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Situational analysis of MDT blister importation and distribution

Procedures, difficulties and recommendations

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Acronyms

ANVISA – Brazilian Health Surveillance Agency

AWB – Air Way Bill

CGPNCH – General Coordination of the National Leprosy Control Program of the MoH

CVS/PAF – Coordination of Health Surveillance of Seaports, Airports, Borders and Customs Areas (ANVISA)

DAF – Department of Pharmaceutical Assistance (Secretariat of Science, Technology and Strategic Resources of the MoH)

Dlog – Department of Logistics (MoH)

GGMED – General Management of Medications (ANVISA) GGPAF – General Management of Seaports, Airports and Borders (ANVISA)

GIPAF – Management and Inspection of Products and Authorization of Corporations at Seaports, Airports, Borders and Customs Areas (ANVISA)

ID – Import Declaration

IL – Import License

MDT – Multidrug Therapy

MoH – Ministry of Health

MoU – Memorandum of Understanding

PAHO – Pan-American Health Organization

PCH – Leprosy Control Program (see CGPNCH)

PO – Purchase Order

SADM – System of Storage and Distribution of Medications (MoH)

SISCOMEX – Integrated System of External Commerce

WHO – World Health Organization

Executive Summary

A five-year Memorandum of Understanding (MoU) was signed by the World Health Organization (WHO) and Novartis in 1999, valid from 2000 to 2005. In 2005, the MoU was renewed for another five years. At the end of 2010, this agreement will have provided enough multidrug therapy (MDT) to cure over 5 million leprosy patients and ensuring near universal coverage of the world's diagnosed patients.

As per the terms of donation of medications, Novartis supplies MDT free of charge, pays for shipment, insurance, supply storage costs in Geneva, and quality control tests conducted by independent laboratories.

Through its network of offices, forwarding agents and suppliers, the WHO maintains constant communication with endemic countries' national programs. As the main public health body of the United Nations, WHO has representatives or contact officials in almost every country, and in Brazil this is PAHO. WHO is responsible for sending medications through forwarding agents which are experienced in shipment handling and fully familiarized with the import and dispatch procedures of the United Nations.

Health service professionals are trained to increase patients' awareness of the importance of adherence to treatment regimens. For this reason, sudden drug shortage must be avoided, as this forces patients to return several times to a health center, discouraging treatment continuity and aggravating endemic situations. To help avoid drug shortages a situational analysis was performed, identifying the difficulties encountered by all those involved in the processes of importation and distribution of MDT blisters donated by Novartis trough WHO.

This document briefly describes the drug importation and distribution process, presents the difficulties faced, and offers recommendations aimed at streamlining and facilitating the process. As a suggestion to solve the problems discussed herein, several actions aimed at optimizing communication between peers are recommended. These actions should make the process more transparent by standardizing and simplifying procedures and documents, mainly by agreeing upon an annual Import License (IL) that encompasses all medication consignments, in accordance with the WHO annual agenda.

Justification

Despite leprosy's infectious nature, it is a treatable disease as long as treatment is given according to established therapeutic guidelines and monitored so as to avoid treatment default. The cure and resulting elimination of the source of infection will interrupt the illness' chain of transmission. Thus, treatment is strategic in controlling endemic situations and an effective MDT delivery plan is necessary to ensure continuous drug supply.

Guaranteeing adherence to a regular course of treatment is an essential and difficult task for health service professionals, as the both the adverse effects and immune reactions presented by the patients lead them to default. Treatment distributed in monthly blisters consists of a combination of drugs - MDT - according to WHO recommendation.

The drugs are ministered following a standard regimen according to operational classification which is based on the number of skin lesions. Patients with up to 5 lesions are treated with the paucibacillary (PB) course and patients with 6 or more lesions with the multibacillary course. The PB regimen consists of 6 blisters which contain two drugs, rifampicin and dapsone, and can be administered in as many as 9 months. The MB regimen consists of 12 blisters which contain 3 drugs, rifampicin,
clofazimine and dapsone, and is administered within 18 months. Rifampicin is only administered in a supervised monthly dose and the delivery of the blisters is done at basic health centers.

Health service professionals are trained to increase patients' awareness of the importance of adherence to treatment regimens. For this reason, sudden drug shortages must be avoided, as this forces patients to return several times to a health center, discouraging treatment continuity and aggravating endemic situations.

It was observed that CGPNCH has been facing difficulties in all phases of the importation and distribution process. Thus, it was concluded that an analysis of the flow of medications would be necessary, seeking out solutions to the challenges all the partners are faced with.

Objective of the Situational Analysis

To identify the difficulties encountered by stakeholders in the importation and distribution of MDT blisters donated by Novartis trough WHO to treat leprosy patients, seeking solutions to streamline the process to avoid drug shortages at the health centers.

Methodology

Analysis of correspondence (memorandums, official letters and emails) and available documentation at the General Coordination of the Leprosy Control Program sent and received during 2009. This was done to identify the difficulties faced during the MDT blister importation process. Based on this study, the partners involved in this process, needed actions, and each partner's outputs were identified. As the participation of all those involved is important, the partners were invited to meetings where process discussions were held in order to confirm the difficulties identified and to discuss possible solutions. In this manner all partners were consulted, and this report presents the drug importation and distribution flow based on the information these partners provided.

Results of the Analysis

Blister MDT Importation and Distribution Processes

The drug importation process is complex, directly involving two Brazilian government agencies, two international institutions, one industry and two private companies. Within these institutions at least 16 different departments are actively involved.

Calculations for annual schedule of medication by DAF / SCTIE

The annual planning process to define the drug needs for leprosy treatment is undertaken by two technical areas of the Ministry of Health, the Department of Pharmaceutical Care (DAF) and the CGPNCH in conjunction with the state coordinators of leprosy control and pharmaceutical care.

The calculations are made for each state using epidemiological criteria and techniques. The MDT forecast for the next period is performed in three ways based on the previous period: (1) the number of reported cases, (2) the number of blisters actually used, and (3) an average of the two previous calculations is taken. The state coordinators may choose the forecast they deem most appropriate. The vast majority opts for the result obtained using the number of blisters that were actually used during the previous period.

Calculation of the annual drug needs by WHO

The base calculations for MDT provision are similar for all countries and estimates of the global needs are compiled based on annual request forms filled by national programs sent to the WHO. The estimated annual supply of MDT of the following year is prepared around August-September of each year.

Provision to countries is essentially based on the amount of MDT required for new cases expected to be diagnosed and registered for treatment, plus the amount of MDT needed for patients already registered for treatment at the beginning of the year.

The factors considered are: a) prediction of case detection based on latest annual data available and trends; b) current prevalence; c) current MDT stock levels and expiration dates (when given); d) other factors that may affect the general MDT needs, such as planned campaigns, expansion of MDT coverage to new areas, etc. As for MDT reserves, the centrally stored drugs are generally taken into account when informed by national programs.

WHO documentation emission

Based on the aforementioned calculations, WHO provides an annual drug shipment plan for the following year. This table contains the numbers of the purchase orders (PO) with the number of invoices for each consignment. Approximately two months before the scheduled drug shipment date of a particular PO the WHO issues the appropriate pro forma invoice(s).

Problem: The problems identified with receipt and processing of information were mainly related to (1) multiple invoices for a single PO, (2) invoices sent separately for a single PO, (3) invoices sent for different POs.

Cases/Facts: PO 200048706 was divided in 4 consignments, resulting in 4 invoices (90006113, 90006164, 90006165 e 90006219) and for PO 200053086 invoice 90006107 was issued. It is important to note that the consignments for all these invoices should be sent from the same place in one shipment. On January 23, 2009, invoices 90006113 e 90006107 were sent directly to the Logistics Department of the MoH (Dlog). On the 17th of February, INVOICEs 90006164, 90006165 and 90006219 were sent to the individual responsible in the CGPNCH . On the 25th of February, eight days later, a request was made for urgent granting of an IL for POs 200048706 and 200053086. If we observe the flowchart it's clear that it would not be possible to obtain an IL in eight days. Given that the documentation was not sent in a single consignment directly to the CGPNCH contact person, several problems occurred in the importation process, impeding the communication between partners and delaying the receipt of the medication. The MDT came in two tranches that were received for distribution in Brazil on April 17^{t} and May 27^{t}, 2009.

Suggestions for improvement:

1. Send correspondence with copies to each contact point in the departments involved in MDT importation and distribution in accordance with Annex 1 (Blister Importation and Distribution Flow);
2. To organize the communication between the stakeholders involved in the process, matters relating to a single Purchase Order (PO) should be addressed in each correspondence. Indicate the number of the PO followed by the number of Invoice in the subject line;
3. Simplify the Import License (IL) request by sending only one Invoice for each PO;

Donation Letter Preparation by PAHO

The donation letter is prepared by the PAHO / WHO General Services and Logistics Support Department. The letter is required to start the import process by CGPNCH. The document is prepared in accordance with the pro forma invoice and signed by the PAHO representative.

Problem: In 2009 there were delays in delivery of the donation letter.

Cases/Facts: (a) For the donation letter to be legalized, it is sent to the Ministry of Foreign Affairs. The protocol sector in this ministry operates on Tuesdays and Thursdays and consequently the time needed for the legalization of a document can be as many to four business days, which delays the delivery of the document to CGPNCH. (b) Absence of a well-defined communication system.

Suggestions for improvement:

4. Cease to notarize the donation letters;
5. Inform the CGPNCH via email once the donation letter has been accepted;

Disclaimer preparation by the CGPNCH

The Disclaimer is a formality by which the program coordination is held responsible for the use of the drugs donated by Novartis trough WHO in country. This document is prepared on the same day that the letter of donation from PAHO is received. The documents are sent by courier to the Health Ministry's Logistics Department, (DLOG). The difficulty mentioned was the delay in receiving the Donation Letter provided by PAHO / WHO.

Import License System Entry by DLOG and subsequent dispatch to ANVISA

As the MDT blisters are not registered at ANVISA, DLOG initiates the process at ANVISA with an exceptional Import License request. The justification for this exception is the importance of the drugs for leprosy treatment. This type of IL request follows a differentiated protocol within ANVISA, requiring detailed analysis of all documentation as if the drugs were being imported for the first

time. DLOG justifies that this rigorous analysis is the reason that the MDT blister import process is so slow.

After verification of the presented documentation the IL request is entered into the system, an official letter for an exception request is prepared together with the pro forma invoice, Donation Letter and Disclaimer. These documents are then sent by courier to ANVISA's Vice-President. No tracking number is provided for this delivery.

Import License Release by ANVISA

Upon receipt of the letter and documents submitted by the DLOG agent, these are routed internally to the General Management of Medications (GGMED). The technical analysis of these documents by GGMED is the most time consuming. After this analysis, the documents are routed for signature by the presiding Director, authorizing their exceptional nature. The process is then routed to the General Office of Ports, Airports and Borders / General Office of Inspection and Control of Inputs, Drugs and Products and (GGPAF/GIPAF), which prepares a memorandum routing the process to Coordination of Health Surveillance at Seaports, Airports, Borders and Customs Areas (CVSPAF/DF) located at the Airport in Brasilia. When the process is received, this department informs the Health Ministry's forwarding agent that an exceptional process has been received, so that the appropriate steps may be taken, continuing the process.

Problem: Exactly how the department communicates this was not confirmed. It seems that this is done informally, as other processes coexist in the daily routine and they are in constant contact. From what was explained there is a backlog system which informs the forwarding agent when he goes to resolve other matters. The information that the exception was released seems to be visible in the system.

Cases/Facts: During the issue process of license IL 10/0055583-0, which was registered for analysis in 11/01/2010, ANVISA requested the documentation be given to the forwarding agent on 21/01/2010, but he only received it 14 days later, given that the IL was released on 04/02/2010. This is a good example of DLOG's difficulty to track processes internally, as in this case, according to ANVISA information, the process was awaiting the presentation of documentation by the forwarding agent for final consent to be granted. As DLOG and the forwarding agent have a very high number of ongoing processes, verification is not done on a daily basis and as a consequence many of the steps are taken days after a stage is concluded.

The events of 2009 indicate the need to make the IL request process status accessible for consultation in SISCOMEX by CGPNCH.

The provision of an IL tracking number and a protocol number from the vice-presidency would allow CGPNCH to monitor the process via e-mail notification that the documentation is being expected.

Suggestions for improvement:

6. Verify the feasibility of informing CGPNCH with the IL analysis and the process numbers within the ANVISA Vice-Presidency so as to allow tracking;

Documentation routing to ANVISA by the Health Department Forwarding Agent

The MoH Forwarding Agent prepares a petition according to the specific ANVISA model, prints the IL under analysis from the SISCOMEX system, fills out a Brazilian tax bill (GRU) for tax exemption and delivers all documentation to CVSPAF/DF.

Problem: Throughout the importation processes in 2009 this was a time-consuming bottleneck. It seems to be a consequence of the poor communication system between ANVISA and the Forwarding Agent. This observation is not shared by the Forwarding Agent, who believes there are no communication issues with ANVISA.

Cases/Facts: Many times the IL had already been released but this was not yet known to the DLOG Forwarding Agent who needs to provide the aforementioned information. The release was only made aware to the Forwarding Agent once pressure was applied by the CGPNCH requesting the status of the IL. It is not clear why the expected documentation is not attached to the process upon process registration with the Vice-Presidency. Perhaps a means of facilitating the process could be discussed with the partners if all the documents were attached at the starting point.

The Forwarding Agent does not acknowledge the difficulties in this process but the delays in documentation delivery occur with the majority of the received shipments. For this company's team this is just a routine process that follows a specified protocol, to which they are accustomed, and continue to strive to do their tasks in the best way according to the established system.

Suggestions for improvement:

7. Discuss with partners the possibility of attaching the documents required to the exceptional IL release request at the moment it is delivered at the Vice-Presidency;
8. Stimulate improved communications between the Health Department Forwarding Agent and ANVISA.

Import License Release by ANVISA - CVSPAF

The CVSPAF examines the documentation (Petition, GRU and IL under analysis) and, if in accordance, the shipment authorization is released in the SISCOMEX.

Problem: In almost all the processes in 2009 the analyzed and authorized ILs laid waiting for documentation that was generally delivered only after insistent telephone calls from the contact person from the CGPNCH

Cases/Fact: ANVISA points out delays in the forwarding agent's delivery of the documents, and that the delivered documentation is often disorganized. ANVISA affirms that this part of the process is very simple and that as soon as the forwarding agent delivers it, the IL is released.

ANVISA receives a very high volume of information and release processes; there is no evidence of process monitoring automation. Each process is handled according to its place in the task processing queue. If the process tracking number were known by CGPNCH, it would be able to monitor the process. This would be the ideal situation and would provide more transparency to the IL issuance process.

Suggestions for improvement:

9. Study the possibility of issuing a single LI to cover the total annual importation forecast in accordance with the documentation supplied by WHO at the beginning of each year.

Electronic Import License Routing by DLOG

After DLOG becomes aware that the IL has been released, it sends an electronic copy of the IL by email directly to the person responsible for the distribution of the drugs from WHO Department of Neglected Diseases Control with a copy to the partners.

Problem: DLOG is not informed by **CVSPAF** when the IL has been released. The process depends on daily checks of the SISCOMEX. As the IL request volume is high, this is not done daily. We were unable to discover how frequent these checks are, but what can be observed is that it is done when CGPNCH requests the information.

Cases/Facts: Numerous telephone calls are placed for each process, both by the states facing drug shortage and by the WHO, with batches of drugs to be shipped pending only IL release. This is very time consuming for the CGPNCH medications contact person and consequently for the partners involved as they will also be consulted by telephone calls. The number of telephone calls from state and municipal workers is incalculable, which combined with the hours spent by public servants not only greatly elevates the cost of the process, but also wears down the CGPNCH, which duly attempts to handle the requests, but has no governance over the process. It is necessary to improve the communication system between the partners involved.

Suggestions for improvement:

6. Verify the possibility of informing CGPNCH of the IL analysis number and the process number assigned by the ANVISA Vice-Presidency so as to facilitate monitoring;

MDT Shipment release by WHO

After receiving the electronic IL, the person at the WHO Department for Control of Neglected Diseases responsible for distribution of the drugs checks the information, and routes it to SANDOZ requesting they take the necessary actions for the drugs to be shipped.

MDT Shipment Release by SANDOZ

When SANDOZ receives the IL it requests its forwarding agents to provide the shipment of the drugs

Cases/Facts: The necessary actions seem to be taken promptly. No comments were made on this part of the process, apart from the long wait for the IL. This delay results in storage costs which need to be calculated in the cost of the drugs.

AWB generation and sending to DLOG by the SANDOZ forwarding agents

Upon receiving the IL the forwarding agents attach the process Invoice, Packing List, Manufacturing and Analysis Certificates and provide the Air Way Bill (AWB). All the details pertinent to the cargo from department from India to delivery in Brazil will be listed on the AWB. The obtained AWB is sent to WHO, which forwards it to DLOG copying CGPNCH and PAHO.

Cases/Facts: In 2009 errors were made in the documentation provided by SANDOZ, but also the partners in Brazil misinterpreted the documentation sent by SANDOZ.

See “comments/recommendations” in the ‘Cargo Release by ANVISA’ section below.

With regards to document interpretation, DLOG emphasized that the documents provided need to be exactly the same as the electronic invoice (pro forma invoice) previously sent. The pro forma invoice, packing list, and certificates must contain the same items that were on the Invoice and the contents to be shipped in the cargo.

Scheduling the Inspection of the Drugs

When the cargo reaches Brazil, the forwarding agent retrieves the original documents at the airline’s cargo department. After reviewing the documentation, the agent requests the Brazilian Federal Revenue Service (RF) for an authorization of preliminary inspection of the drugs. This inspection requires the simultaneous presence of RF inspector and ANVISA inspector, to sign off the inspection. In case cargo was loaded on wooden pallets, a request for inspection by the International Agricultural Surveillance System (VIGIAGRO) must also be made. After this procedure the forwarding agent requests ANVISA’s inspection.

Problem: The participation of inspectors from different government agencies encumbers and delays the process. If wooden pallets are used inspection scheduling is further delayed.

Cases/Facts: The CVSPAF/ANVISA representative suggests that inspection be scheduled one or two days prior to the cargo's arrival, as the time and date of arrival are known as soon as the AWB is sent.

On the other hand, the freight forwarder does not consider pre-scheduling to be necessary, as he considers that these procedures take place in a timely fashion, since the inspectors are onsite every day for other inspections. Apart from this, it was mentioned that it is not uncommon for changes in flights and loading dates to occur

Suggestions for improvement:

10. Study the possibility of not using wooden pallets or, if required to use them, that they be made of treated wood with a stamped certification.

Release of the Drugs by CVSPAF / ANVISA

The release of the drugs is done after document and physical inspection.

It has been requested that the documents be presented in an orderly fashion. The freight forwarder affirms that these are presented according to requirements.

Problem: Several problems were mentioned, such as damaged boxes, discrepancies in the information contained in the box and on the invoice(s), boxes that were damp, etc. Some of these problems appear to be related to the handling of the merchandise after entry into Brazil.

Cases/Facts: ANVISA seeks to streamline procedures in this phase as the process has already been duly evaluated and the documents conferred with regards to the exceptional request. It is important to consider that in case the blisters are registered, this inspection could be more rigorous, emphasizing the need to standardize documents as per the recommendation above.

Suggestions for improvement:

11. Be present for the inspection and removal of the cargo at the time of arrival in Brazil.
12. Request that Sandoz double-checks the documents/cargo at the time of departure from India.

Release of the Cargo by the Brazilian Federal Revenue

After physical inspection the Import Declaration (ID) is registered. After the ID is obtained it is presented at the RF and the cargo is parameterized. Parameterization means that when (1) a red light is obtained all documents must be presented and the cargo inspected; (2) a yellow light, only part of the documentation is inspected, and (3) a green light, the cargo is released without inspection.

Problem: The producer and exporter of the drugs is Sandoz, the buyer is Novartis. That is the information that must be on the IL, but this is not always the case.

Cases/Facts: In the majority of the ILs in 2009 the informed producer is Novartis. This mistake occurs due to the information being retrieved from the "Buyer" field on the Invoice instead of the "Exporter" field. The explanation provided by the Health Department's freight forwarder, that this is how the IL must be filled out, could not be confirmed. These documents will only be verified by the RF in case the cargo is red lighted during "Parameterization". In other words, serious problems with respect to this may still be faced in the future.

Suggestions for improvement:

13. Study the possibility with Novartis to standardize documents, both in English and Portuguese, containing only strictly necessary and simplified information;
14. Urgently study with Novartis the possibility of adding the following words to the INVOICE:
    a. "PRODUTOR" next to EXPORTER
    b. "COMPRADOR" next to BUYER (other than Consignee);

Drug Distribution Ruling by the DAF

The drug distribution ruling is elaborated by the Department of Pharmaceutical Assistance (DAF) within the Secretariat of Science, Technology and Strategic Resources/MoH based on epidemiological data made available by the CGPNCH. This ruling is inserted in the MoH's Logistics system (SISLOG) to advise the Drug Storage and Distribution Service (SADM) of the distribution of the drugs and posterior drug distribution monitoring by the DAF.

Problem: Among the difficulties the DAF faces are the lack of a strategic surplus and the constant drug importation delays. The fact that they do not receive the requested quantities make accomplishing the department's programmed schedule impossible. It was also witnessed that the lack of loose clofazimine compromises the programmed total of blisters. Blisters are cut when the health services face serious cases of reactions in leprosy patients and no separate doses of clofazimine are available for distribution.

Cases/Facts: A request was made of WHO to provide loose clofazimine in both adult and pediatric dosages. They mentioned several clofazimine requests sent to WHO via e-mail and official letters sent to PAHO.

The recommendation to form a strategic surplus was requested via email and later discussed via telephone with the person responsible for drug distribution within the WHO Department of Neglected Disease Control, which has already taken the necessary measures so that a larger quantity than initially planned for 2009 will be sent in 2010. This increase was in accordance with the official letter of December 8, 2009 from SVS. Thus Brazil will receive an additional 176,064 blisters to what was previously planned by WHO as well as 387,600 50mg and 360,000 100mg clofazimine tablets.

Suggestions for improvement:

15. To negotiate the creation of a strategic surplus of MDT with WHO.

16. To ensure the provision of loose clofazimine.

Drug Checking and Distribution by SADM

Once the drugs are received by SADM the documentation is checked against the physical cargo.

Problem: When the cargo arrives at the SADM the following difficulties are faced: (1) lack of previous knowledge of the ongoing process, (2) lack of documentation, (3) divergent information as to the number of shipments, (4) damaged packaging and lack of indication that it is fragile cargo that requires delicate handling. It is evident that the drug distribution cost has been significantly higher than it would be if the strategic surplus existed.

Cases/Facts: SADM suggested that production and analysis certificates be sent in advance, as the analysis of these documents is very detailed and time-consuming. This would reduce the verification tasks when cargo is received to the installment checks against the physical cargo. At the meetings held it was agreed that when the IL is released, the contact person in the CGPNCH will send all the documentation relevant to that cargo. This system has already been put in place, and observations from the last shipment received indicate that this has helped streamline drug distribution.

Suggestion for improvement:

17. That production and analysis certificates be sent in advance to DAF.

Final Considerations:

The situational analysis of the MDT blister importation and distribution process points out several issues that can be resolved or mitigated by simply carefully following procedures. It has been observed that the procedures within ANVISA will continue to take time to process. Shortening the period for obtaining an IL will be possible if all the partners seek out innovative solutions and procedural optimization. The lack of a strategic surplus is the main reason why drugs have been missing at the health centers, distorting the role of CGPNCH which must now answer telephone calls from health centers contacting them directly in the attempt to solve their patients' special situations.

From the moment of entry of the first documents needed to request the IL until the receipt of drugs, the importation process takes an average of 120 days, not including the time required for distribution within the country. The distribution period was only addressed in table "**Blister Importation and Distribution Flow"** (see below) since the time required for such work was not researched, but this can vary from several days to weeks, depending on mode of transportation and location of the clinic concerned.

It is not clear if registering the MDT blisters at ANVISA would reduce the IL issuance period. Theoretically there should be a reduction in the period by 15 days, which is the time required for the analysis of exceptional cases. However, the time taken to obtain an IL via the normal process was not studied.

What will indeed streamline the process is the viability of a global IL request for all drug shipments according to the annual plan sent by WHO.

Blister Importation and Distribution Flow

	Actions / Tasks	Duration 2009* (days)	Forecast duration (days)	Total Forecast (days)
WHO	Sends PO and Invoice – Certificates of Analysis and Production			0
PAHO	Prepares Donation Letter	**15**	2	2
CGPNCH/MoH	Disclaimer preparation	**1**	1	3
Dlog/MoH	Import License System Entry by DLOG and subsequent dispatch to ANVISA	**4**	2	5
ANVISA	**(1)** Internal forwarding; (**2**) Technical analysis of documents by GGMED; **(3)** Presiding Director analyzes and releases under signature; **(4)** GGMED forwards to GGPAF/GIPAF; **(5)**GIPAF prepares memorandum and forwards documents to CVSPAF/DF; **(6)** CVSPAF/DF advises the forwarding agent of the arrival of exceptional goods	**40**	15	20
Dlog/MoH	Documentation routing to ANVISA	**7**	1	21
ANVISA	Import License Release	**5**	1	22
Dlog/MoH	Electronic Import License Routing to WHO	**4**	1	23
WHO	Informs MDT shipment release to SANDOZ	**2**	2	25
SANDOZ	AWB generation	**5 +15****	5+15**	45
WHO forwarding agent	Sends the AWB to Dlog	**3**	3	48
Dlog/MoH forwarding agent MoH	Schedules the inspection of medications	**4**	3	51
CVSPAF/ANVISA	Inspects and releases the medications	**3**	3	54
Federal Internal Revenue	Releases the cargo	**7**	7	61
CVSPAF/ANVISA	Customs release of medications			
Dlog/MoH	Organizes the withdrawal of medications	**2**	1	62
DAF/MoH	Sends distribution schedule and liberates the distribution of the product in the system	**1**	1	63
SADM/MoH	Receives and distributes medications	**2**	5	68
PCH States		**3**	7	75
Municipalities		**3**	7	82
Health Centers		**3**	7	89
Patients	TOTAL average duration - 2009	**128**		

*Average duration (days) – calculations based on available documents; ** Generally sent in **15 days**.