relations, including health TEIs.

Organisational set up. The programme will be delivered by an entrusted entity selected by the Commission services using the criteria specified in section 4.4.1.

Programme Steering Committee. A Steering Committee will be established with a mandate to monitor progress and ensure strategic direction. The Steering Committee will meet at least twice yearly and will be comprised on major stakeholders including at least once country from each REC, the RECs, maternal health bodies (possibly FIGO and the International Confederation of Midwives), representatives from major maternal health development partners (potentially Sida and/ or Germany), and the main implementing partners.

Operational day-to-day management of the programme. The entrusted entity will be responsible for overall coordination of the Action. In this regard, it will hold responsibilities for the management of funds, delivery of results and achievement of programme outcomes. The entrusted entity will be accountable for the contribution of all consortium partners and for the achievement of full value for money.

As part of its prerogative of budget implementation and to safeguard the financial interests of the Union, the Commission may participate in the above governance structures set up for governing the implementation of the action and may sign or enter into joint declarations or statements, for the purpose of enhancing the visibility of the EU and its contribution to this action and ensuring effective coordination. The lead entity in charge of this action is the EU Delegation to Nigeria. The entity in charge of the contract management is the EU Delegation to Nigeria.

5 PERFORMANCE MEASUREMENT

5.1 Monitoring and Reporting

The day-to-day technical and financial monitoring of the implementation of this action will be a continuous process, and part of the implementing partner's responsibilities. To this aim, the implementing partner shall establish a permanent internal, technical and financial monitoring system for the action and elaborate regular progress reports (not less than annual) and final reports. Every report shall provide an accurate account of implementation of the action, difficulties encountered, changes introduced, as well as the degree of achievement of its results (Outputs and direct Outcomes) as measured by corresponding indicators, using as reference the logframe matrix (for project modality) and the partner's strategy, policy or reform action plan list (for budget support).

The Commission may undertake additional project monitoring visits both through its own staff and through independent consultants recruited directly by the Commission for independent monitoring reviews (or recruited by the responsible agent contracted by the Commission for implementing such reviews).

Roles and responsibilities for data collection, analysis and monitoring:

Joint implementation will be promoted and mechanisms to ensure the joint reporting may also be put forward Partners will ensure consistent reporting formats and timeframes in order that the lead partner can compile coordinated reports.

All monitoring and reporting shall assess how well the action promotes the principle of gender equality, takes a human rights-based approach and enables the rights of persons with disabilities including through strengthening inclusion and diversity. Data collected, where approapriate and possible, will be disaggregated by sex and age, and by disability if tenable.

5.2 Evaluation

Having regard to the importance and nature of the action, a mid-term and a final evaluation may be carried out for this action or its components via independent consultants contracted either by the implementing partners or by the Commission.

Mid-term evaluation may be carried out for problem solving and learning purposes, in particular with respect to progress made in contribution to larger programme goals including the potential value of extending to a second phase.

Final evaluation may be carried out for accountability and learning purposes at various levels (including for policy revision, taking into account in particular the fact that the elements of the programme have varying measures of

success; where piloting new approaches, a formative- summative final evaluation will contribute to decision-making about future scale up. Some elements of the program, if successful, will lead to updated maternal care global guidance while others will have a much longer-term, systems strengthening focus.

As part of the TEI, and where practicable, evaluations jointly with contributing Member States will be the preferred option to provide an overview of the action within the larger impact of the TEI.

The Commission shall inform the implementing partner at least 1 month in advance of the dates envisaged for the evaluation missions. The implementing partner shall collaborate efficiently and effectively with the evaluation experts, and inter alia provide them with all necessary information and documentation, as well as access to the project premises and activities.

The evaluation reports may be shared with the partners and other key stakeholders following the best practice of evaluation dissemination. The implementing partner and the Commission shall analyse the conclusions and recommendations of the evaluations and, where appropriate, apply the necessary adjustments.

In addition, all evaluations shall assess to what extent the action is taking into account human rights-based approaches as well as whether and how it contributes to gender equality and women's empowerment and disability inclusion. The evaluation process will include expertise on human rights, disability and gender equality assessment.

Evaluation financing may be covered by another measure constituting a Financing Decision.

5.3 Audit and Verifications

Given the nature of the action, provision for Audit and Verifications for this action or its components is not necessary.

Without prejudice to the obligations applicable to contracts concluded for the implementation of this action, the Commission may, on the basis of a risk assessment, contract independent audit or verification assignments for one or several contracts or agreements.

6 STRATEGIC COMMUNICATION AND PUBLIC DIPLOMACY

The 2021-2027 programming cycle will adopt a new approach to pooling, programming and deploying strategic communication and public diplomacy resources.

In line with the 2022 '[Communicating and Raising EU Visibility: Guidance for External Actions]', it will remain a contractual obligation for all entities implementing EU-funded external actions to inform the relevant audiences of the Union's support for their work by displaying the EU emblem and a short funding statement as appropriate on all communication materials related to the actions concerned. This obligation will continue to apply equally, regardless of whether the actions concerned are implemented by the Commission, partner countries, service providers, grant beneficiaries or entrusted or delegated entities such as UN agencies, international financial institutions and agencies of EU member states.

However, action documents for specific sector programmes are in principle no longer required to include a provision for communication and visibility actions promoting the programmes concerned. These resources will instead be consolidated in Cooperation Facilities established by support measure action documents, allowing Delegations to plan and execute multiannual strategic communication and public diplomacy actions with sufficient critical mass to be effective on a national scale.

Appendix 1 REPORTING IN OPSYS

A Primary Intervention (project/programme) is a coherent set of activities and results structured in a logical framework aiming at delivering development change or progress. Identifying the level of the primary intervention will allow for:

Articulating Actions or Contracts according to an expected chain of results and therefore allowing them to ensure efficient monitoring and reporting of performance;
Differentiating these Actions or Contracts from those that do not produce direct reportable development results, defined as support entities (i.e. audits, evaluations);
Having a complete and exhaustive mapping of all results-bearing Actions and Contracts.

Primary Interventions are identified during the design of each action by the responsible service (Delegation or Headquarters operational Unit).
The level of the Primary Intervention chosen can be modified (directly in OPSYS) and the modification does not constitute an amendment of the action document.

The intervention level for the present Action identifies as (tick one of the 4 following options);

Action level (i.e. Budget Support, blending)		
☒	Single action	Present action: all contracts in the present action
Group of actions level (i.e. top-up cases, different phases of a single programme)		
☐	Group of actions	Actions reference (CRIS#/OPSYS#):
Contract level		
☒	Single Contract 1	Indirect management with an entrusted entity(ies)
	(…)	
Group of contracts level (i.e. series of programme estimates, cases in which an Action includes for example four contracts and two of them, a technical assistance contract and a contribution agreement, aim at the same objectives and complement each other)		
☐	Group of contracts 1	