Request for Applications (RFA):

Tuberculosis Vaccine Development

HIV Vaccines and Prevention

MRC-RFA-SHIP 02-2013

November 2013
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1. INTRODUCTION

The Report on the Revitalisation of the MRC\(^1\) notes that medical research in the country is severely under-funded and highlights that it is critically important for the MRC to increase funding to Universities for extramural health research in order to “sustain vibrant medical research” in South Africa. One of the initiatives that was proposed to address this is the PDP (Product Development Partnership) funding model and this has led to the creation of SHIP (Strategic Health Innovation Partnerships). One of the outcomes of this initiative is that the MRC has entered into a pioneering partnership with the South African Department of Science and Technology (DST).

Over the last decade, the DST has initiated a number of strategic health research, development and innovation initiatives, including:

- South African HIV/AIDS Research Platform (SHARP),
- South African TB Research and Innovation Initiative (SATRII),
- South African Malaria Initiative (SAMI),
- Medical Devices Innovation Platform (MDIP)
- Nuclear Technologies in Medicine and Biosciences Initiative (NTeMBI), and
- Diabetes Research Platform.

The purpose of these strategic health innovation initiatives was to harness the capacity, capabilities and research projects situated at universities, science councils and the private sector and through collaborative efforts, combine these abilities and knowledge towards product development.

The main objective of these health innovation initiatives is to develop new and/or adapt existing drugs, vaccines and other biologicals, diagnostics and medical devices for the priority diseases or medical conditions in South Africa. Through these research and innovation initiatives, contributions will be made to the scientific output in the form of publications and the development of human capacity, but the main emphasis will be on the strengthening of the product development and innovation activities and infrastructure, leading to new and/or improved patents, products, practises and services.

SHIP was established at the MRC in January 2013 with the goal of funding multidisciplinary collaborative product-related research and development to address the priority conditions contributing to the burden of disease in South Africa. SHIP incorporates the health innovation initiatives of the DST in the areas of HIV (SHARP), TB (SATRII), malaria (SAMI), and more recently non-communicable diseases and maternal and child health. It also incorporates MDIP and the National Department of Health-funded activities of the South African AIDS Vaccine Initiative (SAAVI).

SHIP is now seeking to fund a small number of large, highly collaborative programmes in the areas of tuberculosis (TB) vaccine development, HIV vaccines and HIV prevention more broadly.

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2. PROGRAMME GOALS
The purpose of SHIP is to harness the capacity and strengths of local universities, science councils, research institutes and the private sector and, through collaborative efforts, facilitate product research and development in the field of health.

The particular goals of SHIP are to:

i. Develop new drugs and/or improve existing drugs

ii. Improve / repurpose existing drugs for new treatment regimens and/or new indications

iii. Develop new vaccines and/or generate new knowledge that directly impacts vaccine development

iv. Develop new immunological approaches to primary and secondary disease prevention

v. Develop new diagnostics and/or improve existing diagnostics

vi. Develop medical devices

3. PROGRAMME OUTCOMES
The anticipated outcomes of SHIP projects are:

1) Impact:
   - The development of new and/or improved health solutions, products, processes and practises in the priority areas

2) Quality science:
   - High quality projects – quality exceeds quantity
   - Research outputs in the form of publications and patents

3) Capacity Development:
   - Scientists trained and new expertise developed
   - New technology capacity developed

4. CALL FOR SHIP APPLICATIONS: AREAS OF INTEREST – TB VACCINE DEVELOPMENT AND HIV VACCINES AND PREVENTION
Applications will only be considered responsive to this call for applications if they address at least one of the topics or areas below:

4.1 Tuberculosis Vaccine Development:
In order to enable an accelerated vaccine development process and to strengthen the pipeline of TB vaccine candidates, MRC SHIP has launched this call aimed at addressing the significant knowledge gaps and bottlenecks in TB vaccine development.

Obstacles to the development of protective TB vaccines are considerable. Namely, the mechanisms underlying protection against infection and/or disease are not understood; there are no biomarkers known to predict the efficacy of vaccine candidates; and commonly-used animal models do not entirely mimic natural infection nor have they been designed to define the mechanisms underlying natural or vaccine-induced protection from infection or disease. Furthermore, much of the focus in the field of TB vaccine development has been on driving T cell responses against immunodominant antigens with the goal of increasing the proportion of infected individuals that remain disease-free. Although numerous candidate vaccines are in the pipeline, it is currently impossible to define efficacy against disease without the long and costly Phase IIb/III clinical trials. (For additional information about current candidates and ongoing assessment, see The TB Vaccine Blueprint. 2012. Tuberculosis. 92: S1-S35.)
The Goals 
This RFA seeks to identify projects that will help meet at least one or more of the following interrelated goals—

(1) To develop and investigate novel approaches to identify potential biomarkers or risk of infection or disease and, in the context of vaccine efficacy studies, correlates of vaccine-induced protection from infection or disease.
(2) To develop improved models for vaccination and challenge studies in animals and humans to understand protective immunity and evaluate pre-exposure; post-exposure anti-latency and therapeutic vaccines.
(3) To develop novel vaccine technologies across formulation, design and delivery.

These goals, along with proposal requirements and submission instructions, are described in greater detail below.

The Scope 
The purpose of this RFA is to define and develop ideas that, if pursued, will lead to the attainment of three inter-related goals. These goals are synergistic with those identified within the BMGF TB Vaccine Accelerator Program. These goals are described below with ideas and projects that would be considered within (or outside) the scope of each goal.

Scope of Goal 1: Proposals are invited for projects that pursue hypothesis-driven approaches aimed at the discovery of biomarkers of disease and novel immune correlates. Proposals that seek to elucidate the mechanisms of natural protective immunity; the interplay between adaptive and innate immunity; unconventional immune cells; triggers of disease progression; transmission; antigenic repertoire and mucosal immunity would be considered responsive to the call. Approaches that deploy new investigative technologies such as genomics, proteomics and bioinformatics are encouraged.

Scope of Goal 2: Proposals are invited for projects that pursue hypothesis-driven approaches aimed at improvement of animal and human models for vaccination and challenge studies. While several models are in use for vaccine development, it is unclear how predictive they are of outcomes in humans. Without direct comparison with human clinical trial data, it will be impossible to determine the overall predictive value of any model. Through this RFA, we seek proposals that, together, will identify properties of Mtb and conditions of exposure associated with the natural establishment of infection; allow such properties and conditions to be mimicked in optimized models and Mtb to be tracked throughout exposure, elimination, transient, and/or persistent infection; and identify host and/or mycobacterial markers that distinguish among these outcomes. The identification of all critically relevant properties of these natural transmission models could allow for their future duplication in artificial transmission models.

Scope of Goal 3: Proposals are sought for projects that investigate new formulations; delivery mechanisms or routes of administration for TB vaccines.

This call does NOT support the funding of clinical trials but will support leveraging the collection and analysis of additional samples in prospectively planned studies and purpose collected isolates within clinical trials provided the work is not being duplicated.

Proposals are requested for the use and analysis of sample repositories from existing cohort samples with well-defined disease outcomes, in order to identify potential immune correlates for vaccine development. Of interest, is sampled population diversity and differences in geographic location, consortia are therefore integral in responding to this call. Proposals must demonstrate
complementarity and novelty of the proposed investigation as compared to the current work in the field. Proposals from consortia targeting HIV-uninfected adolescents and young adults will have priority.

Examples of topics considered within the scope of the three stipulated goals:

- Identification of markers of exposure, prevention of infection, transient infection, and clearance of infection;
- Immune biomarkers discovery using systems biology and leveraged well characterized clinical samples;
- Vaccine approaches aimed at inducing antibody-mediated immunity, e.g., directed against the surface constituents of naturally-transmitted Mtb, including:
  - Efficient identification of such surface constituents, their immunogenicity and if/how these constituents differ in circulating strains;
  - Design and formulation of vaccine candidates based on the above;
  - Proof of concept testing of such in models of, or models mimicking, natural transmission;
- Definition of how above antibodies perturb the interaction of Mtb with host cells such as lung macrophages and dendritic cells;
- Vaccine approaches aimed at the induction of durable innate lymphocyte responses to Mtb glycolipids and proof of concept testing thereof;
- Development of reliable methods for identifying and studying highly-exposed individuals who remain uninfected and individuals who rapidly clear infection;
- Formal testing of the notion that individuals who skin-test convert (TST+ to TST-), or go from IGRA+ to IGRA-, have cleared prior infection;
  - Identification of protective immune signatures in such individuals;
- Methods for: quantifying live, infectious Mtb in the air (i.e., inoculum load in closed natural transmission settings); improving control and consistency in natural transmission models (e.g., time of exposure, level of exposure); and/or improving efficiency of natural transmission models (e.g., time to universal exposure to infectious Mtb);
- Characterization of the relevant biological characteristics of Mtb transmitted from human-to-human in typical settings, in concert with the development of in vitro Mtb growth and preparation conditions that result in bacteria that closely approximate those of naturally-transmitted Mtb (particularly in their surface architecture) and that can be aerosolized and transmitted without losing these relevant properties;
- Highly sensitive methods for ‘marking’ mycobacteria subpopulations in order to allow tracking of those with unique phenotypes and to explore key differences in infectivity and clearance by expanding planned cohorts and/or clinical trials in high incidence or exposure areas particularly in an adolescent/young adult population.

Examples of proposals that would be considered outside the scope of and, as such, would not be considered for funding:

- Approaches that closely resemble those already being implemented or under investigation e.g. duplication of existing studies;
- Conventional T cell antigen discovery;
- Adjuvant discovery;
- Exploratory/unbiased discovery studies without a testable and feasible hypothesis;
- Incremental improvements to approaches already implemented or under investigation that fall outside the specific areas listed above;
- Epidemiology or infection/disease prevalence studies;
- Utilization or improvement of artificial challenge models that do not address shortcomings discussed above;
- Genome association studies;
- Studies of existing natural transmission models without a focus on optimization of the parameters discussed above;
- Models of latency or disease.

4.2 HIV Vaccines:

Despite the encouraging results from the RV144 trial, which demonstrated modest efficacy of a vaccine candidate regime, many questions remain to be answered on how to effectively protect against HIV infection and the complex immunological and viral interactions and processes involved. It is also vital that the development of novel vaccine candidates continue, building on the knowledge that has been generated from a number of HIV vaccine trials to date. In order to address some of these issues, SHIP is seeking proposals in the following areas of HIV vaccine research and development:

- Vaccine platform development: We are specifically seeking novel or improved vaccine platforms that can be applied to HIV, TB and other diseases. These platforms should build on current knowledge of what types of systems work best in the clinical setting, particularly for the target diseases, and should preferably have demonstrated proof of concept. Novel adjuvants may also be included.

- Mucosal immunity: Proposals should focus specifically on how to apply current knowledge on mucosal immunity in HIV infection to vaccine development and HIV prevention more broadly. Proposals may also include ancillary studies linked to clinical trials that investigate mucosal responses and their role in potential protection against HIV infection.

- Hypothesis-driven, lab-intensive studies leveraging clinical samples: These studies should be linked to existing clinical cohorts or form ancillary studies around current and new HIV vaccine trials and should aim to answer specific scientific questions (such as understanding correlates of protection) or generate unique reagents (such as broadly neutralizing antibodies against circulating strains) that will inform vaccine development. Proposals in this area may include an element of cohort support.

- Functional cure of HIV: Here we are seeking proposals for studies that build on the recent international cases of functional cure of HIV. These could include detailed studies on long-term non-progressors, very small-scale clinical studies on ARV and/or bNAB or other treatment regimes that may lead to functional cure and new animal models in this regard. Collaborations with existing/future structures are encouraged.

4.3 HIV Prevention:

SHIP is seeking proposals in the following areas of HIV prevention:

- New or improved HIV prevention methods, devices, drugs/biologicals, and combinations: Proposals should preferably be product focused, i.e. aimed at developing new or improved microbicides, HIV prevention devices, and combination treatments aimed at HIV prevention. Small-scale clinical studies on new HIV prevention methods may be considered, subject to the availability of funding.

5. APPLICATION SCHEDULE

The timelines for the application process are shown in Table 1.
Table 1. Application timelines

<table>
<thead>
<tr>
<th>Stages</th>
<th>Date/period</th>
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<tr>
<td>1. Publication of call</td>
<td>22 November 2013</td>
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<tr>
<td>2. Deadline for submitting applications</td>
<td>14 February 2014</td>
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<td>4. Evaluation period (indicative)</td>
<td>18 February – 30 April 2014</td>
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<tr>
<td>5. Feedback to applicants (indicative):</td>
<td></td>
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<tr>
<td>Official letter (award decision)</td>
<td>May 2014</td>
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<tr>
<td>6. Grant agreement finalised (indicative)</td>
<td>July 2014</td>
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6. ELIGIBILITY CRITERIA

Investigators from South African universities, science councils (including the MRC) and other public research organisations who hold a PhD, MBChB or equivalent degree are eligible to apply.

Local not-for-profit companies, research institutes, civil society groups and non-governmental organizations that conduct research and/or product development may apply directly for SHIP funding but should preferably have at least one local university or science council collaborator.

Private companies (South African and foreign entities registered as private, for-profit companies) may not apply for funding directly but may be included as sub-contractors if they provide a service or capability that is not available among the project partners.

Foreign collaborators (research institutions, universities etc.) may be included in the project but will not receive SHIP funding.

Foreign not-for-profit companies, research institutes, civil society groups and non-governmental organizations that conduct research and/or product development may not apply for funding directly but may be included as sub-contractors if they provide a service or capability that is not available among the project partners and/or not available locally.

**Preference will be given to multi-disciplinary proposals involving 2 or more institutions and where proof of concept has already been demonstrated. Successful applicants may be requested to partner/collaborate if 2 or more similar projects are submitted by different investigators.**

7. FUNDING CRITERIA

There is no maximum funding amount per project. However, submissions requesting a total budget over R15M will need to be especially strongly motivated and must demonstrate a clear product related deliverable within the timescale of the project. Projects must be budgeted on a milestone basis and extrapolated to an annual budget. Funding will be awarded for three years, subject to the project team meeting agreed milestones and the availability of funding.

An institution may not submit more than 3 applications as the principal recipient. However, there is no limit to the number of times an institution is listed as a collaborator on submissions by other primary recipients.

Allowable costs include:
- **Personnel:** Only personnel carrying out product based research and development are allowed to claim costs. Researchers and PIs who receive a salary from the host institution as permanent or fixed term staff members may NOT claim salary reimbursement from SHIP grants;
- **Consultants:** These may include both local and/or foreign consultants who provide a service or capability that is not available among the project partners. A motivation is required. Preference should be given to local service providers;
- **Equipment:** Partial or full support for the cost of equipment may be requested. Funding for equipment and infrastructure is allowed but is limited to a maximum of 20% of the budget and must be directly required for the project;
- **Supplies and consumables;**
- **Sub-contracts:** These may be to any local or international organization that provides a service or capability that is not available among the project partners but is essential to the project;
- **Travel & accommodation:** Must be directly related to the execution of the project;
- **Other research costs;**
- **Institutional overhead:** An indirect costs rate of 5% to a maximum of R250k will be allowed.

Non-allowable costs include:

- Purchase or construction of a building;
- Rental costs for space that is owned by the institutions participating in the project;
- Recruitment costs for staff;
- Attendance at conferences;
- Institutional overheads on funds that are being “on-granted” to consortium partners; and
- Purchase of office furniture.

### 8. APPLICATION GUIDELINES AND PROCESS

All applications must be submitted using the [SHIP Proposal Template](#) and [SHIP Application Budget Template](#) posted on the MRC website or obtainable from the SHIP projects administrator, Nereshnee Moodley ([nereshnee.moodley@mrc.ac.za](mailto:nereshnee.moodley@mrc.ac.za)). The length of the proposal should not exceed 20 single spaced pages, excluding the title page and annexures.

The Proposal should be submitted in Word or clean PDF format (PDF conversion from Word and NOT a scanned document) and the Budget should be submitted in Excel format. Only the signature page may be submitted separately as a scanned document. Annexures may be submitted separately or as part of the Proposal. All documents should be submitted via email to [ship.rfs@mrc.ac.za](mailto:ship.rfs@mrc.ac.za) before close of business (5 pm) on **14 February 2014**.

The SHIP website includes a [Frequently Asked Questions](#) section. Potential applicants may also direct any queries to:

- **SHIP Director:** Richard Gordon ([richard.gordon@mrc.ac.za](mailto:richard.gordon@mrc.ac.za))
- **HIV Programme Manager:** Michelle Mulder ([michelle.mulder@mrc.ac.za](mailto:michelle.mulder@mrc.ac.za))
- **TB Programme Manager:** Roxana Rustomjee ([roxana.rustomjee@mrc.ac.za](mailto:roxana.rustomjee@mrc.ac.za))
- **SHIP Administrator:** Nereshnee Moodley ([nereshnee.moodley@mrc.ac.za](mailto:nereshnee.moodley@mrc.ac.za))

Please read through this RFA in its entirety and ensure that your application, budget and institution are in compliance with all of the rules and eligibility criteria provided. Proposals for projects that do
not meet all of the eligibility criteria and/or do not directly respond to the call areas will not be reviewed, regardless of their quality. You are strongly encouraged to contact SHIP if you are unsure about the eligibility or responsiveness of your project.

9. EVALUATION PROCESS
There will be a four-step review, evaluation and approval process, viz,

- SHIP will screen the proposals for responsiveness to all the specified administrative and procedural provisions required in the RFA. If the application is found to be incomplete or unresponsive to the provisions described in the RFA, the application will be returned to the institution without further review.
- Proposals that meet the eligibility criteria will be submitted for peer-review by local and international reviewers to assess the scientific merit (and other review criteria as specified below).
- The SHIP Scientific Advisory Committee will collate the results of the reviews and recommend applications for funding to the SHIP Steering Committee.
- A protocol development workshop will be convened for successful applicants responding to the TB vaccine development call. A recommendation to amalgamate and/or redefine individual proposals may result.
- A final decision on applications to be funded will be made by the SHIP Steering Committee and approved by the Executive Management Committee of the MRC.

The process is shown in Figure 1.

![Figure 1: SHIP Approval Process](image-url)
9.1 Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field. Preference will be given to projects that are multi-disciplinary and involve 2 or more institutions and where proof of concept has already been demonstrated.

Significance. Does the science address an as yet unmet health need? Will the project likely result in a new and/or improved health product, practise or solution? If so, is there a viable market and would the potential cost be acceptable? How important is the science to improvement of scientific knowledge, technical capability, and/or clinical practice in the intended field as well as more broadly? Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? How will successful development of the product, practise or solution change patient outcomes?

Investigator(s). Is the team a single institution or PI or large, multi-institutional and multi-disciplinary? Are the PIs, collaborators, and other researchers well suited to the project? Do they have appropriate experience and training and a demonstrated record of accomplishments in their field(s)? If the project is collaborative in nature, do the investigators have complementary and integrated expertise? Are their leadership approach, governance and organisational structure appropriate for the project?

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Is the science/approach highly innovative? Is a new or improved product practise or solution likely to result from the project? What is the stage of development of the technology – is it still basic research or has proof of concept been demonstrated? Is the technology risk high or low? Is the IP position sound, i.e. is there the likelihood of generating strong and protectable IP with freedom to operate (limited prior art)? Is the competitive landscape and the strategic fit of the research well defined? What is the market potential of the proposed product?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are the milestones and deliverables clearly thought through and articulated? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Are all of the necessary components for product development in place and/or available to the investigators? What are the main limitations/obstacles in the development chain?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Budget available. The strongest applications will be funded and the budget will be prioritised accordingly.
10. **GRANT PAYMENTS**
Grants will be paid to the institution where the PI is employed. The disbursement of funds will be according to the disbursement schedule agreed to by the MRC and the institution and will be set out in the agreement between the parties.

11. **RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR**

11.1 **Reporting**
All PIs must submit six-monthly and annual reports from the year of receipt of the grant. Reports must be completed on the template provided by the MRC.

11.2 **Scientific compliance**

11.2.1 **Ethics**
All PIs are required to maintain the highest ethical and safety standards in conducting the research, particularly when human and animal subjects are involved. It is the responsibility of the PI to comply with all relevant regulations in this regard, including those of the institution at which the research is carried out. An ethics approval certificate/letter from a National Health Research Ethics Committee approved Institutional Ethics Committee must be submitted to the MRC in respect of successful applications before full funding can be released.

11.2.2 **Intellectual Property Rights**
Funding by the MRC is subject to the provisions of the *Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008*. Further, SHIP requires that intellectual property is managed in a manner that ensures “Global Access.” Global Access requires that (a) the knowledge and information gained from funded projects be promptly and broadly disseminated, subject to intellectual property protection, where appropriate, and (b) the intellectual property be made available and accessible at an affordable price to people most in need within developing countries.

11.2.3 **Change of Project Leadership**
Note that grants are made to the host institutions and not to individuals. In the event the principal investigator leaves the Institution for whatever reason, the MRC must be informed (where possible, prior to the departure of the PI from the institution), of proposed alternate arrangements for the continued management and leadership of the project, with complete documentation that demonstrates the qualifications of the alternate leadership. After reviewing the proposed change, the MRC may decide to terminate the award if there is a determination of insufficient continuing expertise to lead the approved research to a successful conclusion.

If the new PI is approved by the MRC, she/he will be required to sign an amendment to the Funding Agreement and submit a CV as well as a revised management plan.

12. **IMPORTANT INFORMATION**
Please take note of the following important information:
i. The MRC will utilise the results of the peer review to determine which meritorious applications receive funding. The MRC may also consider additional factors such as a balance in the range of topics supported in making its final determinations;

ii. Based on the scientific merit of the applications and/or budget limitations, the MRC may award fewer or more grants than expected;

iii. The MRC may award grants with different funding amounts and/or different durations;

iv. The MRC may seek to verify any information provided by applicant’s through independent research or by third parties approved by the MRC;

v. The MRC assumes no responsibility for costs incurred in responding to this RFA or any further invitations or communications;

vi. The MRC reserves the right to amend or withdraw the RFA at any time;

vii. The MRC may use text, video or other visual representation submitted by successful applicants on the MRC website or on MRC materials for publicity and/or public awareness;

viii. The MRC will provide written summaries of the review findings for those applications found responsive and submitted to the review process. Note that reviewers’ names will not be shared with the applicants.

13. CONTACT DETAILS

Please direct your requests for information and questions/queries to:

SHIP Director:
Dr Richard Gordon
email: richard.gordon@mrc.ac.za

SHIP HIV Programme Manager:
Dr Michelle Mulder
email: michelle.mulder@mrc.ac.za

SHIP TB Programme Manager:
Dr Roxana Rustomjee
email: roxana.rustomjee@mrc.ac.za

SHIP administrator:
Ms Nereshnee Moodley
Phone: (021) 938 0382
email: nereshnee.moodley@mrc.ac.za

Please refer to the SHIP website (http://ship.mrc.ac.za) for regular updates on frequently asked questions.