



_____, 2020

[Partner Organization]
[att:]
[address]

RE: Donation Agreement: LNG IUS donations by ICA Foundation

Dear _____,

Partner Organization, [*name of the partner organization to be inserted*] as listed above, (“Partner Organisation”) has approached ICA Foundation (“ICA”) for the purpose of possible donations of the levonorgestrel intrauterine system, LNG IUS (“Product”) by the ICA to Partner Organization for use in its service programs. The purpose of ICA is to serve the needs of women and families in resource-poor settings in the developing countries to achieve their desired family size and birth spacing through the use of contraceptive products. To serve its purpose, ICA provides a contraceptive medicinal product, LNG IUS, to non-governmental and public sector organizations for use in their programs subject to the terms and conditions of this Agreement.

In accordance therewith, ICA agrees to donate the Product for Partner Organization to make available the Product through its clinics and outreach sites in the Territory for a 5-year period based on the program progress, uptake and provided that the Partner Organization is continuously fulfilling its obligations under this agreement. “Territory” shall mean [*to be inserted*]. ICA will make a separate decision on each shipment and the quantities of the Product to be donated based on the donation request made by the Partner Organization, the uptake and demand of the Product in the Territory and the timeliness and accuracy of the Partner Organization’s reporting.

Non-compliance with any of the requirements of this agreement may result in the withdrawal of donated Product by the ICA Foundation.

1. Partner Organization agrees not to use the Product for biomedical research purposes, including clinical trials.
2. Partner Organizations may charge a reasonable price for the insertion / removal of each Product (“Service Fee”). Such Service Fee, including for both insertion and removal of the

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BUSINESS ID 1885477-6



Product, shall be affordable for women in resource poor settings in the Territory (i.e. no more than the equivalent of \$15 USD), and should preferably be paid at the time of insertion. If the Partner Organization charges part of its Service Fee at the time of product removal, it must ensure that no woman is denied service to remove her LNG-IUS, even if she is not able to pay. Partner Organizations will not charge users any other fees for the Product than the Service Fee. The ICA Foundation shall be kept informed of the amount of any Service Fee, and will consider exceptions to this policy under extraordinary circumstances only.

3. Partner Organization agrees not to distribute, make available or otherwise provide the Product outside the Territory or to providers outside of its service delivery mandate.

4. Partner Organization agrees to maintain full and accurate client records and agrees to provide ICA with regular updates at least twice a year (i.e., by the end of April and by the end of September) or as requested on the following items:

- numbers of Product received since the inception of the partnership;
- expiration date of the current Product stock;
- numbers of the Product inserted by Partner Organization per each country of the Territory;
- numbers of the Product removed by Partner Organization per each country of the Territory;
- numbers of the Product in the stock;
- changes in Partner Organization's provision of the Product to clients;
- number of trainings provided and number of participating healthcare providers;
- cost charged to clients for insertion/removal of Product;
- additional activities completed or planned to increase demand and awareness for the Product; and
- additional comments regarding any further information or concerns about number of products inserted, questions of storage, expiration, device removal, etc.

5. Partner Organization and ICA have entered into the separate Pharmacovigilance Agreement as attached herein.

6. Partner Organization shall ensure that all the personnel who insert or remove the Product are properly trained and supervised on client counseling on all available family planning methods as well as insertion and removal of the Product. Partner Organization will inform

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ICA regularly on the training activities performed. Furthermore, clients will be given informed choice on method selection, use and removal.

7. Partner Organization agrees to provide ICA with its plans for systematic removal of the Product and agrees to have the Product removed free of charge:

- (i) at any time upon the user's request,
- (ii) because of any manufacturer recall of the Product, or
- (iii) five years after the insertion of the Product.

The Product removal plans should also account for potential contingencies such as closure of Partner Organization or its programs.

8. Partner Organization is responsible for obtaining an import license or waiver from the local authorities to import and use the Product in the Territory if it is not registered (currently the Product is registered in Ghana, Kenya and Nigeria). ICA can provide a donation certificate, pro-forma invoice and some other documents (e.g. certificate of origin, certificate of analysis and packing list) for the import permit purposes, if needed.

9. If there are other Organization(s) receiving donations, from ICA Foundation in the same country as is covered by this MOU, Partner Organization agrees to form (if new) or join (if existing) a community of practice with the other Organizations to share their experiences around clinical guidelines, training standards, supply chain, client counseling, and reporting. In the event that one or more Organizations has a surplus or shortage of LNG-IUS, the Foundation may request that the Organizations cooperate in transferring products to one another to avoid stockouts and product expiration.

10. Partner Organization is acting for its own account and may not provide the product to any other organization not within the terms of this agreement or its service delivery mandate or without separate prior approval of ICA. Partner Organization understands that ICA may not necessarily be able to provide the Product in amounts or within the timeframe that Partner Organization desires.

11. Partner Organization shall comply with all applicable laws and regulations of the Territory.

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The above conditions and principles shall govern the donations of the Product by ICA to Partner Organization and are accepted by Partner Organization by returning a duly signed copy of this letter.

Yours sincerely,

ICA Foundation

Agreed and accepted:

[Partner Organization]

By: _____

Attachment: Pharmacovigilance Agreement

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