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Case Study

Donation of Contraceptive Products through Special Import Permits: A Case Study in Zambia and Nigeria

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Abstract

Introduction: Securing a special import permit for the donation of an unregistered contraceptive product can be a viable option to import the product in an expedited manner. However, this process can be difficult due to varying country requirements and the availability of accurate and timely information.

Case description: This paper will explore the process for securing import permits for donated contraceptive products in Zambia and Nigeria, comparing national guidelines to applicant experiences and providing recommendations to future applicants.

Discussion and evaluation: In practice, application requirements and timelines for special import permits in Zambia and Nigeria differed from national guidelines. Despite these differences, special import permits can be secured more quickly than formal product registration, which is a slower but more sustainable solution.

Conclusion: Due to a lack of comprehensive and up-to-date guidelines online for some low- and middle-income countries (LMICs), the regulatory community is encouraged to share their experiences with special import permit application processes.

Keywords: Contraceptives, Donations, Import Permits, Medicines; National Regulatory Authorities' (NRAs); Registrations; Regulatory; Regulatory Affairs, Zambia Medicines Regulatory Authority (ZAMRA), National Agency for Food and Drug Administration and Control (NAFDAC)

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1. Introduction

Access to safe, effective and quality medicines and vaccines for all is one of the targets of the Sustainable Development Goals. (1) However, the availability of such medicines, vaccines, and other health products depends on adequately resourced National Regulatory Authorities' (NRAs) ability to implement and adhere to thorough regulatory standards. (2) Ideally, health products enter a country via regulatory pathways that lead to full product registration. This ensures that all products on the market are safe, effective, and consistently meet approved quality standards.

However, although pursuing formal product registration is the ideal pathway, it can be a time-consuming process and can take months to years to receive marketing authorization approval. In emergency settings or natural disasters, access to critical and life-saving health products may need to be expedited. In other cases, such

as a clinical trial or pilot testing a product in a new market, registration of a product may not be a necessary first step. In these instances, securing an import permit for a donation of an unregistered pharmaceutical product can be a viable option. This paper will explore the process by which import permits were secured for donated contraceptive products in Zambia and Nigeria, detailing the required documents and fees, observed timelines, and variation between expected and observed outcomes.

The donations and resulting import permits discussed in this paper were facilitated by the Expanding Effective Contraceptive Options (EECO) project, which is funded by the United States Agency for International Development (USAID) and led by WCG Cares (WCG), an international nonprofit organization with expertise in product introduction and global regulatory affairs. The purpose of importing the donated contraceptive products was for pilot testing in new markets.

Special import permits for unregistered medicines

Special import permits are a short-term solution for making an unregistered, donated product available in a country for a variety of reasons. Per WHO guidelines, quality standards from the donor country should be upheld for the product being donated. (3) A formal registration route is preferable when time allows, as it gives the NRA the opportunity to evaluate the product based on local regulations and policies and ensures long-term and sustainable access to the product in the country.

Import permit requirements and timelines vary by country, as does the availability of information about these processes that can be accessed online. One of the major differences between high-income countries and LMICs is the availability and accuracy of online information about regulatory requirements. For this reason, it is strongly recommended that applicants confirm requirements with the NRA prior to submitting an application. At a minimum, the following documentation is often required for import permit applications: 1) a Certificate of Pharmaceutical Product (CPP) to confirm the marketing status of the product in the exporting country and to provide the importing country with information about the pharmaceutical product, 2) a Good Manufacturing Practice (GMP) Certificate to attest that the product manufacturer is compliant with established quality guidelines, and 3) the applicable Certificate of Analysis (CoA) from the donated batch to ascertain that it meets predetermined product release specification(s) and quality. National regulatory agencies vary in their willingness to approve import permits for unregistered products. If approved, import permits can be a faster albeit temporary way to get donated product in country.

Case Descriptions

We present here two case studies of special import processes that were followed in Zambia and in Nigeria,

to illustrate the difference between published guidelines and WCG's pathway to approval in each country.

2. Overview of the Zambia Regulatory Framework

The Zambia Medicines Regulatory Authority (ZAMRA) is the Statutory National Medicines Regulatory Body for Zambia. The main objective of ZAMRA is to ensure that all medicines and allied substances being made available to the Zambian people consistently meet set standards of quality, safety and efficacy. ZAMRA regulates and controls the manufacture, importation or exportation, distribution, and sale of medicines and allied substances.

Zambia Case Study: Import Permits for Hormonal IUS Donated Between 2015- 2019

Since 2015, WCG has facilitated the donation of the Levonorgestrel-releasing Intrauterine System (hormonal IUS) contraceptive product in Zambia. The hormonal IUS product was donated to EECO partner in Zambia, the Society for Family Health (SFH), for pilot testing in public sector clinics, and the Zambia Association of Gynaecologists & Obstetricians (ZAGO), for distribution at public sector hospitals.

WCG successfully applied for and received special import permits for the donated IUS product in Zambia in compliance with the Guidelines for Drug Donation (including ARVs) to the Republic of Zambia, published in 2005. (4) These guidelines provide the principles and procedures for recipient organizations and Government Ministries in their efforts to effectively manage drug donations. However, they do not provide a stepwise process for applying for an import permit for donated products. **Figure 1** below shows the step by step process that WCG followed to obtain the necessary authorizations for donated products in Zambia.

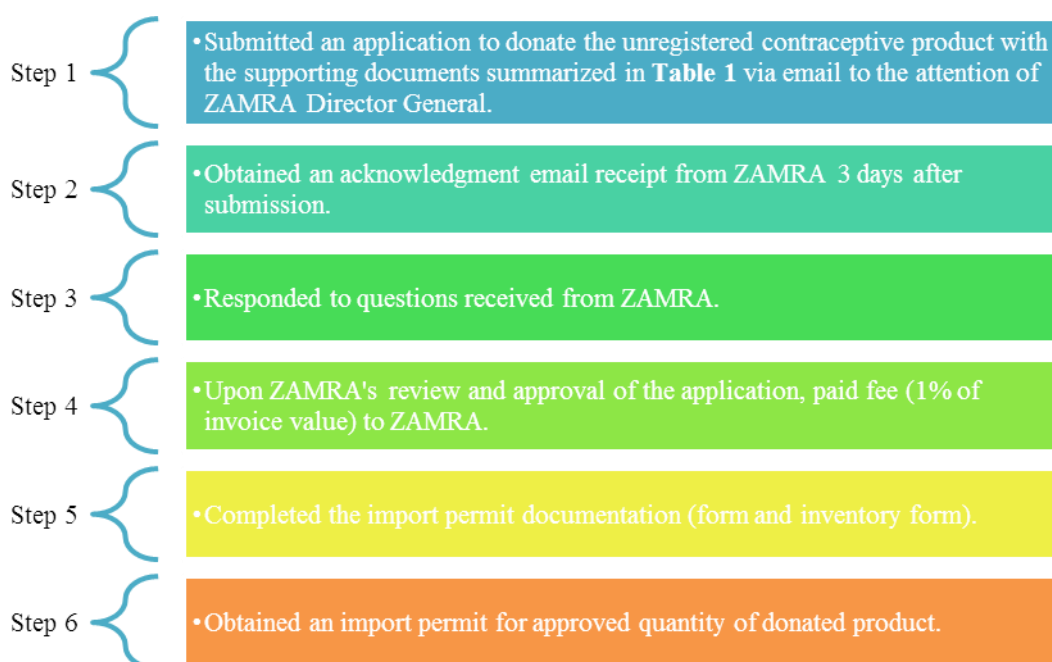


Figure 1. Process to Obtain an Import Permit for an Unregistered Donated Product in Zambia

Summary of the ZAMRA requirements, processing timelines, and costs

Requirements, timelines, and costs for the ZAMRA import permit application are detailed in **Table 1**. First, the items listed under ‘Required Documents’ in the second column under the header ‘Additional documentation requested’ show additional documents that were provided at the request of ZAMRA beyond what was listed in their guidelines. Secondly, the ZAMRA guidelines suggest that the timeline to approval takes approximately two weeks. For the six import permits that were submitted to ZAMRA, the time to approval ranged from 1 day to 65 days, while the average time for the six permits submitted was 37 days. Applicable fees and import permit length of validity were consistent with the guidelines.

It is worth noting that the regulatory authority may request additional information from the applicant if the product does not have marketing authorization or a registration license in Zambia. The applicant may be asked if they intend to register the donated product in Zambia, as ZAMRA’s mandate is to ensure that all medicines and allied substances being made available to the Zambian people meet standards for quality, safety, and efficacy. ZAMRA may also question the donation plan and the number of products per year that an applicant intends to donate. Generally, for large and continuous donations, ZAMRA may request that the applicant submit an application for product registration. Lastly, ZAMRA may inquire as to whether there is a pharmacovigilance plan between the donor and recipient for safety surveillance of the product.

Table 1. Summary of ZAMRA Requirements, Timelines and Fees

Parameters	Per ZAMRA guidelines	Authors’ Experience
Required Documents	<ol style="list-style-type: none"> 1. Application letter 2. Certificate of donation 3. Proforma Invoice with packaging list 4. ZAMRA application form for an import permit 5. ZAMRA inventory form 6. Certificate of Analysis (for the batch to be donated) 	<ol style="list-style-type: none"> 1. Application letter 2. Certificate of donation 3. Proforma Invoice with packaging list 4. ZAMRA application form for an import permit 5. ZAMRA inventory form 6. Certificate of Analysis (for the batch to be donated) Additional documentation requested: <ol style="list-style-type: none"> 1. Registration certificate in the Country of Origin 2. GMP Certificate 3. Certificate of Pharmaceutical Product, WHO-format
Timeline	According to the Importation and Exportation regulations (Statutory Instrument No.57 of 2017), the applicant shall be notified by ZAMRA, within 14 days of receipt of an application about their decision.	On average, approvals took 37 days, ranging from 1 day to 65 days. Below is the summary of application history: 1 st application for an import permit for 200 IUS units: 54 days to approval 2 nd application for an import permit for 200 IUS units: 18 days to approval 3 rd application for an import permit for 800 IUS units: 65 days to approval 4 th application for an import permit for 800 IUS units: 29 days to approval 5 th application for an import permit for 800 IUS units: 57 days to approval 6 th application for an import permit for 1,600 IUS units: 1 day to approval
Language of samples artwork used	Does not specify	Samples artwork was submitted in English and this was acceptable to ZAMRA.
Working Standard / Reference Standard, Stability and CPP	Per the guideline, “donated drugs should be authorized for sale in the country of origin and manufactured in accordance with International Standards of Good Manufacturing Practice. Where necessary, World Health Organization-type Certificate of Pharmaceutical Product will be requested as recommended by the World Health Certification Scheme on the quality of pharmaceutical products moving in International Commerce.”	The GMP certificate and CPP from the country of origin were submitted and this was acceptable to ZAMRA.

Costs	1% of the invoice FOB value as a preclearance fee.	Fee is consistent with guideline. However, cash payment in the local currency is required.
Import Permit Validity	One calendar year.	Validity is consistent with the guideline. The import permit specifies the production batch approved, product quantity approved, and the donation recipient in-country.

3. Overview of the Nigeria Regulatory Framework

In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) regulates and controls the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, medical devices, packaged water, chemicals, and detergents (collectively known as regulated products). NAFDAC offers guidelines for approval to import products by government agencies, international bodies, and multinational organizations. (5,6)

In Nigeria, an application for an import permit was submitted in 2019 by a local representative in Nigeria on behalf of WCG for the EECO project. The import permit was for 1,000 units of a progesterone vaginal ring contraceptive product for a pilot service delivery project. Because this was a new contraceptive product in Nigeria, the pilot service delivery project was designed to allow for the controlled introduction into the market. **Figure 2** below shows the process that WCG followed to obtain an import permit for an unregistered donated product in Nigeria.

Nigeria Case Study: Import Permit for a Contraceptive Product Donated in 2019

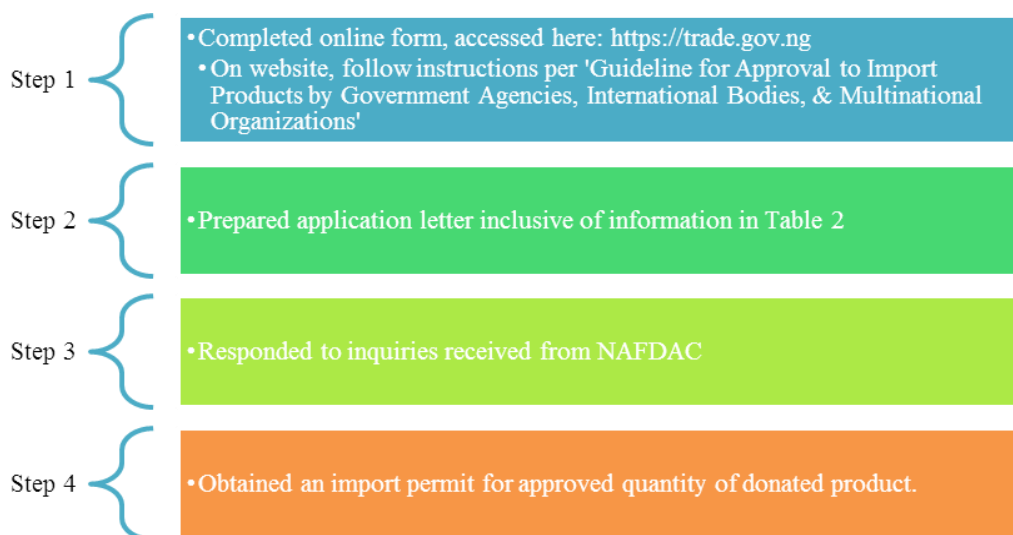


Figure 2. Process to Obtain Import Permit for an Unregistered Donated Product in Nigeria

Summary of the NAFDAC requirements, processing timelines, and costs

Requirements, timelines, and costs for the NAFDAC import permit application are detailed in **Table 2**. The items listed under ‘Required Documents’ in the second column under the header ‘Additional documentation requested’ show additional documents that were provided at the request of NAFDAC beyond what was listed in their guidelines. Regarding cost, the guidelines state that there is no cost for an import permit, which is

what we observed. However, you’ll see that we have included the cost for customs clearance for additional transparency. After application submission, formal queries are communicated to the applicant via written correspondence by NAFDAC. According to the NAFDAC guidelines, the applicant has 90 working days to respond to any NAFDAC queries; however, a delay in response can result in a delay in approval. The guidelines suggest that the time to approval for an import permit is approximately 4-6 weeks.

Table 2. Summary of NAFDAC requirements, timelines and fees

Parameters	Per NAFDAC guideline	Authors’ Experience
Required Documents	1. Submit a written application to the Director-General (NAFDAC) on the donor’s letter head, stating the following: <ol style="list-style-type: none"> The profile of the donor The purpose of the donation The intended recipient population The list of regulated products indicating batch numbers where appropriate Date markings and quantity 	1. Submit a written application to the Director-General (NAFDAC) on the donor’s letterhead, stating the following: <ol style="list-style-type: none"> Donated drug name Quantity to be donated Who is donating the drug and to whom it is being donated

	<p>2. CUSTOMS CLEARANCE: Applicants intending to clear donated items should submit an application on company letterhead addressed to the Director General (NAFDAC). The following documents should be attached to the application for customs clearing (7):</p> <ol style="list-style-type: none"> Application letter (as referenced above) Name and address of the manufacturer Single Goods Declaration Form Commercial Invoice Pre-arrival Assessment Report Form M Bill of Lading/Airway Bill Packing List Letter of Undertaking Evidence of approval from Director General Photocopy of the payment advice <p>Photocopy of NAFDAC receipt of payment</p>	<p>Additional documentation requested:</p> <ol style="list-style-type: none"> Copy of international passport for applicant Export certificate GMP certificate Certificate of Pharmaceutical Product Port of Entry Purpose of drug Expiration date for donated batch (must have at least 6 months of shelf life upon arrival in Nigeria) Country of origin Method of shipping <p>2. CUSTOMS CLEARANCE: Documents are consistent with the guidelines.</p>
Timeline	Timeline: 4-6 weeks to approval.	13 days to approval.
Language of samples artwork used	All medicines should be labeled in English	The language of samples artwork submitted was consistent with the guideline.
Working Standard / Reference Standard, Stability and CPP	Per the guideline, “all donated medicines should be obtained from a reliable source and comply with quality standards in both the donor country and Nigeria. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.”	The GMP certificate and CPP from the country of origin were submitted and this was acceptable to NAFDAC.
Costs	None	There is no cost to submit an import permit application to NAFDAC. Note: At the time of customs clearance of the product, a fee will be collected that is subject to change. (8) In our case, we paid 13,500 Naira (\$35 USD).
Import permit validity	Approval is valid for 1 year. All permits expire on 31 December.	Validity is consistent with the guideline.

4. Discussion and Evaluation

During the special import permit application processes in Zambia and Nigeria, we observed variation between national guidelines and practice in two main areas: required documents and timeline to approval.

In both countries, NRAs required more documents for special import permits than listed in national guidelines. In Zambia, the required additional documents included the certificate in the country of origin, the GMP certificate, and the Certificate of Pharmaceutical Product – all documents that are also required for full product registration. In Nigeria, the additional required documents also include the GMP certificate and Certificate of Pharmaceutical Product, as well as documents relevant for shipping and import. While the additional documents required for Zambia and Nigeria are documents that a manufacturer would be expected to have for a product registration application, the process of applying for a special import permit following national guidelines and subsequently receiving queries for additional documentation can result in delays in the process. However, overall, the documentation required

for securing a special import permit is substantially less than for pursuing full product registration.

Timeline to approval was the second area where we observed variation between national guidelines and practice. In Zambia, national guidelines state that the applicant shall be notified of a decision regarding their application within 14 days of receipt, whereas we experienced an average time to notification of 37 days across six special import permit applications, with a range from 1 to 65 days. In Nigeria, we submitted only one application, but the guidelines listed 4-6 weeks to notification, and we received notification of approval in 14 days. In both countries, though time to approval varied from the guidelines (negatively for Zambia, positively for Nigeria), it is worth noting that application processes were substantially faster than pursuing full product registration, which can take months to years to gain approval.

As described, special import permit applications require less documentation and are faster than pursuing full product registration, and therefore can be a preferable solution in cases where a product is needed in a

temporary or timely manner and where the product is not intended for sale. In the authors' case, special import permits allowed us to gain a limited supply of product in country for pilot testing, training, and advocacy while we simultaneously pursued full product registration. Full product registration remains the recommended pathway for sustainability.

5. Conclusion

Securing an import permit for the donation of unregistered medical products can be an appropriate solution to make a product available in time-sensitive or short-term use cases with donated products. As discussed in this case study, import permit application processes not only vary from country to country but can also vary between what is stated in country-specific guidelines and what is observed in practice. To ensure an effective and expedient application process, it is advised to confirm import permit requirements with the NRA prior to submitting the application, as well as to identify a local partner and/or partner with experience securing an import permit in the target country. In an effort toward greater transparency in the regulatory community, WCG and the EECO project encourage those who have secured import permits in countries where the process differed from the guidelines to publish their findings for shared learning among colleagues.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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