

Terms of Reference for Request for Proposals

Fleming Fund Country Grant to Kenya

1. Overview of this grant

This is a Request for Proposals (RFP) for a Country Grant to support surveillance of antimicrobial-resistant bacteria in Kenya. It has been created in response to a Request for Support from the Government of Kenya (GoK). The grant will be funded by the UK Department of Health and Social Care (DHSC), under its Fleming Fund Grants Programme, which is managed by Mott MacDonald, the Management Agent.

This Fleming Fund Country Grant for Kenya will focus on strengthening One Health governance for Antimicrobial Resistance (AMR) surveillance by capacitating the national AMR coordination committee and technical working groups, supporting ownership and alignment and scaling up a One Health AMR mentoring scheme.

In the human health sector, the grant will support the further implementation of the national AMR surveillance strategy, focusing on capacitating the National Public Health Laboratory (NPHL) and designated sentinel surveillance sites to improve laboratory performance, data quality, biosafety and biosecurity, and to encourage greater clinical engagement with microbiology services to drive demand for diagnostic bacteriology services. The grant aims to support Kenya in developing a quality assured surveillance system to enable full implementation of the World Health Organization's Global AMR Surveillance System (GLASS).

In the animal health sector, the grant will facilitate the implementation of the national surveillance strategy, again capacitating laboratories, improving quality, biosafety and biosecurity, and data management, and increasing the flow of good quality samples.

The Grantee will be responsible to Mott MacDonald for all aspects of the grant, including the management of any partners, their performance, technical delivery and financial accountability. The Grantee will be expected to sign the Grant Agreement and will be expected to enter into sub-granting arrangements with partners on the same back-to-back terms.

The Grantee will need to work in close coordination with the National Antimicrobial Stewardship Interagency Committee, which has been formed to address AMR in Kenya, and other national stakeholders. The Grantee will also be required to harmonise efforts on this Country Grant with other types of grants under the Fleming Fund Grants Programme, namely Regional Grants and the Fleming Fellowship Scheme.

This grant is expected to last until September. Grant applications should be in the region of £6 million, including all capital and recurrent costs, overheads and management costs.

2. Overview of the Fleming Fund

2.1 Introduction

The UK Government has established the Fleming Fund to respond to the global threat of drug-resistant infections due to bacterial Antimicrobial Resistance (AMR). The Fleming Fund will be a critical tool in achieving the resolution of the 68th World Health Assembly, 2015 (WHA A68/20), and in realising the 'Political Declaration of the High-Level Meeting of the United Nations General Assembly (UNGA) on

Antimicrobial Resistance, 2016'. These recognise that urgent cross-sectoral rationalisation of antimicrobial use, and prevention and control of infections in humans, animals, food, agriculture, and aquaculture sectors, are key to tackling AMR and call for: innovative research and development; affordable and accessible antimicrobial medicines and vaccines; improved surveillance and monitoring; increased governance on antimicrobial use; and increased international cooperation to control and prevent AMR.

The Fleming Fund aims to address critical gaps in surveillance of antimicrobial-resistant bacteria in low- and middle-income countries (LMICs) in Asia and Sub-Saharan Africa. Countries in these areas are set to bear the highest burden of drug resistant infections. A Global Action Plan on Antimicrobial Resistance (GAP-AMR) has been developed by the World Health Organization (WHO), which acts as the blueprint for a multi-stakeholder global response to averting a global health crisis caused by AMR.¹ The Fleming Fund comprises a number of workstreams (see www.flemingfund.org for more information). One workstream provides support to the Tripartite Alliance – the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE) and the World Health Organization (WHO) – as part of the OH approach. Through funding to the Tripartite Alliance, the Fleming Fund has contributed to the development of National Action Plans (NAPs) in Sub-Saharan Africa, South and South East Asia, and to the building of the evidence base and guidance for AMR surveillance. This work will be critical for the overall success of the Fleming Fund Grant Programme and underpins the delivery of the portfolio of Country and Regional Grants and the Fleming Fellowship Scheme, as these will target capacity gaps identified in NAPs. The Fleming Fund also funds initiatives in academic institutions to develop guidance on the development of AMR surveillance systems.

The Fleming Fund Grants Programme is the largest stream of financial support available through the wider Fleming Fund. The DHSC has appointed Mott MacDonald as the Fleming Fund Management Agent for the Fleming Fund Grants Programme. Mott MacDonald is a global company with expertise in multi-sectoral international development and fund management. On behalf of the UK Government, Mott MacDonald is responsible for funding allocation and oversight of all investments made across the whole portfolio of grants in different activities and in different countries.

The aim of the Fleming Fund Grants Programme is to improve the ability of recipient countries to diagnose drug-resistant infections, with an emphasis on bacterial infections, and to improve data and surveillance to inform policy and practice at national and international levels. The overall goal is to avert the human and economic burden of AMR.

The geographic focus of the Fleming Fund Grants Programme is 20-24 LMICs from Sub-Saharan Africa, and South and South East Asia. It can provide financial support up to 2021 to participating countries via three funding channels:

- Country Grants
- Fleming Fellowship Scheme Grants
- Regional Grants

The Fleming Fund will be independently evaluated by Itad, a specialist evaluation firm appointed by DHSC for this purpose.

1.1 Problem statement to be addressed by the Fleming Fund

The main issues to be addressed by Fleming Fund Country Grants are outlined below:

¹ <http://www.who.int/antimicrobial-resistance/global-action-plan/en/>

- There are too few trained microbiologists to undertake the volume of testing required for representative surveillance on AMR.
- There are few health facilities that routinely undertake bacterial culture; still fewer facilities that meet the requirements for accreditation, or which do routine antimicrobial susceptibility testing.
- There is no culture of surveillance for AMR in healthcare delivery and there are barriers to developing it.
- There is little perceived use of surveillance data on any level, including low demand for the data from policy makers.
- There is a lack of knowledge on the use and consumption of antimicrobial agents across One Health sectors.
- There is a lack of antimicrobial stewardship.
- Logistical challenges are significant: transporting samples in a safe and secure manner under challenging transport conditions; ensuring a quality assured and sustained supply chain for reagents and consumables; and ensuring appropriate servicing of equipment are a few examples.
- Surveillance systems (national, regional and global) that do exist are often vertical in nature, are not linked, and are not integrated.
- There are weak One Health structures and there is poor inter-sectoral collaboration.
- There is a heterogeneous picture across countries and regions in terms of starting points, political will, capability, and donor interest and engagement.
- There are poorly defined and applied quality assurance standards in laboratory testing.
- There is lack of understanding on transmission patterns and drivers such as inappropriate use of antimicrobial drugs across all sectors.

1.2 Fleming Fund investment areas and outputs

To address the problems above, the Fleming Fund Grants Programme invests in:

- Laboratory infrastructure enhancement.
- Human resource strengthening and workforce reforms.
- Surveillance systems strengthening.
- Building foundations for AMR surveillance data use.
- Promoting rational use of antimicrobial medicines.

Investment in these areas is expected to achieve the following outputs:

- Improved laboratory skills and conditions for bacterial identification and Antimicrobial Susceptibility Testing (AST); and, therefore, improved data quality.
- A Strengthened One Health workforce with a range of relevant skills for AMR surveillance.
- Stronger AMR surveillance systems and processes at country and regional levels.
- Higher demand for AMR data at regional, country, subnational and facility levels.

- Better knowledge of country level patterns of prescribing practice and use of antimicrobials (particularly for bacterial infection) across sectors.

Fleming Fund outputs are expected to contribute to the following country outputs:

- Increase in quality and quantity of AMR and AMU data collected.
- AMR and AMU data shared in country to support evidence-based policy and practice
- AMR and AMU data shared internationally to improve and inform the global response, in particular via the WHO GLASS programme for human health AMR data.

The RFPs for Country Grants have been designed to ensure that investments and activities contribute directly to outputs. Grantees are expected to adhere to and demonstrate this alignment and contribution to outputs in their applications.

1.3 Core principles within the Fleming Fund Grants Programme

The Fleming Fund is built on four core principles. Grantees are expected to demonstrate how they will align with these principles while implementing the grant.

- 1) Country Ownership:** The Fleming Fund Grants Programme will be implemented in line with national plans and aspirations, as laid out in the National Action Plan. Unless there are good reasons not to do so, Fleming Fund grants will chiefly invest in public sector laboratories and surveillance systems, thereby supporting national public health systems.
- 2) One Health:** The Fleming Fund recognises that the problem of AMR is a great danger to human health and cannot be controlled without a One Health approach. A specific set of One Health investment parameters has also been developed and is summarised below. This approach is aligned with key documents and guidelines from OIE² and FAO³ as well as the Global Action Plan.
 - a. Collaborative multi-sectoral governance of AMR:** Leadership and resourcing of AMR surveillance and mitigation measures in all sectors that contribute to the emergence of AMR.
 - b. Integrated AMR and antimicrobial use and consumption surveillance in all sectors:** Surveillance in humans, livestock, aquaculture, crops, food and the environment to produce information that is interpreted by multi-sectoral teams to help understand factors associated with AMR emergence within and between sectors.
 - c. AMR mitigation policies and programmes prioritised across multiple sectors:** Evidence-based policies and programmes for AMR mitigation measures that are prioritised across the relevant sectors, based on information generated through AMR and AMU/C surveillance in all sectors.
- 3) Alignment of Approach:** The Fleming Fund Grants Programme will seek to invest in areas which complement and build on work done to date, rather than create new systems. Grant applicants will need to demonstrate that they understand other actors' work in the field of improved laboratory capacity (both within and outside the sphere of AMR surveillance), improved disease surveillance, and the One Health approach. The Fleming Fund Grants Programme will assess grants for duplication of efforts and/or the development of parallel

² OIE Standards, Guideline and Resolution on Antimicrobial resistance and the use of antimicrobial agents;

³ The FAO Action Plan on Antimicrobial Resistance, 2016-2020.

systems. To the extent possible, prospective Grantees will need to demonstrate how their proposals add value to existing and planned investments and systems.

- 4) **Sustainability:** The Fleming Fund Grants Programme will focus assistance on national systems with a view to long-term sustainability. Investment size and scope should, as far as possible, be aligned with national government spending so that systems created with Fleming Fund grants are sustainable within the public health system. We also recognise that the public good of conducting AMR surveillance means medium- to long-term support, and it is expected that countries that demonstrate good performance will have access to additional funds to provide ongoing support.

2.5 Fleming Fellowship Scheme

The Fleming Fellowship Scheme is part of the broader Fleming Fund Grants Programme and is managed by Mott MacDonald. Fellowships provide funding to support on-the-job training over an 18- to 24-month programme of structured learning, mentoring and skills development for four to eight Fellows in each investment country. The Fellowships do not duplicate basic training, rather they focus on building advanced skills and leadership to promote the application of best practice in identified 'Beneficiary Institutions', while promoting the One Health principle. Beneficiary Institutions are organisations such as AMR reference laboratories national epidemiology units in the human and animal health sectors, hospitals and/or national drug administration agencies that add strategic value and complementarity to achieve the Fleming Fund's aims in the country. They are also institutions most likely to derive sustainable benefit from the Fellowship activities.

The initial focus of the Professional Fellowship Scheme is on strengthening the quality of laboratory diagnostic data and the analysis and use of AMR and AMU surveillance data in Beneficiary Institutions. Fellows in each country are supported by mentors who provide the expertise required to support the needs of the Fellows as well as to help them to improve the sustainability of AMR programmes in their institution. The data they generate will be applied to deliver evidence-based approaches to tackling AMR, for example to improve antimicrobial stewardship.

Priority areas to be supported through the Fellowship Scheme are discussed by a Mott MacDonald scoping team together with the national AMR committee in each country and reviewed with the Beneficiary Institutions to which they are assigned. A template is provided for each Fellowship terms of reference which is adapted to the Beneficiary Institutional needs. One, or at most two, expert 'Host Institutions' are matched with all the Fellowships in a specific country. The Host Institution is drawn from a preselected pool, and after attending an initial workshop with the Fellows and Beneficiary Institution, the Host Institution develops a budgeted work plan. Once workplans and budgets have been agreed by Mott MacDonald, Fellows are formally accepted, and their Fellowship activities expensed through the Host Institution.

2.6 Fleming Fund activities in Kenya to date

This is the first Fleming Fund Country Grant to be released in Kenya. In preparation for this grant, Mott MacDonald carried out a Scoping Visit in July 2018 which was followed, in December 2018 and January 2019, by Positioning Activities.

Key stakeholders in the animal and human health sectors have been consulted throughout the process, with strong leadership by the National Antimicrobial Stewardship Inter-Agency Committee – Technical Committee (NASIC-TC) and its secretariat, and high-level political support for the grant. Scoping and Positioning, which included assessments of seven public health laboratories and five animal health laboratories, confirmed the need to enhance AMR, AMC and AMU surveillance capacity in humans and animals. The visits identified key gaps and challenges and mapped other stakeholders working in laboratory strengthening. The process concluded with a two-day grant design workshop and consultation in which GoK and the Fleming Fund team agreed grant objectives and outputs in line with the country's National Action Plan for the Prevention and Containment of Antimicrobial Resistance.

3. The current AMR situation in Kenya

3.1 Policy and strategy environment/National Action Plan for AMR

A National Situational Analysis was published in 2011, supported by the Global Antimicrobial Resistance Partnership (GARP). The situational analysis was updated in 2016, although the update is not yet published.

A National Policy on Prevention and Containment of AMR was published in June 2017, identifying several policy issues which were incorporated as strategic objectives in the National Action Plan for the Prevention and Containment of Antimicrobial Resistance (NAP). The NAP (2017 – 2022) was published in the same month. The development of the NAP was supported by WHO, FAO, OIE, CDC and USAID, and efforts are currently underway to map all the partners and stakeholders involved in AMR work to ensure well-coordinated national implementation in line with the priorities of the NAP.

The National Antimicrobial Stewardship Interagency Committee (NASIC) is the highest policy and governance body responsible for all AMR activities. The NASIC has recently evolved from the NASAC (National Antimicrobial Stewardship Advisory Committee) which had a more limited advisory function. NASIC is made up of three multisectoral components: a Steering Committee (responsible for policy direction, resource mobilisation, budget and workplan approvals), a Technical Committee (responsible for implementation of the NAP, coordinating with stakeholders, and advising on guidelines, rules and regulations) and a Secretariat (responsible for linking NASIC at national and county levels, coordinating policy implementation at both those levels, stakeholder engagement, representing the national AMR effort, engaging technical advisers and supporting the functions of the TWGs). The Steering Committee has not yet met in its new incarnation, but the Technical Committee is expected to have met at least once by the time the grant commences. The Secretariat has multisectoral staff who are very active, including the AMR Focal Point, but it lacks resources to support the work of the other parts of NASIC more fully.

Five Technical Working Groups have been established to support implementation of the NAP. The AMR Surveillance and Research Technical Working Group has representatives from human health, animal health and other ministries, and has primary responsibility for strengthening surveillance of AMR and AMU in animal and human health. The other TWGs are for Awareness and Advocacy; Regulation; Training and Guidance; and Infection Prevention and Control. All will be expected to draw on AMR data to inform their activities and advice; however, capacity to do this is limited.

Kenya is involved in several networks and partnerships working on AMR. It has a major Wellcome Trust programme and is a member of the Global Antibiotic Resistance Partnership (GARP) and the Alliance for the Prudent use of Antibiotics (APUA) Chapter Network. It is also the host to the African head office for ReAct Africa, an independent multidisciplinary network which advocates for global engagement on AMR.

3.2 One Health

Kenya is one of the top 20 countries for endemic zoonoses, in large part due to poverty and the frequent human-animal interface. Kenya has a well-functioning zoonotic disease unit with clear terms of reference to support implementation of the International Health Regulations (IHR) 2005 and is in the process of updating the current Zoonotic Diseases Unit Strategic Plan (2012-2017) and the One Health Strategic Plan (2012-2017). However, neither of these directly address AMR.

The NAP takes an integrated approach to AMR. At national level, the AMR Secretariat is hosted and coordinated by the Ministry of Health, and includes the Ministry of Agriculture, Livestock, Fisheries and Irrigation. NASIC membership includes relevant National Ministries and County departments, agencies responsible for health and agriculture, and associated parastatals. Although the Ministries of Environment and Natural Resources, Education Science and Technology, National Treasury and Industry, Trade and Cooperatives have been involved in the discussions around the development of the NAP, their engagement to date has been minimal as their roles have not been clearly articulated. The NASIC hopes to re-engage with them once there is local data to support their involvement.

At county level, lead departments (health and agriculture) are expected to establish County Antimicrobial Stewardship Interagency Committees (CASICs), with similar functions to those of the NASIC and composed of County Executive Committee members, County Chief Officers of relevant departments, technical County Directors, and relevant experts. County representatives are invited to attend national meetings to address implementation of the NAP, and ongoing engagement is vital due to the challenges in achieving national implementation in a devolved healthcare system. In terms of surveillance, the role of the National Government is to develop and support the implementation of the surveillance system, support data collection, and develop guidelines for compulsory reporting of AMU and AMR trends, while the County Governments are tasked with mobilising resources to implement the surveillance strategy, facilitating transmission of data to National Government, and disseminating AMR surveillance data to the county stakeholders. Both national and county governments are expected to work together to build laboratory capacity to support AMR surveillance.

Recognizing the need to harness and include all the data from different research institutes and activities carried out in Kenya on AMR, the ministries are exploring possibilities and are engaged in discussions to come up with structural partnerships with leading research institutes so that relevant AMR research data is incorporated into the national AMR surveillance system, for mutual benefit to the country and the different agencies.

3.3 AMR Surveillance – human health

Some surveillance on AMR is underway in several sites by way of research programmes conducted by Universities with links to referral hospitals, but results are not reported through formal ministry channels. These programmes enabled Kenya to contribute data on almost 1000 isolates to the WHO 2014 Global Report on Surveillance⁴, although almost half of these were non-invasive *N. gonorrhoea* or *Shigella spp.* No data was reported in the Early Implementation Report 2017-2018.⁵

A National Antimicrobial Resistance Surveillance Strategy (2018 – 2022) has been approved. Priority organisms have been identified based on the WHO GLASS priority list and additional local priorities;

⁴ Antimicrobial resistance: global report on surveillance. Geneva: World Health Organisation; 2014.

⁵ Global antimicrobial resistance surveillance system (GLASS) report: early implementation 2017-2018. Geneva: World Health Organization; 2018

roles and responsibilities have been identified, and surveillance quality and reporting standards have been agreed. The strategy is being piloted in two sites, Kitale and Thika, which have received substantial support from US-CDC and the World Bank. A 2018 assessment of these sites by NPHLS and US-CDC reported that, while basic laboratory equipment and information systems were in place, AST and reporting capacities need to be strengthened.⁶ Plans are in place to improve these capacities, including training, reagent supply, and updating information systems, and ongoing support will be needed. A small amount of data from the pilot sites has been reported to NPHLS.

More broadly, the Joint External Evaluation (JEE) 2017⁷ reported that although many of Kenya's 128 public health laboratories can detect and report AMR, several major challenges remain in the implementation of the NAP and AMR strategy. These include weak technical capacity, inadequate and inconsistent laboratory supplies, inadequate infrastructure in many hospitals, and limited financial and material resources. The JEE also noted that despite communication campaigns and efforts, there is still a lack of clear understanding of the importance of microbiology in hospitals by management and clinicians. The report advised that technical capacity for the detection and reporting of AMR in laboratories needs to be improved, especially at subnational level; and a centralized laboratory surveillance reporting system is needed (including establishment of a national database), covering the data from both public health and veterinary sectors.

The National Public Health Laboratory (NPHL) has been designated as the AMR co-ordinating laboratory. Additionally, the KEMRI Centre for Microbiology Research (CMR) is a WHO Collaborating Centre for enteric pathogens which provides additional reference functions. Both laboratories are located within the Kenyatta National Hospital grounds. NPHL provides a quality control (QC) service for the sites participating in surveillance, testing a subset of isolates to confirm results, and collating the data for reporting to the NASIC. CMR is primarily a research laboratory, but provides QA support and training, and also confirmatory testing for samples with unusual resistance profiles.

Kenya is part of the East Africa Public Health Laboratory Networking (EAPHLN) project funded by World Bank. Support has been given to several laboratories including Machakos, Kitale, Eldoret and NPHL. This included construction, equipment, training and human resource strengthening.

USAID will shortly be active in AMR surveillance in Kenya through its Infectious Disease Detection and Surveillance (IDDS) and Medicines, Technologies and Pharmaceutical Services (MTaPS) programmes. These are likely to support laboratory capacity including for AMR; similarly, CDC will continue its support to Kenya by supporting the development of the surveillance system in response to lessons learned from the pilot sites and expanding the programme to other major facilities. Careful co-ordination of programmes through the NASIC and national focal point will therefore be required.

3.4 AMR Surveillance – animal health

Surveillance in animal health will be under the direction of the Directorate of Veterinary Services of the Ministry of Agriculture, Livestock, Fisheries and Irrigation.

A draft surveillance plan, including both active and passive surveillance for AMR and AMU in the agricultural sector, is in its final stages of adoption, although passive surveillance in AMR has not yet started. For active surveillance, in collaboration with the FAO, a pilot of the surveillance plan in poultry is in progress, focusing on *Staphylococcus aureus*, *E. coli*, and *Salmonella spp.* Several laboratories have been assessed using the FAO ATCLASS tool.

⁶ Centers for Disease Control and Prevention Kenya: Annual Report 2017

⁷ Joint External Evaluation of IHR Core Capacities of the Republic of Kenya. Geneva: World Health Organization; 2017

Kenya has also received support from the Fleming Fund through a grant to FAO for a review of its legislation relevant to AMU in livestock and a baseline review of antimicrobial use in agriculture, including data on the veterinary medicines supply chain.

Surveillance will be carried out at Regional Veterinary Investigation Laboratories (RVIL) with the Central Veterinary Laboratory (CVL) being the reference centre. The University of Nairobi Veterinary Pathology Laboratory will be an additional part of the surveillance system providing training and academic input to surveillance design and analysis. The Veterinary Epidemiology and Economics Section (VEES) within DVS, will be responsible for data management, and submission of data to the National Database at the NPHLS. They will also contribute to surveillance protocol development and production of regular reports.

Following devolution, a County Directorate of Veterinary Services (CDVS) structure was put in place and each county is now responsible for managing their own activities, including animal disease surveillance. The central level provides guidance to CDVS but there is no direct supervision between the DVS and CDVS. There is no specific budget line for animal disease surveillance at national level: this is devolved to county level.

Development partners engaged in AMR surveillance in animal health include FAO and OIE. FAO was a key partner in developing the NAP and surveillance strategy and has completed reviews of the legislative framework relevant to AMU, in the animal health sector. FAO has also supported training for the Central Veterinary Laboratory and six other sites in bacterial identification and AST.

3.5 Laboratory capacity – human health

The Fleming Fund Team has assessed the proposed reference laboratory at NPHLS, and seven public hospital laboratories which have been designated as the initial sentinel surveillance sites for human health. These laboratories are at referral and teaching hospitals (level five and six hospitals) in Mombasa, Thika, Machakos, Nakuru, Eldoret and Kisumu, and Kenyatta National Hospital, the national referral hospital (see section 4.2).

The microbiology laboratory at NPHL is ISO accredited as a clinical laboratory and for provision of proficiency testing. Currently its main workload is in providing services for outbreak investigation, mainly for diarrhoeal disease. It also runs a national proficiency testing programme, with 3 distributions annually to 25 participating sites. Several staff have masters degrees in microbiology and have had training in molecular techniques. The laboratory is generally well equipped and has a VITEK II and BACTEC 9050. Space is adequate and no major structural renovations are required. However, it will require a formal assessment of electrical supply to ensure reliable supply to critical instruments. The laboratory is limited by lack of budget for reagents and consumables, and there is no formal transport system for transporting samples from referring laboratories. Staff in the NPHL biomedical engineering section are trained in maintenance of biosafety cabinets and provide this as a service to other sites around the country.

Data aggregation and analyses for the surveillance system will also take place at NPHL. An epidemiologist is in post, but more capacity building will be required.

To fulfil its expanding role as an AMR reference service, NPHL will need training and ongoing technical support to improve its capabilities in confirming resistance phenotypes, determining AMR mechanisms, carrying out data analysis, and applying data to inform priorities. The LIMS system needs to be strengthened by providing reliable internet connectivity.

The size and capacity of the surveillance laboratories vary between sites, however, all are performing some culture work and several have automated blood culture instruments. All laboratories visited are

on the WHO-AFRO SLIPTA scheme. Biosafety and biosecurity are generally adequate but will require strengthening in terms of equipment, materials and staff training. Maintenance of equipment is also variable between sites and will need strengthening. While some sites have reliable stock management systems, others reported that procurement could take months, leading to long stockouts. Quality of reagent depends on whether laboratories can procure directly from suppliers or are dependent on central procurement services.

3.6 Laboratory capacity – animal health

The Fleming Fund team visited the proposed reference laboratory (CVL) and four of the five surveillance sites: the regional veterinary investigation laboratories in Mariakani, Nakuru and Kericho along with University of Nairobi Veterinary Pathology Laboratory. The regional laboratory at Eldoret was not assessed and this will need to be performed by the grantee. Each regional laboratory supports more than 3 counties.

All laboratories visited are currently performing bacterial culture, identification and AST to some degree, including milk for mastitis and post mortem samples. There is a no comprehensive AMR surveillance system, and testing is usually performed for diagnosis and outbreak investigation. The laboratories are run from their own budgets.

None of the laboratories are participating in a proficiency testing scheme for AMR, and there is no standardised QA/QC mechanism in place. Maintenance of equipment is a problem due to lack of budget for preventative maintenance and limited availability of biomedical engineers. Procurement of reagents and consumables is usually via national procurement processes and is often slow, leading to long stock-out periods. The quality of the purchased supplies is variable. The RVILs will require a formal assessment of electrical supply as frequent power cuts and generator issues mean that UPS and surge protection will be needed to ensure reliable supply to critical instruments. Biosafety and biosecurity will also need strengthening for all the laboratories.

All the veterinary laboratories, with the exception of UNVPL, are in the process of being connected to SILAB for Africa, a laboratory information management system (LIMS) supported by FAO and Standards and Markets Access Programme (SMAP). This is a web-based system with the main server being held at CVL and allows real time monitoring of laboratory activity at the sites, however unreliable internet connectivity remains a challenge.

3.8 Appropriate use of medicines

Pharmaceutical management is overseen by the Pharmacy Division at the MOH (Policy) and the Pharmacy and Poisons Board (PPB) which has a mandate for human medicines, ensuring quality, safety and efficacy of medicines and advising the government on all aspects of drug regulation. In the human health sector, dispensing antibiotics without prescription is illegal but occurs in practice: one study estimated that 70% of pharmacists dispensed antibiotics without a doctor's prescription.⁸ Self-medication is often driven by financial barriers to accessing formal healthcare.

Among healthcare workers in facilities, there is insufficient knowledge about appropriate use of antimicrobials. The JEE recommends more systematic implementation of existing treatment guidelines and the development of a training curriculum for antimicrobial stewardship. Progress is being made: medicines and therapeutic committees are being established in hospitals, and clinical guidelines have recently been developed to guide management of patients presenting with possible

⁸ Situation Analysis and Recommendations: Antibiotic Use and Resistance in Kenya. Kenya: GARP – Kenya working group 2011

infection. There has also been an AMR awareness campaign for hospital IPC teams and antimicrobial stewardship training modules are now included in the IPC training course.

The regulation for use and trade of medicines in animal health is undertaken by the Veterinary Medicines Directorate (VMD, a semi- autonomous government agency) of the state department for livestock in the Ministry of Agriculture, Livestock Production, Fisheries and Irrigation. The VMD was recently established, therefore collaboration and knowledge exchange between PPB and VMD should be enhanced.

With support from SMAP, the directorate of Veterinary Services has developed and published guidelines for the prudent use of antimicrobials in the livestock sector. It is proposed that adherence to these guidelines will be compulsory by all registered veterinary surgeons and paraprofessionals and will be overseen by the Kenya Veterinary Board, which regulates and advises the government on all matters regarding animal health in Kenya. However, these guidelines need to be published in adequate quantities and disseminated to the intended targets for them to have the intended impact.

In the animal health sector, use of antimicrobials in farm animals is widespread, with 90% of use reported to be for therapeutic applications,⁹ although this may, for some farmers, encompass prevention as well as treatment. More than half of the antimicrobials used are tetracyclines and sulphonamides. Growth promotion has not been identified as an important source of antimicrobial use in livestock in Kenya, and the level of usage in fisheries is currently unknown.

As in human health, the use of drugs for treatment is regulated by law, but enforcement and monitoring are inadequate. Veterinarians in rural areas are scarce and the cost of their services are high, meaning that farmers frequently purchase drugs without prescription.

Although legislation exists, in practice the capacity of both PPB and VMD to carry out effective regulation of outlets is very limited.

There is currently no national surveillance strategy for AMC or AMU in either the human health or animal health sector. The MOH has participated in the WHO supported Global Point Prevalence Survey, and in 2018 the University of Nairobi carried out a Point Prevalence Survey in three public hospitals: the results of this are pending.

4. Scope of this Country Grant

4.1 Grant Objectives and Outputs

Objectives and outputs for this Country Grant are summarised below with more details in Section 7. Applicants should will respond to this RFP by developing and proposing costed activities, and by proposing appropriate indicators (see Section 9). All inputs must be permitted under the list of Eligible Funding Items as outlined in Annex 1. For human health, the Country Grant is intended to support / improve implementation of the WHO GLASS programme and Grantees should refer to the roadmap for GLASS participation produced by the London School of Hygiene and Tropical Medicine (<https://amr.lshtm.ac.uk/wp-content/uploads/sites/12/2016/11/AMR-Surveillance-Protocol.pdf>)

⁹ *ibid.*

Objective 1: A strengthened One Health governance structure for AMR, AMU and AMC surveillance

Output 1.1: The NASIC functions effectively as the AMR National Coordinating Centre for surveillance in Kenya

Output 1.2: The multi-sectoral AMR Surveillance and Research Technical Working Group provides technical support to the AMR surveillance systems in human and animal health

Output 1.3: AMR, AMC and AMU surveillance results are shared with other technical working groups to inform their activities

Output 1.4: National ownership and alignment of Fleming Fund activities with other inputs is ensured

Output 1.5: The existing One Health AMR mentoring scheme is scaled up

Objective 2: A strengthened AMR and AMU/AMC surveillance system in the human health sector

Output 2.1: NPHL has increased capacity to function as a reference laboratory and supporting centre for AMR surveillance

Output 2.2: The human health AMR surveillance system has improved capacity for data management

Output 2.3: Sentinel laboratories function well and are included in an AMR laboratory network

Output 2.4: Biosafety and security are ensured at the reference laboratory and at surveillance laboratories

Output 2.5: All laboratories have adequate levels of quality assurance and control

Output 2.6: Clinical staff at the surveillance sites demonstrate increased utilization of microbiology services.

Output 2.7: A sustainable specimen transportation system is developed and functional

Output 2.8: An AMC/AMU surveillance strategy is developed and implemented

Objective 3: A strengthened AMR and AMU/AMC surveillance system in the animal health sector

Output 3.1: CVL has the capacity to function as a reference laboratory and supporting centre for AMR surveillance

Output 3.2: A national database of verified AMR data, with associated metadata, is maintained, data is analysed, and reports on AMR trends are produced

Output 3.3: All the laboratories in the surveillance network produce reliable bacterial identification and AST results

Output 3.4: Good quality samples from broilers and layers are regularly sent to laboratories from selected counties for culture and AST.

Output 3.5: Biosafety and biosecurity are ensured at the reference laboratory and at surveillance laboratories

Output 3.6: Quality management system is improved to ensure reliable results

Output 3.7: A sustainable specimen transportation system is developed and functional

Output 3.8: An AMC and AMU surveillance strategy is developed and implemented

4.2 Selected laboratories

Table 1: List of selected laboratories for the Kenya Country Grant

Site assessment*	Laboratory	Location	Type of site#
MA	National Public Health Laboratory	Nairobi	HH
MA	Coast Provincial General Hospital	Mombasa	HH
MA	Machakos Level 5 Hospital	Machakos	HH
MA	Thika Level 5 Hospital	Thika	HH
MA	Nakuru Provincial General Hospital	Nakuru	HH
MA	Moi Teaching and Referral Hospital	Eldoret	HH
MA	Jaramogi Oginga Odinga Teaching and Referral Hospital	Kisumu	HH
MA	Kenyatta National Hospital	Nairobi	HH
MA	Central Veterinary Investigation Laboratory	Nairobi	AH
MA	University of Nairobi Veterinary Pathology Laboratory	Nairobi	AH
MA	Regional Veterinary Investigation Laboratory	Mariakani	AH
MA	Regional Veterinary Investigation Laboratory	Nakuru	AH
MA	Regional Veterinary Investigation Laboratory	Kericho	AH
G	Regional Veterinary Investigation Laboratory	Eldoret	AH

*MA: assessed by Management Agent; G: to be assessed by Grantee

HH: Human Health; AH: Animal Health

4.3 Duration and phasing of the grant

This country grant to Kenya is expected to last until September 2021.

4.4 Funding envelope

Grant applications should be in the region of £6 million, including all capital and recurrent costs, overheads and management costs. This should include a placeholder budget of £1.3m for renovating and equipping the human health laboratories (including reagents relevant for GLASS pathogens), and £0.6m for the animal health laboratories.

Mott MacDonald is responsible for ensuring Value for Money (VfM) on behalf of the UK Department of Health throughout the Grant programme and will carefully consider how the proposal addresses efficiency, effectiveness, economy and equity in delivering the Request for Proposal (RFP) outputs in relation to the proposed costs. The Guidance Notes for the Grant Application Form provide more information on different dimensions to be considered as part of a VfM approach.

4.5 Procurement

During the site assessments, the Management Agent compiled an indicative procurement list of laboratory equipment, reagents and consumables. The grantee is expected to conduct a full assessment of the Eldoret Regional Veterinary Laboratory, and to confirm the requirements for the other laboratories in Table 1 to develop a procurement plan for the laboratories and surveillance sites. The assessments will utilise tools provided by the management agent and should include assessment of infrastructure to determine what renovations are required and have been used to estimate the placeholder budgets above.

The grantee will work in consultation with the Management Agent, the Management Agent's procurement supplier (International Procurement Agency) and the UK Department of Health and Social Care, to determine the most suitable method of procurement for laboratory equipment, and to develop reliable stock management and supply systems for consumable and reagents.

The lead grantee will also be expected to:

1. assist with the importation and delivery of equipment and consumables to recipient sites;
2. work closely with the procurement partner (whether IPA or an alternative organisation) to ensure the appropriate delivery sequence of items;
3. maintain an asset register of all items defined as assets by the programme;
4. regularly monitor the items that have been procured by Fleming Fund Grants Programme to ensure:
 - (i) items are being used for intended purpose;
 - (ii) items are being maintained appropriately; and
 - (iii) to report any misuse or misappropriation of assets to the Management Agent.

5. Key partnerships, alignment and coordination

The Country Grant must be delivered in alignment with and support delivery of the NAP and the sector specific surveillance strategies.

The grantee will be expected to work with the AMR NASIC and secretariat to align with other AMR related initiatives including those undertaken by bilateral and multilateral agencies such as CDC, USAID, FAO, OIE and WHO. The activities to be supported will be in AMR, AMC and AMU surveillance.

In addition, the Grantee will need to build collaborations and coordination with local academic and research institutions at different levels for technical and other support. Attention will be needed to make the best possible use of the existing initiatives and capacities, and to avoid duplication, particularly with programmes run by the World Bank, CDC and USAID.

6. Complementing other grants from the Fleming Fund Grants Programme

The Country Grant for Kenya is expected to work effectively with other grants under the Fleming Fund Grants Programme at the regional level, including the Fleming Fellowship Scheme. For details see www.flemingfund.org.

The Fleming Fund Regional Grant programme, also managed by Mott MacDonald, will focus on strengthening networking and data sharing on AMR at the regional level. The grantee is expected to liaise, through Mott MacDonald, with this programme where relevant, to maximise the sharing of AMR data and learning at the regional and global levels.

Detailed Objectives and Outputs

7.1 Objective 1: A strengthened One Health governance structure for AMR, AMU and AMC surveillance

Output 1.1: The NASIC functions effectively as the AMR National Coordinating Centre for surveillance in Kenya

NASIC has been established as the AMR National Coordinating Centre (ANCC). The role of the ANCC is to coordinate all surveillance activities and the national surveillance network, oversee data analysis and dissemination, ensure logistics and procurement support to the national surveillance system, and have responsibility for data management. This has not yet been operationalised: more work needs to be done on the details including staffing, resourcing and how some of the proposed responsibilities will work in practice.

By the end of the grant we expect that the following will have been achieved:

- a) The NASIC (Steering Committee, Technical Committee and Secretariat) has the capacity to fulfil its function as the One Health AMR National Coordinating Centre. NASIC reviews and interprets AMR, AMC and AMU results and recommendations from the multi-sectoral AMR surveillance and research TWG, in a One Health context.
- b) NASIC regularly disseminates interpreted data/reports to global, regional, national and subnational levels for use in updating/developing policies and guidelines.
- c) NASIC is reporting data into GLASS and OIE.
- d) NASIC has disseminated the human and animal health surveillance strategies to national and subnational levels.
- e) NASIC has developed and operationalized an M & E framework for AMR surveillance activities.

Output 1.2: The multi-sectoral AMR Surveillance and Research Technical Working Group provides technical support to the AMR surveillance systems in human and animal health

The multi-sectoral AMR Surveillance and Research Technical Working Group is responsible for strengthening surveillance and understanding of local and national resistance patterns and antimicrobial use in animal and human health. The multi-sectoral TWG has been established, the terms of reference have been developed, but the capacity of the multi-sectoral TWG to function effectively and implement the ToRs needs to be increased. The Secretariat supports the work of the multi-sectoral TWG, but resources are an issue.

By the end of the grant we expect that the following will have been achieved:

- a) The multi-sectoral TWG demonstrates an increased understanding of One Health and provides appropriate technical support to surveillance sites.
- b) The multi-sectoral TWG reviews AMR, AMU and AMC results and interpretations provided by sector-specific TWGs and makes policy recommendations to NASIC regarding further surveillance, research and actions related to AMR, AMC and AMU.

- c) The TWG provides oversight of the implementation of the surveillance systems e.g. by advising on selection of surveillance sites, reviewing SOPs, advising on surveillance laboratory standards, data generation and reporting and monitoring and evaluation.
- d) Two annual reports have been delivered on AMR, AMC and AMU.
- e) The Secretariat has the capacity to support the work of the TWG e.g. by ensuring data flow from NPHL to the TWG.

Output 1.3: AMR, AMC and AMU surveillance results are shared with other technical working groups to inform their activities

While primary responsibility for surveillance lies with the Surveillance and Research TWG, the four other multisectoral TWGs are all expected to draw on AMR data to inform their activities and advice. However, capacity to do this is limited.

By the end of the grant we expect that the following will have been achieved:

- a) The technical working groups understand AMR, AMC and AMU data and relate it to their focus sectors.
- b) The Secretariat supports the work of the Surveillance and Research TWG e.g. by ensuring data flow from NPHL to the TWGs.
- c) The Secretariat has an established system for information sharing

Output 1.4: National ownership and alignment of Fleming Fund activities with other inputs is ensured

As described in section 3, there are several development partners with current or pending activities in the AMR field in Kenya. This presents both opportunities and challenges to NASIC, as co-ordination through the national structures is essential to ensure activities are aligned with national priorities and to minimise duplication. GoK has made a clear statement of its intent to remain in the driving seat, coordinating and monitoring inputs, and to plan for long term sustainability. However, the NASIC requires support to ensure adequate co-ordination.

By the end of the grant we expect that the following will have been achieved:

- a) The NASIC Secretariat operates a functional coordination mechanism, for example maintaining a live workplan and budget to capture implementing partner contributions and convening regular meetings to bring partners together for co-ordination.
- b) The NASIC Secretariat has increased engagement with stakeholders both within government (at national and county levels) and among the wider stakeholder community e.g. development partners and research organisations engaged in AMR.
- c) The NASIC has identified strategies for increasing the national budget contribution to AMR surveillance in both animal and human health sectors.

Output 1.5: The existing One Health AMR mentoring scheme is scaled up

Significant capacity for microbiology and AMR surveillance exists in the non-government sector which could be a valuable technical resource for the state system. At the same time, contact across different sectors could encourage greater stakeholder engagement with the national AMR effort. NASIC intends

to develop and implement a One Health AMR mentoring scheme across public, private, and research laboratories in human and animal health following a successful pilot in surveillance sites.

As the surveillance systems develop, the intention is to expand the mentoring system so that government laboratories already in the system mentor those who are joining. Other ideas for the mentoring scheme involve developing a pool of technical experts who could be available in person or online, and, where relevant, including clinical staff.

The video conferencing facility provided by the World Bank in four surveillance site hospitals has been used successfully for training in AMR and should be expanded to all surveillance sites, both human and animal, so that it can support mentoring. Some staff also use videoconferencing to meet with NPHL and receive supportive supervision, a potentially more sustainable alternative to incurring transport costs for field visits.

By the end of the grant we expect that the following will have been achieved:

- a) A mentoring scheme is in operation across all human and animal health surveillance sites, with a curriculum and ToRs for mentors / mentees
- b) An increased number of professionals are engaged in the mentoring scheme.
- c) There is a plan in place to extend the scheme to human and animal laboratories beyond the current network to ensure ongoing expansion of the surveillance programme.

7.2 Objective 2: A strengthened AMR and AMU/AMC surveillance system in the human health sector

Output 2.1: NPHL has increased capacity to function as a reference laboratory and supporting centre for AMR surveillance

The National Public Health Laboratory has been selected as the national reference service for the AMR surveillance programme. A summary of its capacity is included in section 3.5 above. Areas which may require support from the grantee include:

- a) Ensuring Power Supply. The laboratory needs to have a reliable power supply to allow vital equipment to operate full time. However, the grant should not replace those functions which should be undertaken by GoK e.g. paying the electricity bill.
- b) Inventoried biorepository with associated SOPs and policies for use.
- c) Supervision: NPHL needs to expand its supervisory role as a reference laboratory. This will include assistance in provision of SOPs and bench aids suitable for sentinel laboratories to use, and support for provision of bacteriology EQA to sentinel sites. This may also include supportive supervision of subordinate laboratories.
- d) Human resources:
 - Training for good quality bacterial identification and AST, and for advanced confirmation / characterisation of phenotype
 - Support for technical staff in sentinel sites
 - Training in epidemiology / data management
- e) Supply of Reagents and Consumables. A mechanism should be designed that takes into consideration the national policy and guidelines in the procurement and supply of

consumables, ensuring the most efficient and effective way of obtaining the products to reduce stockouts and wastage of reagents.

- f) Ensuring the necessary equipment is in place with appropriate maintenance contracts, training and QA programmes.
- g) Strategy for dealing with Biosafety Level 3 pathogens. As the national reference laboratory, it is important that NPHL is prepared for handling dangerous pathogens. The laboratory should be assisted to develop plans for dealing with these beyond the life of the grant.

By the end of the grant we expect that the following will have been achieved:

- a) The bacteriology laboratory at NPHL has a reliable power supply protected from power fluctuations.
- b) Equipment identified in the assessment is purchased and staff are trained in its operation.
- c) A stock management system is in place to ensure reliable supply of reagents and consumables for surveillance activities. This includes a plan for sustainability beyond the end of the Fleming Fund grant.
- d) A collection of the necessary control strains is maintained at NPHL.
- e) NPHL has the capacity to do confirmatory testing, including bacterial identification, AST, MIC testing, phenotypic testing to confirm ESBL- and carbapenem-producing organisms, and quality control of results from referring sites.
- f) NPHL is supporting all operational surveillance sites with training and mentorship in bacterial identification, AST, and data entry and analysis.
- g) SOPs for referrals have been developed and are in use.
- h) A programme of continuing professional development for staff at the reference laboratory is in progress with a sustainability plan for beyond the Fleming Fund grant
- i) An EQA program arranged by NPHL for its subordinate laboratories is in progress.
- j) A simple biorepository has been established to ensure storage of relevant isolates, with associated SOPs for selection, storage and use of isolates.
- k) A strategy for dealing with Biosafety Level 3 pathogens is in place.

Output 2.2: The human health AMR surveillance system has capacity for data management

The human health surveillance strategy specifies how data should flow and the responsibilities of participating entities in the system, however currently there is limited functionality. Data is submitted centrally, but quality control is minimal, and submission is inconsistent. There is no real-time reporting and data from the two participating surveillance sites has to be manually tracked by the national coordinator. WHONET is not being used in any of the Fleming Fund surveillance sites that have been assessed by the MA: some laboratories operate a LIMS system and require an additional microbiology module to incorporate central reporting, while some labs do not have a LIMS and will need WHONET installation and training in the first instance. There is some epidemiology capacity at NPHLS which should be strengthened.

By the end of the grant we expect that the following will have been achieved:

- a) All surveillance sites show an increase in the quantity and quality of the data reported over the lifetime of the grant.
- b) All surveillance sites are recording data electronically and capturing both laboratory and clinical data.
- c) Appropriate software (WHONET/LIMS) is installed and in use at NPHL and the surveillance sites.
- d) A national data repository has capacity to handle all data from sites.
- e) All sites are receiving IT support to maintain LIMS/WHONET as necessary, with a plan for how this is to be continued after the end of the grant.
- f) Data quality checks are being carried out at site and national level.
- g) NPHL is able to monitor and report timeliness and quality of data recording. This may include via an internet accessible dashboard.
- h) NPHL demonstrates the capacity to analyse the data aggregated from the system and generate clinically useful reports and other data summaries.
- i) Clinical and laboratory staff at all sites have been trained in analysis of their own data.

Output 2.3: Sentinel laboratories function well and are included in an AMR laboratory network

All the surveillance sites possess functioning microbiology laboratories; however, they will need support to provide high quality surveillance data, including additional equipment, ongoing maintenance, assistance with procurement and development of stock management systems. Sites will also require IT support to ensure timely reporting while minimising the burden on laboratory staff for data entry.

The Grantee will need to reconfirm the procurement requirements as assessed by the Management Agent. Working with ministries and other donors to avoid duplication, the Grantee should ensure the laboratories have the necessary equipment and service contracts. The Grantee should support the laboratories to ensure consistent supply of quality reagents and consumables, and to develop IT and data management systems.

By the end of the grant we expect that the following will have been achieved:

- a) All renovations identified by the assessment and as agreed with the Management Agent have been completed.
- b) All equipment identified by the assessments and agreed with the Management Agent has been purchased and installed, with the necessary maintenance /s service contracts and staff training, and a sustainability plan to ensure ongoing maintenance and training beyond the life of the grant
- c) Each surveillance laboratory has adequate stocks of reagents and consumables, a stock management system, and a sustainability plan to ensure continuation beyond the life of the grant
- d) Staff demonstrate competency in specimen processing, bacterial identification, AST, and reporting, with adequate documentation of QC processes
- e) Each laboratory has a functioning IT platforming allowing efficient entry of surveillance data.

- f) All surveillance sites are contributing surveillance data suitable for inclusion in the WHO Glass database.
- g) SOPs and bench aids are in place and being used, with relevant QC processes

Output 2.4: Biosafety and biosecurity are ensured at the reference laboratory and at surveillance laboratories

Biosafety and biosecurity are pillars of a well-functioning laboratory. The Ministry of Health in Kenya has issued a Biosafety and Biosecurity Guideline document; however, biosafety and biosecurity issues were observed in most of the laboratories visited and the Grantee will need to provide the necessary inputs to ensure the safety of laboratory personnel and the wider public.

By the end of the grant we expect that the following will have been achieved:

- a) The laboratories are equipped with appropriate safety equipment and staff are wearing personal protective equipment while conducting testing
- b) Biosafety cabinets are operational, maintained and being used by staff appropriately
- c) Functioning Biosafety and Biosecurity systems are in place at all laboratories

Output 2.5: All laboratories have adequate levels of quality assurance and control

All laboratories should be working to the same high-quality standard. Staff should be adequately trained, and appropriate QC organisms need to be available on site and used to monitor the quality of work. The national EQA scheme must also be strengthened for the anticipated expansion of the surveillance system.

By the end of the grant we expect that the following will have been achieved:

- a) Quality management systems are in place in all laboratories.
- b) Reference strains for IQC are available and being used. The resulting IQC data is being collected and monitored regularly at a national level.
- c) A strengthened nation EQA scheme is supported, with all surveillance sites participating
- d) NPHL is confirming identity and susceptibility profile of 5-10% isolates from surveillance samples at each site.
- e) Surveillance site laboratories are working towards accreditation.
- f) Quality and completeness of laboratory and clinical data is being monitored and improves over the course of the grant.

Output 2.6: Clinical staff at the surveillance sites demonstrate increased utilization of microbiology services.

In some surveillance sites, few samples are submitted to the microbiology laboratory, meaning that data is likely to be under-representative. **Engagement with clinical staff will be necessary across all sites to ensure appropriate sampling of patients, collection of epidemiological and demographic data (patient data) and appropriate response to culture results.** This is critical for establishing a sustainable, passive surveillance programme. Laboratories will need to report results in a timely manner in order to inform patient care, and clinical staff should also be responding to culture results appropriately.

By the end of the grant we expect that the following will have been achieved:

- a) Increased number of good quality samples sent to the laboratory, with acceptable contamination rates and relevant clinical data recorded on the request form
- b) Results are communicated to clinicians in a timely manner
- c) Clinicians and pharmacists at the surveillance sites demonstrate an improved understanding of how to incorporate bacteriology results into their practice.
- d) Data generated at the site is analysed locally and being used to inform hospital level decisions on training, stewardship and drug policies. This may be via Medicines and Therapeutic Committees, Antimicrobial Stewardship Committees or similar entities

Output 2.7: A sustainable specimen transportation system is developed and functional

A transportation system, in which samples can be shipped between laboratories in a secure and reliable manner without significant delays, is a critical part of a properly functioning AMR surveillance system. Kenya has already developed a protocol for this in human health but has insufficient funding to operate it effectively. No protocol has been developed for the animal health sector, however the animal health surveillance sites are planned to be close to the human health sites and a shared transport system may be feasible.

The Grantee should provide support to identify strategies to improve transportation of samples throughout Kenya. This should be developed (in consultation with NASIC and other partners supporting surveillance) into a well-functioning system and incorporated into laboratory funding mechanisms to allow for sustainability.

By the end of the grant we expect that the following will have been achieved:

- a) A sustainable, functional transportation system to ship samples and isolates from collection sites to surveillance laboratories and from surveillance laboratories to the reference laboratories
- b) Samples can be reliably tracked from sampling site to the laboratory
- c) Training in sample packing and handling has been delivered to all surveillance sites.

Output 2.8: An AMC /AMU surveillance strategy is developed and implemented

There is currently no AMC or AMU surveillance strategy for Kenya and developing this is a priority. The country has previously participated in a Point Prevalence Survey (PPS) for AMU and GoK intends to expand the coverage of this to some of the sentinel sites and to private hospitals and community pharmacies. Other options that should be considered to assess AMC include consumption data analysis using data from the national regulator, the National Hospital Insurance Fund and the four pilot UHC counties, and analysing imports, manufacturing and distribution data. The grantee should support the development and implementation of a national strategy and plan for AMC and AMU surveillance.

By the end of the grant we expect that the following will have been achieved:

- a) A national strategy for AMU and AMC surveillance has been developed (by month 6 of the grant).
- b) AMC surveillance has been conducted at national level
- c) AMU data has been obtained from agreed sites

- d) IT system developed for management of consumption data linking national medicines regulatory authority, surveillance sites, and resistance data
- e) Surveillance protocols are improved on the basis of the data analysed
- f) NASIC disseminates results to care providers, policy makers and programme managers at county and national level
- g) A sustainable plan is in place for continuing AMC and AMU surveillance beyond the end of the grant

7.3 Objective 3: Strengthened AMR and AMU/AMC surveillance system in the animal health sector

Output 3.1: CVL has the capacity to function as a reference laboratory and supporting centre for AMR surveillance

The Central Veterinary Laboratory at Kabete in Nairobi has been selected as the reference laboratory for the animal health surveillance. The laboratory is currently undergoing major refurbishment and will be moving to a new building, anticipated to be in the next few months. The current capabilities of CVL are described in section 3.6, and the Grantee will need to update the assessment following the move to the new building.

The Grant will provide support for the CVL to undertake the following its role as AMR reference laboratory:

- Supervision and diagnostic expertise to support the regional laboratories
- Maintain quality diagnostic systems in regional laboratories contributing to surveillance, including:
 - Coordinate production of bench guides/flow charts
 - Develop SOPs to include all the bacteria in the surveillance programme
 - Training/mentoring on quality control (QC) and internal quality assurance system (IQAS)
 - External quality assessment (EQA) in regional veterinary laboratories and CVL.
- Maintain a collection of relevant ATCC or NCTC strains
- Maintain an inventoried national biorepository of important isolates
- Participate in an international EQA scheme
- Develop the capability to undertake more advanced diagnostic methods

By the end of the grant we expect that the following will have been achieved:

- a) CVL runs an EQA with the regional laboratories participating in the AMR surveillance programme
- b) CVL is participating in an international EQA scheme
- c) CVL is performing confirmatory QC testing on a subset of isolates sent from the regional laboratories, and conducts MIC testing on a representative sample of isolates
- d) CVL has the capability to conduct phenotypic testing to confirm ESBL-, acquired AmpC and/or carbapenemase-producing organisms.
- e) CVL has the capability to serotype the major *Salmonella* species found in animals in Kenya.
- f) An inventoried national biorepository has been established, with SOPs for selection, storage and use of isolates.

- g) Collaboration established with academic groups such as University of Nairobi Pathology Laboratory and ILRI in order to maximise use of isolates and data for research and creation of training programs or protocols as needed.

Output 3.2: A national database of verified AMR data, with associated demographic and epidemiological data is maintained, data is analysed, and reports on AMR trends are produced.

Data from the surveillance on animals will be analysed by the Veterinary Epidemiology and Economics unit (VEES). An electronic survey tool called Kenya Animal Bio-surveillance System (KABS) is currently used for collecting data in passive surveillance, and this could be expanded to include active AMR surveillance data to minimise the burden on staff.

Most of the surveillance laboratories use the SILAB LIMS, however, there is no interface to merge KABS and SILAB data at VEES. Currently data analysis is being performed using MS Excel and basic data analysis is carried out by KABS to provide immediate feedback to the sender and take action if an outbreak is suspected. Consequently, a data management system and data analysis software are needed for VEES (e.g. WHONET), ideally with linkage between SILAB and KABS.

By the end of the grant we expect that the following will have been achieved:

- a) The LIMS has been rolled out to all laboratories and staff have been trained in data entry.
- b) Integration of the LIMS and data collection systems so that laboratory results are accurately matched to demographic and epidemiological details
- c) Data is regularly backed up and sent to VEES for collation into a national database
- d) Data analysis software, such as WHONET, is installed and staff are using it effectively to analyse surveillance data.
- e) Quarterly reports of AMR surveillance results and interpretation are produced alongside the quarterly epidemiological bulletin.
- f) VEES produces results from analyses of the AMR surveillance data and shares with the stakeholders as necessary.
- g) Methods of maintaining high throughput and encourage use of laboratories are presented to stakeholders.

Output 3.3: All the laboratories in the surveillance network produce reliable bacterial identification and AST results

All the surveillance sites will need support to provide high quality surveillance data, including additional equipment, ongoing maintenance, assistance with procurement and development of stock management systems. Sites will also require IT support to ensure timely reporting while minimising the burden on laboratory staff for data entry.

The Grantee will need to reconfirm the procurement requirements as assessed by the Management Agent. Working with ministries and other donors to avoid duplication, the Grantee should ensure the laboratories have the necessary equipment and service contracts. The Grantee should support the laboratories to ensure consistent supply of quality reagents and consumables

By the end of the grant we expect that the following will have been achieved:

- a) A poultry AMR surveillance plan is implemented in co-ordination with the VEES team. The plan should be based on standard protocols e.g. from FAO where published, and / or the protocol provided by the Management Agent (developed in collaboration with Massey University, New Zealand).
- b) A protocol for AMR surveillance in dairy cattle has been developed, in co-ordination with the VEES.
- c) The surveillance plans and protocols include all relevant SOPs for sample collection, processing and laboratory testing.
- d) Ownership and understanding of surveillance protocol design (including sample size calculations, representativity issues, farm selection, biases, etc) and AMR data analysis are such that analysis and protocols can be carried out and adapted to future needs
- e) Laboratories are producing reliable culture, identification and AST results

Output 3.4: Good quality samples from broilers and layers are regularly sent to laboratories from selected counties for culture and AST.

The surveillance plan above should develop the protocols to ensure that regular sampling is done from the relevant poultry sectors. The Grantee will need to work with the surveillance sites and laboratories to ensure that good quality samples are taken and processed appropriately. This should also include any samples sent from sick animals, to ensure that passive surveillance data is also captured.

By the end of the grant we expect that the following will have been achieved:

- a) Field laboratory staff are trained in sample collection, handling and transportation methods that ensure good quality samples and staff safety. Teams should take into consideration sampling logistics to minimise field and transportation costs
- b) Appropriate epidemiological and demographic data is collected and can be linked to bacteriology results
- c) Appropriate isolates are forwarded from RVILs to CVL for confirmatory testing and archiving as appropriate.

Output 3.5: Biosafety and biosecurity are ensured at the reference laboratory and at surveillance laboratories

At present, there are no guidelines on biosafety and biosecurity for AH laboratories, although a draft policy in occupational safety and health policy for veterinary laboratories in Kenya is expected to be completed in 2019. The Grantees should work with laboratories to develop and implement Biosafety and Biosecurity policies, including for management of laboratory waste.

By the end of the grant we expect that the following will have been achieved:

- a) The laboratories are equipped with appropriate safety equipment and staff are wearing personal protective equipment while conducting testing
- b) Biosafety cabinets are operational, maintained and being used by staff appropriately
- c) Functioning Biosafety and Biosecurity systems are in place in all sites

Output 3.6: Improved quality management systems ensure reliable results

Quality management within the surveillance system needs improvement. Currently CSLI standards and harmonised SOPs are being rolled out across laboratories with some associated training, however further standardisation and training is required. A formal EQA system is also needed.

By the end of the grant we expect that the following will have been achieved:

- a) SOPs are in place and are being used by all relevant staff
- b) Quality management systems have been established at each laboratory which are sustainable beyond the life of the grant
- c) Laboratories are participating in EQA programmes for bacterial identification and AST. For the reference laboratory this should be an international scheme, and for the surveillance laboratories this can be an international scheme or as provided by the reference laboratory.

Output 3.7: A sustainable specimen transportation system is developed and functional

A transportation system, in which biological material can be shipped between laboratories in a secure and reliable manner without significant delays, is a critical part of a properly functioning AMR surveillance system. Kenya has already developed a protocol for this in human health but has insufficient funding to operate it effectively. No protocol has been developed for the animal health sector, however the animal health surveillance sites are planned to be close to the human health sites, and it is therefore possible that a transport system could be shared.

The grantee should provide support to identify strategies to improve transportation of samples from collection sites to laboratories, and from surveillance laboratories to the reference laboratory.

By the end of the grant we expect that the following will have been achieved:

- a) A sustainable, functional transportation system is in operation, to ship samples from collection sites to surveillance laboratories and from surveillance laboratories to the reference laboratory
- b) Samples can be reliably tracked from sampling site to the laboratory
- c) Training in sample packing and handling has been delivered to all surveillance sites.

Output 3.8: An AMC and AMU surveillance strategy is developed and implemented

As above, there is no formal surveillance strategy for AMC / AMU yet developed for Kenya. In the animal health sector, the strategy should take into consideration the stages in the value chain at which data can most usefully be collected. AMC data is likely to be most usefully collected at the national level, while AMU data could be collected at retailer and/or farm levels. The Grantee should work with the NASIC and relevant TWG to develop a feasible strategy to ensure collection of reliable, good quality, meaningful data.

By the end of the grant we expect that the following will have been achieved:

- a) An AMC and AMU surveillance strategy is developed, costed and agreed by month 12 of the grant. However, it can be adapted as lessons are learnt as pilot surveillance are conducted.
- b) A pilot study of AMU has been carried out
- c) Surveillance protocols are improved in response to the data analysed
- d) IT system developed for management of consumption data linking national medicines regulatory authority, surveillance sites, and resistance data

- e) NASIC disseminates results to AH care providers, policy makers and programme managers at county and national level, and to other stakeholders (e.g. OIE)
- f) A plan is in place for continuing AMC and AMU surveillance beyond the end of the grant.

7. Lead Grantee Roles and Responsibilities

The main role of the grantee will be to plan and execute outputs and deliver the objectives listed above. The Grant is designed as an AMR laboratory capacity building and systems strengthening intervention. The grantee is responsible for providing, either through in-house resources alone, or through a partnership or consortium, the expert technical assistance and high-quality support needed to strengthen the selected reference and surveillance sites' capability and capacity to generate and share AMR, AMC and AMU surveillance data on both a national and international basis.

8. Measuring success

Country Grants will eventually be expected to generate results that can be tracked using a standard set of indicators that will monitor progress and achievements within and across Country Grants. A copy of the full list of indicators will be shared in the Application Pack.

However, for the first Country Grant, it is important to note that:

- (i) Applicants are not expected to select from and use these indicators for this first Country Grant. While it is possible that some of the formal indicators may trigger towards later stages of the grant award, the likelihood of this will be reviewed and discussed by Mott MacDonald with the successful applicant.
- (ii) For the purposes of this grant, process level indicators will be used to track progress against the work plan. The grantee is expected to utilise the indicators proposed above or to propose alternative SMART indicators in line with the outputs summarised above. These will then be negotiated and agreed with Mott MacDonald as the Management Agent.
- (iii) No Country Grant will be expected to use all the Fleming Fund indicators. Instead a relevant sub-set of indicators will be proposed by the grantee for joint agreement with Mott MacDonald.
- (iv) The Fleming Fund will be independently evaluated by ITAD, a specialist evaluation firm, who have been appointed by the UK Department of Health and Social Care for this purpose. In addition to measuring grant performance against the objectives and outputs stated above, the grant will also be monitored on the implementation of, and adherence to, the Fleming Fund grant principles described above. All grants are subject to review and evaluation by the evaluators, and full co-operation with the evaluators by all grantees is expected.

9. Application requirements

10.1 Grant Eligibility Criteria

Potential grant applicants must satisfy the following eligibility criteria before applications will be assessed in detail. Applicants:

- Must demonstrate that they are competent organisations responding to this call for proposals.

- Must have an appropriate track-record in supporting laboratory capacity development, surveillance, capacity building, and One Health.
- Must have experience of programme implementation in Kenya.
- Must demonstrate that they are registered to work within the country, including the provision of essential documents such as articles of incorporation.
- Must demonstrate an understanding of the necessary permissions to operate in Kenya.
- Must be prepared to accept the Grant Agreement terms.
- Must be able to provide the same information and assurances for all sub-grantees, where the application is from a consortium.
- Should be able to provide all information required for due diligence checks, including clear evidence of financial standing and systems of financial management and control.
- Should be able to provide evidence of suitability in the form of references from clients and donors for previous work undertaken within the last three years.
- Can be a single organisation or consortium, though the latter must clearly identify a Lead Grantee with the appropriate governance and coordination mechanisms to manage sub-grantees.
- Lead Grantees can be:
 - International Non-Governmental Organisations (iNGOs) and other non-profits;
 - UN Agencies;
 - Private companies;
- Consortium members (sub-grantees) can be:
 - National institutes such as universities
 - Government-owned enterprises or institutions, provided they are legally and financially autonomous
- All grantees and sub-grantees must establish that they
 - Are legally and financially autonomous
 - Operate under commercial law
 - Are not dependent agencies of national governments
 - Have exemplary grant management practices with strong and enforced anti-corruption measures

10.2 How to apply

Prospective lead grantees must register their interest to apply by emailing flemingfundESA@mottmac.com to receive an invitation to **the Applicant Information Session**, and an **example of the Application Pack**.

The Applicant Information Session will be organised in **Nairobi, Kenya, on 02 May 2019**. The details of the venue will be shared with applicants registering their interest.

Ahead of the AIS, an example Application Pack will be shared and will include the application form, budget and milestones template and Guidance Notes. Following the AIS, the **official Application Pack** will be sent out to prospective Grantees who have registered their interest to apply for the grant.

To apply, please complete the application form provided, in line with the Guidance Notes, by the deadline indicated in Section 10.5.

Note the key requirements set out at the beginning of the Country Grant Application Form:

- When submitting the application document, press “Reply All” from the **official Application Pack automated email** that you received with the application documents attached. Do not send it to us from a new email, and do not modify the Subject-line. Only “Reply All” emails will register the documents in our system.
- Keep file sizes as low as possible - there is a 9MB size limit to each individual email that can be received by the grant submission software. You can submit documents by sending multiple emails attaching submission documents to each one. Please follow the instruction (above) using “Reply All” to the original email.
- The submission deadline is: **17:00 Kenya Time (GMT+3) Friday, 31 May 2019**
- Applicants should observe the word limit. Additional words outside the limit will be disregarded.
- All documents included as part of the proposal must be submitted by separate e-mail in Word, Excel, and PDF format (body font: Calibri 11pt). Do not send through as zipped files.
- You should include a covering letter, signed by the person authorised to represent your organisation for the submission of this proposal.
- This application is conditional upon your acceptance of the grant agreement (format will be shared in the application pack).

Proposals that do not satisfy these criteria may not be accepted.

10.3 Evaluation criteria

The Application Pack will include the application form, indicating the scoring and weighting for each section of the application. The Application Pack will also contain Guidance Notes explaining what we are looking for in terms of a good quality response for each question, including approach to Value for Money (VfM).

We would be assessing the application on the following key areas:

- Technical capacity to address the different aspects of AMR covered by this Country Grant.
- Ability and preparedness to bring stakeholders together in an effective and productive working arrangement, promoting a One Health approach.

10.4 Restrictions/limitations

Any conflict of interest, or potential conflict of interest, should be declared to Mott MacDonald when applicants are registering their interest to apply for the grant. If a conflict of interest, or potential conflict of interest, arises after that point the prospective grantee must clearly declare this in their proposal.

10.5 Key dates

Publication of RFP: **15 April 2019**

Deadline for registering interest to receive the Application Pack: **21 April 2019**

Applicant Information Session: **02 May 2019**

Deadline for registering to apply for Grant: **03 May 2019**

Application deadline: **31 May 2019, 17:00 Kenya Time (GMT+3)**

Anticipated start date of grant: **09 July 2019**

10.6 Contact details and support information

Any questions on the Request for Proposals should be sent to flemingfundESA@mottmac.com. The Management Agent will endeavour to respond to queries within 72 hours.

Annex 1: Eligible funding items

Laboratory Infrastructure Enhancement

- Infrastructure: renovation, redecoration, electricity and water supply, environmental controls, waste and waste disposal.
- Equipment: appropriate equipment for the level of capability; biosafety and biosecurity equipment; automated culture and identification platforms; IT equipment.
- Reagents, durables & consumables: appropriate media, reagents, culture plates, etc; glassware; sample collection consumables.
- Transport and logistics: vehicles or contracted services for transport of goods, and people; safe and secure transport of specimens and samples; logistical support for surveys.

Human Resource Strengthening and Workforce Reforms

- Training: clinical, veterinary, agricultural and One Health surveillance protocols; biosafety and biosecurity; microbiology, laboratory science and laboratory management; epidemiology and surveillance; genomics; IT training.
- Long-term support: ongoing and refresher training according to the competency and capabilities framework; Fleming Fellowship Scheme.

Surveillance System Strengthening

- Governance: support for AMR Coordination Committees & working groups; operational planning; cross-sectorial meetings and strategy reviews; evaluation(s).
- Quality assurance and control: site visits and audits, laboratory twinning / mentoring.
- Data: transfer and storage; safety and security; analysis software and training.
- Recurrent costs: utilities, maintenance of equipment, upkeep of laboratory space, small maintenance, personnel costs.

Building Foundations for Surveillance Data Use

- Support to build demand for AMR data: general awareness among prescribers, dispensers and agricultural consumers (i.e. farm workers, agribusiness); publication charges; workforce training.
- Evidence based strategy, policy and practice change: data / information sharing conferences, meetings and initiatives; conference attendance; IT platforms for data sharing and awareness / transparency.

Rational use of Antimicrobial Medicines

- AMU/C surveillance: development of strategies for AMU/C surveillance; use of AMU data for appropriate prescribing / informing stewardship programmes.