# Appendix 1

## National regulatory authority participation agreement and undertaking for national regulatory authority focal point(s)

### Appendix 1, Part A

*Agreement to participate in the collaborative procedure between the World Health Organization (WHO) Prequalification Team (WHO/PQT) and national regulatory authorities (NRAs) in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines*

#### Details of NRA

Name of NRA: Rwanda Food and Drugs Authority ("the NRA")

Postal address: KN 3 Road Kicukiro/Kigali

Country: Rwanda ("the Country")

Telephone number (please include codes): +250 788634679

Email (please indicate contact details as appropriate for inclusion in the list of participating NRAs maintained on the WHO website): charles.karangwa@rwandafda.gov.rw

#### Scope of agreement

Applicants for national registration of a particular WHO-prequalified pharmaceutical product or vaccine (hereafter referred to as "Applicants") may express their interest to the NRA in the assessment and accelerated registration of this product ("the Product") in the Country under the "Collaborative Procedure between WHO/PQT and NRAs in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products or vaccines" (hereafter referred to as "the Procedure").[1]

Subject to the NRA agreeing to conduct such assessment and consider such accelerated registration of the Product under the Procedure (by submitting

[1] If the applicant for national registration is not the same as the WHO prequalification (PQ) holder, the WHO PQ holder must confirm to the NRA and to WHO/PQT by an authorization letter (as per the template annexed to Appendix 3, Part A) that the applicant is acting for, or pursuant to rights derived from, the WHO PQ holder, and that the WHO PQ holder agrees with the application of the Procedure in the country concerned.

the form reproduced in Part B of Appendix 3 attached to the Procedure to WHO/PQT through the restricted-acce ss website), the NRA hereby confirms for each such Product that it will adhere to, and collaborate with the WHO/PQT and the Applicant for registration of the Product in accordance with the terms of the Procedure.

### Confidentiality of information

Any information and documentation relating to the Product and provided by WHO/PQT to the NRA under the Procedure may include but shall not necessarily be limited to:

- the full WHO/PQT assessment and inspection outcomes (reports) and if relevant, also results of laboratory testing;
- information and documentation on variations (as defined in WHO guidelines[2]), as well as information and documentation on any actions \taken by WHO/PQT or NRAs post-prequalification of the Product;
- all such data, reports, information and documentation being hereinafter referred to as "the Information".

As regards sharing the outcomes of assessments, inspections and laboratory testing, only data owned by the WHO PQ holder and WHO/PQT are shared. Sharing of any other data is subject to additional agreement of the data owners concerned.

WHO/PQT agrees to make such information available to the NRA through a restricted-access website exclusively for the purpose of the assessment and accelerated registration of the Product in the Country and any post-registration processes that may be required, in accordance with and subject to the terms of the Procedure ("the Purpose"). The NRA agrees to treat any Information provided by WHO/PQT as aforesaid as strictly confidential and proprietary to WHO/PQT, the WHO PQ holder/Applicant and/or parties collaborating with WHO/PQT and/or the WHO PQ holder/Applicant. In this regard, the NRA agrees to use such Information only for the Purpose and to make no other use thereof. Thus, the NRA undertakes to maintain the Information received from WHO/PQT in strict confidence, and to take all reasonable measures to ensure that:

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[2] *For pharmaceutical products*: WHO guidelines on variations to a prequalified product. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-seventh report. Geneva: World Health Organization; 2013: Annex 3 (WHO Technical Report Series, No. 981), (and any updates thereto).
*For vaccines*: http://www.who.int/immunization_standards/vaccine_quality/variations_pq_vaccine/en/ (and any updates thereto).

- the Information received from WHO/PQT shall not be used for any purpose other than the Purpose;
- the Information shall only be disclosed to persons who have a need to know for the aforesaid Purpose and are bound by confidentiality undertakings in respect of such information and documentation which are no less stringent than those contained herein.

The NRA warrants and represents that it has adequate procedures in place to ensure compliance with its aforesaid obligations.

The obligations of confidentiality and restrictions on use contained herein shall not cease on completion of the Purpose.

The obligations of confidentiality and restrictions on use contained herein shall not apply to any part of the Information which the NRA is clearly able to demonstrate:

- was in the public domain or the subject of public knowledge at the time of disclosure by WHO/PQT to the NRA under the Procedure; or
- becomes part of the public domain or the subject of public knowledge through no fault of the NRA; or
- is required to be disclosed by law, provided that the NRA shall in such event immediately notify WHO/PQT and the Applicant in writing of such obligation and shall provide adequate opportunity to WHO/PQT and/or the Applicant to object to such disclosure or request confidential treatment thereof (provided always, however, that nothing contained herein shall be construed as a waiver of the privileges and immunities enjoyed by WHO/PQT and/or as submitting WHO/PQT to any national court jurisdiction).

Upon completion of the Purpose, the NRA shall cease all use and make no further use of the Information disclosed to it under the Procedure, and shall promptly destroy all of the Information received from WHO/PQT which is in tangible or other form, except that the NRA may retain copies of the Information in accordance with its established archival procedures, subject always, however, to the above-mentioned obligations of confidentiality and restrictions on use. The Purpose for each product shall be deemed completed as soon as:

- the WHO PQ holder/Applicant discontinues participation in the Procedure for the particular product;

- the Product is deregistered by the NRA and/or delisted by WHO/PQT.

The access right of the NRA's focal point(s) to the restricted-access website will cease automatically upon the NRA ceasing to participate in the Procedure. If and as soon as an NRA focal point is replaced by a new focal point or ceases to be an employee of the NRA, such focal point's access to the restricted-access website shall automatically terminate.

The NRA agrees that it has no right in or to the Information and that nothing contained herein shall be construed, by implication or otherwise, as the grant of a licence to the NRA to use the Information other than for the Purpose.

### Timelines

In respect of each Product that the NRA agrees to assess and consider for accelerated registration under the Procedure, the NRA undertakes to abide by the terms of the Procedure, including but not limited to the following timelines for processing each application:

- within 90 calendar days of regulatory time[3] after obtaining access (through the restricted access website) to:
  - the data submitted to WHO/PQT for prequalification of the Product and owned by the WHO PQ holder,
  - the full WHO/PQT assessment and inspection outcomes (reports),

  the NRA undertakes to take a decision on the national registration of the Product;

- within 30 working days of the NRA's decision on national registration of the Product, the NRA undertakes to inform WHO/PQT of this decision and of any deviations from WHO conclusions during prequalification (with an indication of the reasons for such deviations) by completing and submitting the form attached as Appendix 3, Part C to the Procedure to WHO/PQT through the restricted-access website;

[3] Regulatory time starts after a valid application for the registration according to the Procedure has been received and access to the confidential information has been granted (whichever is the later) and continues until the date of decision on registration. The regulatory time does not include the time granted to the applicant to complete missing parts of the documentation, provide additional data or respond to queries raised by NRAs.

- if a national variation procedure results in the nationally-registered product being no longer the same[4] as the WHO-prequalified product, or if and to the extent a variation of a WHO-prequalified product is not followed by a variation of the nationally-registered product and as a consequence, the nationally-registered product is no longer the same as the WHO-prequalified product, the NRA undertakes to inform WHO/PQT thereof (together with an indication of the reasons for such deviations) within 30 days of the conclusion of the national variation procedure or within 30 days of having received access to the information and documentation provided by WHO/PQT, as the case may be (i.e. by completing and submitting the form attached to the Procedure as Appendix 4 to WHO/PQT through the restricted-access website);[5]
- the NRA undertakes to inform WHO/PQT in the case that the NRA deregisters or suspends the registration of the Product in the Country, by completing and submitting the form attached to the Procedure as an Appendix 4, to WHO/PQT through the restricted-access website, and to do so promptly if this decision is based on quality, safety or efficacy concerns, and within 30 days if this decision is based on other reasons.

### Focal points for access to restricted-access website

The NRA has designated the person(s) listed below to act as focal point(s) for access to WHO/PQT's restricted-access website. The undertaking(s) completed and signed by the focal point(s) is (are) attached hereto as an Appendix to this agreement.

Any change in designated focal points must be communicated to WHO/PQT without delay in writing and will be subject to the new focal point having signed and submitted to WHO/PQT the undertaking reproduced in Appendix 1, Part B to the Procedure. The NRA also undertakes to inform WHO/PQT if and as soon as a designated focal point ceases to be an employee of the NRA.

[4] Within the context of this Procedure, the same pharmaceutical product/same vaccine is characterized by the same product dossier; the same manufacturing chain, processes and control of materials and finished product, in the case of vaccines also by the same batch release scheme; the same active ingredient and finished product specifications; and the same essential elements of product information for pharmaceutical products, in the case of vaccines by the same product information, packaging presentation and labelling.

[5] If the fact that a WHO-prequalified product has been registered in a country pursuant to this Procedure has been made public, any subsequent deviations should also be made public.

## Focal point for inspections

*If applicable, this should be the same focal point as for the "WHO/PQT Collaborative Procedure with NRAs in inspection activities" (http://who.int/prequal, "Inspections"). The same person should be designated for inspections of pharmaceutical products and vaccines.*

1.

Mr/Ms/~~Dr~~

First name (and initials): Edouard

Surname/family name: Munyangaju

Title in NRA: Drugs & Food inspections and Compliance Division Manager

Email: emunyangaju@rwandafda.gov.rw

Telephone: +250788857525

■ A signed Undertaking is attached.

## Focal point(s) for dossier assessment

*For dossier assessment, different persons can be nominated for pharmaceutical products and vaccines. The same person may be nominated to be the focal point for inspections and dossier assessment. If additional person(s) are nominated for dossier assessment, please complete the details below.*

2.

~~Mr~~/Ms/~~Dr~~ as a focal point for dossier assessment of

pharmaceutical products only ☐

pharmaceutical products and vaccines ☒

First name (and initials): Clarisse

Surname/family name: Irasabwa

Title in NRA: Drugs & Health Technologies Assessment & Registration Division Manager

Email: cirasabwa@rwandafda.gov.rw

Telephone: +250788639507

■ A signed Undertaking is attached

3.

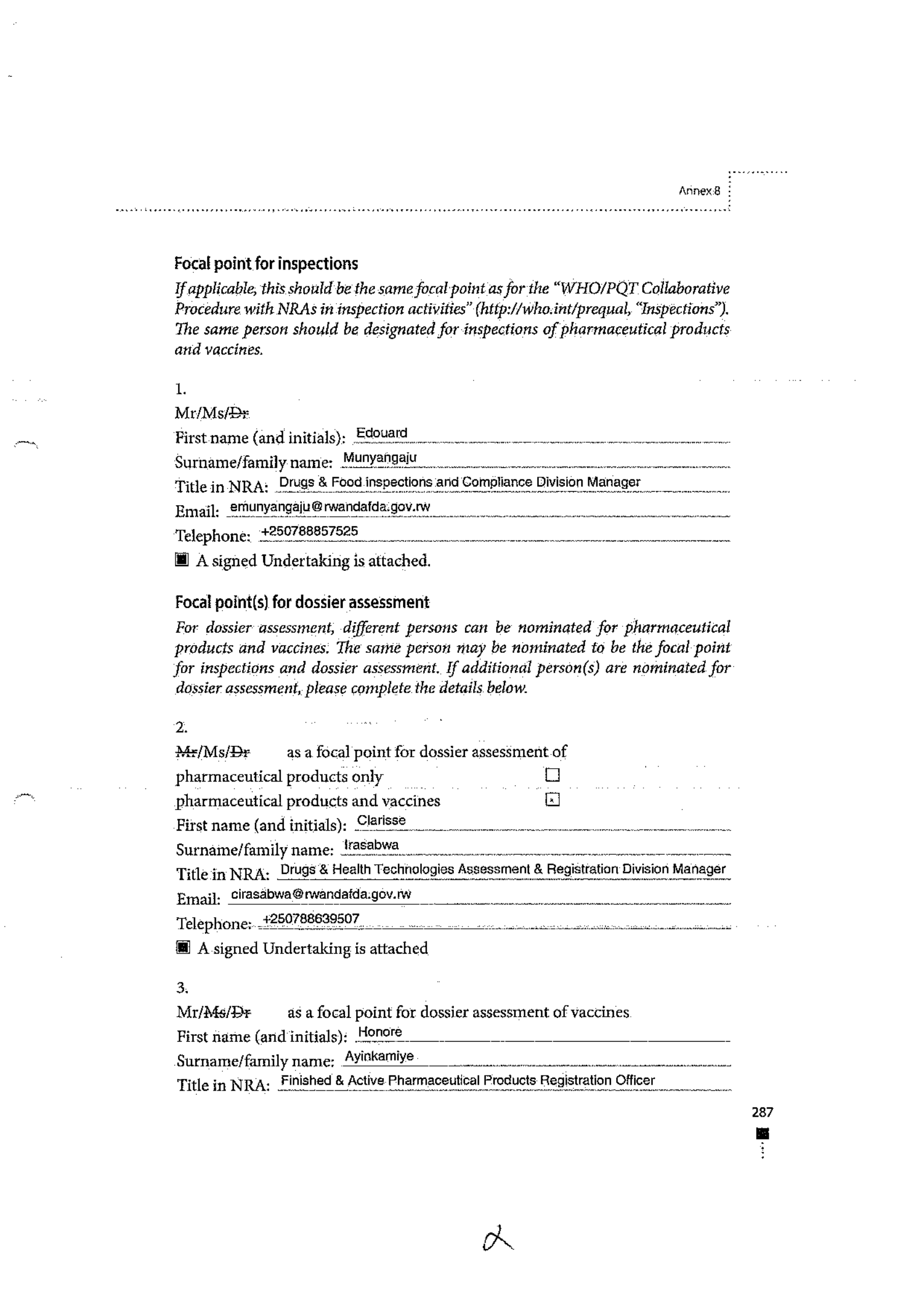
Mr/~~Ms~~/~~Dr~~ as a focal point for dossier assessment of vaccines

First name (and initials): Honore

Surname/family name: Ayinkamiye

Title in NRA: Finished & Active Pharmaceutical Products Registration Officer





Email: hayinkamiye@rwandafda.gov.rw

Telephone: +250788802853

■ A signed Undertaking is attached

## Miscellaneous

The NRA agrees that WHO/PQT may list its name on the WHO/PQT website as a participant in the Procedure. Except as provided hereinbefore, neither party shall, without the prior written consent of the other party, refer to the relationship of the parties under this Agreement and/or to the relationship of the other party to the Product, the Information and/or the Purpose, in any statement or material of an advertising or promotional nature.

This Agreement shall not be modified except by mutual agreement of WHO and the NRA in writing. The NRA furthermore undertakes to promptly inform WHO/PQT of any circumstances or change in circumstances that may affect the implementation of this Agreement.

The parties shall use their best efforts to settle amicably any dispute relating to the interpretation or execution of this Agreement. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or in the absence of agreement, with the UNCITRAL Arbitration Rules in effect on the date of this Agreement. The parties shall accept the arbitral award as final.

It is agreed furthermore that nothing contained in this Agreement shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national and international law, and/or as submitting WHO to any national court jurisdiction.

Agreed and accepted for pharmaceutical products and vaccines.

For the NRA

Signature: _____

Name: Charles Karangwa

Title: Ag.Director General

Place and date: Kigali 17 JAN 2020

Attachments:

Signed Undertaking(s) of NRA focal point(s) (Appendix 1, Part B)

# Appendix 1

## Agreement of the national regulatory authority to participate in the collaborative procedure in assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities

***Coordinated by the World Health Organization (WHO)***

### Details of national medicines regulatory authority (NRA)

Name of NRA: Rwanda Food and Drugs Authority ("the NRA")

Postal address:. KN 3 Road Kicukiro/Kigali

Country: . Rwanda

Telephone number (please include codes): . +250 788634679

Email: . charles.karangwa@rwandafda.gov.rw

### Scope of agreement

Applicants for national registration of a pharmaceutical product or vaccine approved by a stringent regulatory authority (reference SRA) (hereafter referred to as "Applicants") may express their interest to the NRA for the assessment and accelerated registration of this product ("the Product") in the country under the "*Collaborative procedure in assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities*" (hereafter referred to as "the Collaborative procedure of reference SRA approved products" or "the Procedure").[1]

Subject to the NRA agreeing to participate in the Procedure and conduct such assessment and consider such accelerated registration of the product under the Procedure, the NRA hereby confirms for each such product that it will adhere to, and collaborate with, the Applicant for marketing authorization of the product and if relevant with the respective reference SRA and WHO in accordance with the terms of the Procedure.

[1] If the applicant for national registration is not the same as the reference SRA registration/marketing authorization holder, the reference SRA registration holder must confirm to the NRA with an authorization letter that the applicant is acting for, or pursuant to rights derived from, the reference SRA registration holder, and that the reference SRA registration holder agrees with the application of the Procedure in the country concerned.

## Confidentiality of information

Any information and documentation relating to the product and provided by the Applicant or reference SRA to the NRA under the Procedure may include but shall not necessarily be limited to:

- the registration dossier as defined by the Procedure
- the full reference SRA assessment and inspection outcomes (reports);
- information and documentation on variations, as well as information and documentation on any actions taken by the reference SRA after national registration of the Product;
- all such data, reports, information and documentation being hereinafter referred to as "the Information".

As regards sharing the outcomes of assessments and inspections, full reference SRA assessment and inspection reports are shared by Applicants with participating NRAs with the agreement of the respective reference SRA. Should any data in the assessment and inspection report be hidden for whatever reason, the nature and scope of missing data will be clearly indicated. Sharing of any data by the reference SRAs is subject to consent of the data owner.

The Applicant and reference SRA agree to make the Information available to the NRA exclusively for the purpose of the assessment and accelerated registration of the Product in the Country and any post-registration processes that may be required, in accordance with and subject to the terms of the Procedure ("the Purpose"). The NRA agrees to treat any Information provided by the Applicant and reference SRA as aforesaid as strictly confidential and proprietary to the Applicant, parties collaborating with the Applicant and/or reference SRA as relevant. In this regard, the NRA agrees to use such Information only for the Purpose and to make no other use thereof. Thus, the NRA undertakes to maintain the Information received from the Applicant and reference SRA in strict confidence, and to take all reasonable measures to ensure that:

- the Information received from the Applicant or reference SRA shall not be used for any purpose other than the Purpose;
- the Information shall only be disclosed to persons who have a need to know for the aforesaid Purpose and are bound by confidentiality undertakings in respect of such information and documentation, which are no less stringent than those contained herein.

The NRA warrants and represents that it has adequate procedures in place to ensure compliance with its aforesaid obligations.

The obligations of confidentiality and restrictions on use contained herein shall not cease on completion of the Purpose.

The obligations of confidentiality and restrictions on use contained herein shall not apply to any part of the Information which the NRA is clearly able to demonstrate:

- was in the public domain or the subject of public knowledge at the time of disclosure by the Applicant or reference SRA to the NRA under the Procedure; or
- becomes part of the public domain or the subject of public knowledge through no fault of the NRA; or
- is required to be disclosed by law, provided that the NRA shall in such event immediately notify the reference SRA and the Applicant in writing of such obligation and shall provide adequate opportunity to the reference SRA and/or the Applicant to object to such disclosure or request confidential treatment thereof.

Upon completion of the Purpose, the NRA shall cease all use and make no further use of the Information disclosed to it under the Procedure, and shall promptly destroy the Information received from the Applicant and the reference SRA, which is in tangible or other form and is not archived in accordance with archival procedures established by the NRA. The Purpose for each product shall be deemed completed as soon as:

- the reference SRA authorization holder/Applicant discontinues participation in the Procedure for the particular product;
- the Product is deregistered by the NRA and/or ceases to be authorized by reference SRA.

The NRA agrees that it has no right in or to the Information and that nothing contained herein shall be construed, by implication or otherwise, as the grant of a licence to the NRA to use the Information other than for the Purpose.

Should WHO staff or external experts independent on the Applicant or NRA be provided with an access to the Information in order to coordinate the Collaborative reference SRA procedure or provide an expert opinion, an access to the Information shall be subject to a confidentiality undertaking.

## Timelines

In respect of each Product which the NRA accepts to assess and consider under the Procedure, the NRA undertakes to abide by the terms of the Procedure, including but not limited to the following timelines for processing each application:

- within 90 calendar days of regulatory time[2] after obtaining the assessment and inspection outcomes (reports) and validated QIS-SRA as well as receipt of validated submission, the participating NRA undertakes to take a final decision on the national registration of the Product;
- within 30 calendar days of regulatory time after obtaining the assessment outcomes (reports) and evidence of approval for variations and validated QIS-SRA (where applicable) as well as receipt of data submitted to the reference SRA for the variations, the participating NRA undertakes to take a final decision on the variation of the Product.

## Miscellaneous

The NRA agrees that WHO may list its name on the WHO-PQT website as a participant in the reference SRA Procedure. Except as provided hereinbefore, neither party shall, without the prior written consent of the other party, refer to the relationship of the parties under this Agreement and/or to the relationship of the other party to the Product, the Information and/or the Purpose, in any statement or material of an advertising or promotional nature.

This Agreement shall not be modified except by mutual agreement of WHO and the NRA in writing. The NRA furthermore undertakes to promptly inform WHO/PQT of any circumstances or change in circumstances that may affect the implementation of this Agreement and its participation in the Procedure. This Agreement can be invalidated by a written note from the NRA to WHO. Validity of this Agreement expires at termination of the Procedure, which will be publicly announced.

## Focal point(s) for communication

The NRA has designated the person(s) listed below to act as a focal point(s) for communication concerning the Procedure.

Title: Ms.

Name: Clarisse Irasebwa

Position: Drugs & Health Technologies Assessment & Registration Division Manager

[2] Regulatory time starts after a valid application for the registration according to the Procedure has been received and access to the confidential information has been granted (whichever is the later) and continues until the date of decision on registration. The regulatory time does not include the time granted to the applicant to complete missing parts of the documentation, provide additional data or respond to queries raised by NRAs.



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Email: cirasabwa@rwandafda.gov.rw
Telephone: +250788639507

Title: Mr
Name: Edouard Munyangaju
Position: Drugs & Food inspections and Compliance Division Manager
Email: emunyangaju@rwandafda.gov.rw
Telephone: +250788857525

Agreed and accepted
For the NRA

Signature: .
Name: . Charles Karangwa
Title: . Ag. Director General
Place and date: .

## Appendix 1, Part B

### Undertaking for NRA focal point(s)

The undersigned:

~~Mr~~/Ms/~~Dr~~

First name (and initials): Edouard

Surname/family name: Munyangaju

Title in NRA: Drugs & Food inspections and Compliance Division Manager

Name of NRA: Rwanda Food and Drugs Authority ("the NRA")

Country: Rwanda ("the Country")

Email: emunyangaju@rwandafda.gov.rw

Telephone: +25078857525

Applicants for national registration of WHO-prequalified pharmaceutical products or vaccines (hereafter referred to as "Applicants") may express their interest to the national regulatory authority (NRA) in the assessment and accelerated national registration of such products under the "Collaborative Procedure between the World Health Organization (WHO) Prequalification Team (WHO/PQT) and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines" (hereafter referred to as "the Procedure").[6]

Subject to the NRA agreeing to conduct such assessment and consider such accelerated registration of a WHO-prequalified product under the Procedure, WHO/PQT will communicate confidential Information (as hereinafter defined) relating to each such product to the NRA, and the NRA will communicate outcomes of the national registration procedure and post-registration actions in respect of such products to WHO/PQT, through a restricted-access website, which can be accessed only by the focal points designated by the NRA, including the undersigned. For the purpose of accessing the restricted-access website and downloading Information and uploading reports in accordance with and subject to the terms of the Procedure, WHO/PQT will provide the undersigned with a secret access code. The undersigned undertakes to treat this access code as strictly confidential and not to disclose it to any other person whatsoever. The undersigned furthermore undertakes

[6] If the applicant for national registration is not the same as the WHO PQ holder, the WHO PQ holder must confirm to the NRA and to WHO/PQT by an authorization letter (as per the template annexed to Appendix 3, Part A) that the applicant is acting for, or pursuant to rights derived from, the WHO PQ holder, and that the PQ holder agrees with the application of the Procedure in the country concerned.

to take all precautionary measures that may be needed to prevent any other person whatsoever from obtaining the aforesaid secret access code and from accessing the restricted-access website (i.e. except for the other designated focal points who have signed this Undertaking).

"Information" as aforesaid means any information and documentation relating to a WHO-prequalified product to be provided by WHO/PQT to the NRA under the Procedure, including but not necessarily limited to:

- the full WHO/PQT assessment and inspection outcomes (reports) and if relevant, also results of laboratory testing;
- information and documentation on subsequent variations (as defined in WHO guidelines[7]), as well as information and documentation on any actions taken by WHO/PQT or NRAs post-prequalification of the Product.

As regards sharing the outcomes of assessments, inspections and results of laboratory testing, only data owned by the WHO PQ holder and WHO/PQT are shared. Sharing of any other data is subject to additional agreement of the data owners concerned.

The undersigned confirms that:

1. the NRA has bound him or her to obligations of confidentiality and restrictions on use no less stringent than those contained in Appendix 1, Part A to the Procedure; and that
2. the aforesaid obligations of confidentiality and restrictions on use shall not cease on completion of the assessment and accelerated registration of any product in the Country, nor on completion of any post-registration processes that may be required, nor on the undersigned ceasing to be an employee of (or ceasing to have another relationship with) the NRA.

The undersigned shall automatically cease having the right to access the restricted-access website when the NRA designates a new focal point to replace the undersigned or when the undersigned ceases to be an employee of the NRA.

This Undertaking shall not be modified except by mutual agreement of WHO and the undersigned in writing. The undersigned furthermore undertakes

[7] *For pharmaceutical products:* WHO guidelines on variations to a prequalified product. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-seventh report. Geneva: World Health Organization; 2013: Annex 3 (WHO Technical Report Series, No. 981), (and any updates thereto). *For vaccines:* http://www.who.int/immunization_standards/vaccine_quality/variations_pq_vaccine/en/ (and any updates thereto).

to promptly inform WHO/PQT of any circumstances or change in circumstances that may affect the implementation of this Undertaking.

The parties shall use their best efforts to settle amicably any dispute relating to the interpretation or execution of this Undertaking. In the event of failure of the latter the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or in the absence of agreement, with the UNCITRAL Arbitration Rules in effect on the date of this Undertaking. The parties shall accept the arbitral award as final.

It is agreed furthermore that nothing contained in this Undertaking shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national and international law, and/or as submitting WHO to any national court jurisdiction.

Agreed and accepted by the undersigned:

Signature: _____

Name: Edouard Munyangaju

Title in NRA: Drugs & Food inspections and Compliance Division Manager

Place and date: 16/01/2020

## Appendix 1, Part B

### Undertaking for NRA focal point(s)

The undersigned:

~~Mr~~/Ms/~~Dr~~

First name (and initials): Clarisse

Surname/family name: Irasabwa

Title in NRA: Drugs & Health Technologies Assessment & Registration Division Manager

Name of NRA: Rwanda Food and Drugs Authority ("the NRA")

Country: Rwanda ("the Country")

Email: cirasabwa@rwandafda.gov.rw

Telephone: +250788639507

Applicants for national registration of WHO-prequalified pharmaceutical products or vaccines (hereafter referred to as "Applicants") may express their interest to the national regulatory authority (NRA) in the assessment and accelerated national registration of such products under the "Collaborative Procedure between the World Health Organization (WHO) Prequalification Team (WHO/PQT) and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines" (hereafter referred to as "the Procedure").[6]

Subject to the NRA agreeing to conduct such assessment and consider such accelerated registration of a WHO-prequalified product under the Procedure, WHO/PQT will communicate confidential Information (as hereinafter defined) relating to each such product to the NRA, and the NRA will communicate outcomes of the national registration procedure and post-registration actions in respect of such products to WHO/PQT, through a restricted-access website, which can be accessed only by the focal points designated by the NRA, including the undersigned. For the purpose of accessing the restricted-access website and downloading Information and uploading reports in accordance with and subject to the terms of the Procedure, WHO/PQT will provide the undersigned with a secret access code. The undersigned undertakes to treat this access code as strictly confidential and not to disclose it to any other person whatsoever. The undersigned furthermore undertakes

[6] If the applicant for national registration is not the same as the WHO PQ holder, the WHO PQ holder must confirm to the NRA and to WHO/PQT by an authorization letter (as per the template annexed to Appendix 3, Part A) that the applicant is acting for, or pursuant to rights derived from, the WHO PQ holder, and that the PQ holder agrees with the application of the Procedure in the country concerned.

to take all precautionary measures that may be needed to prevent any other person whatsoever from obtaining the aforesaid secret access code and from accessing the restricted-access website (i.e. except for the other designated focal points who have signed this Undertaking).

"Information" as aforesaid means any information and documentation relating to a WHO-prequalified product to be provided by WHO/PQT to the NRA under the Procedure, including but not necessarily limited to:

- the full WHO/PQT assessment and inspection outcomes (reports) and if relevant, also results of laboratory testing;
- information and documentation on subsequent variations (as defined in WHO guidelines[7]), as well as information and documentation on any actions taken by WHO/PQT or NRAs post-prequalification of the Product.

As regards sharing the outcomes of assessments, inspections and results of laboratory testing, only data owned by the WHO PQ holder and WHO/PQT are shared. Sharing of any other data is subject to additional agreement of the data owners concerned.

The undersigned confirms that:

1. the NRA has bound him or her to obligations of confidentiality and restrictions on use no less stringent than those contained in Appendix 1, Part A to the Procedure; and that
2. the aforesaid obligations of confidentiality and restrictions on use shall not cease on completion of the assessment and accelerated registration of any product in the Country, nor on completion of any post-registration processes that may be required, nor on the undersigned ceasing to be an employee of (or ceasing to have another relationship with) the NRA.

The undersigned shall automatically cease having the right to access the restricted-access website when the NRA designates a new focal point to replace the undersigned or when the undersigned ceases to be an employee of the NRA.

This Undertaking shall not be modified except by mutual agreement of WHO and the undersigned in writing. The undersigned furthermore undertakes

[7] *For pharmaceutical products:* WHO guidelines on variations to a prequalified product. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-seventh report. Geneva: World Health Organization; 2013: Annex 3 (WHO Technical Report Series, No. 981), (and any updates thereto). *For vaccines:* http://www.who.int/immunization_standards/vaccine_quality/variations_pq_vaccine/en/ (and any updates thereto).

to promptly inform WHO/PQT of any circumstances or change in circumstances that may affect the implementation of this Undertaking.

The parties shall use their best efforts to settle amicably any dispute relating to the interpretation or execution of this Undertaking. In the event of failure of the latter the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or in the absence of agreement, with the UNCITRAL Arbitration Rules in effect on the date of this Undertaking. The parties shall accept the arbitral award as final.

It is agreed furthermore that nothing contained in this Undertaking shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national and international law, and/or as submitting WHO to any national court jurisdiction.

Agreed and accepted by the undersigned:

Signature: _____

Name: Clarisse Irasabwa

Title in NRA: Drugs & Health Technologies Assessment & Registration Division Manager

Place and date: Kigali, 16/01/2020

## Appendix 1, Part B

### Undertaking for NRA focal point(s)

The undersigned:

~~Mr~~/Ms/~~Dr~~

First name (and initials): Honore

Surname/family name: Ayinkamiye

Title in NRA: Finished & Active Pharmaceutical Products Registration Officer

Name of NRA: Rwanda Food and Drugs Authority ("the NRA")

Country: Rwanda ("the Country")

Email: hayinkamiye@rwandafda.gov.rw

Telephone: +250788802853

Applicants for national registration of WHO-prequalified pharmaceutical products or vaccines (hereafter referred to as "Applicants") may express their interest to the national regulatory authority (NRA) in the assessment and accelerated national registration of such products under the "Collaborative Procedure between the World Health Organization (WHO) Prequalification Team (WHO/PQT) and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines" (hereafter referred to as "the Procedure").[A]

Subject to the NRA agreeing to conduct such assessment and consider such accelerated registration of a WHO-prequalified product under the Procedure, WHO/PQT will communicate confidential Information (as hereinafter defined) relating to each such product to the NRA, and the NRA will communicate outcomes of the national registration procedure and post-registration actions in respect of such products to WHO/PQT, through a restricted-access website, which can be accessed only by the focal points designated by the NRA, including the undersigned. For the purpose of accessing the restricted-access website and downloading Information and uploading reports in accordance with and subject to the terms of the Procedure, WHO/PQT will provide the undersigned with a secret access code. The undersigned undertakes to treat this access code as strictly confidential and not to disclose it to any other person whatsoever. The undersigned furthermore undertakes

[A] If the applicant for national registration is not the same as the WHO PQ holder, the WHO PQ holder must confirm to the NRA and to WHO/PQT by an authorization letter (as per the template annexed to Appendix 3, Part A) that the applicant is acting for, or pursuant to rights derived from, the WHO PQ holder, and that the PQ holder agrees with the application of the Procedure in the country concerned.



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to take all precautionary measures that may be needed to prevent any other person whatsoever from obtaining the aforesaid secret access code and from accessing the restricted-access website (i.e. except for the other designated focal points who have signed this Undertaking).

"Information" as aforesaid means any information and documentation relating to a WHO-prequalified product to be provided by WHO/PQT to the NRA under the Procedure, including but not necessarily limited to:

> the full WHO/PQT assessment and inspection outcomes (reports) and if relevant, also results of laboratory testing;
>
> information and documentation on subsequent variations (as defined in WHO guidelines[7]), as well as information and documentation on any actions taken by WHO/PQT or NRAs post-prequalification of the Product.

As regards sharing the outcomes of assessments, inspections and results of laboratory testing, only data owned by the WHO PQ holder and WHO/PQT are shared. Sharing of any other data is subject to additional agreement of the data owners concerned.

The undersigned confirms that:

1. the NRA has bound him or her to obligations of confidentiality and restrictions on use no less stringent than those contained in Appendix 1, Part A to the Procedure; and that
2. the aforesaid obligations of confidentiality and restrictions on use shall not cease on completion of the assessment and accelerated registration of any product in the Country, nor on completion of any post-registration processes that may be required, nor on the undersigned ceasing to be an employee of (or ceasing to have another relationship with) the NRA.

The undersigned shall automatically cease having the right to access the restricted-access website when the NRA designates a new focal point to replace the undersigned or when the undersigned ceases to be an employee of the NRA.

This Undertaking shall not be modified except by mutual agreement of WHO and the undersigned in writing. The undersigned furthermore undertakes

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*For pharmaceutical products:* WHO guidelines on variations to a prequalified product. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-seventh report. Geneva: World Health Organization; 2013: Annex 3 (WHO Technical Report Series, No. 981); (and any updates thereto).
*For vaccines:* http://www.who.int/immunization_standards/vaccine_quality/variations_pq_vaccine/en/ (and any updates thereto).

to promptly inform WHO/PQT of any circumstances or change in circumstances that may affect the implementation of this Undertaking.

The parties shall use their best efforts to settle amicably any dispute relating to the interpretation or execution of this Undertaking. In the event of failure of the latter the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or in the absence of agreement, with the UNCITRAL Arbitration Rules in effect on the date of this Undertaking. The parties shall accept the arbitral award as final.

It is agreed furthermore that nothing contained in this Undertaking shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national and international law, and/or as submitting WHO to any national court jurisdiction.

Agreed and accepted by the undersigned:

Signature: _____

Name: Honore AyinKamiye

Title in NRA: Finished & Active Pharmaceutical Products Registration Officer

Place and date: KIGALI, 17th January 2020