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# Sanitary Registries in the Dominican Republic: Updates in the renewal process

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## News

With the creation of the General Directorate of Drugs, Foods and Sanitary Products (hereinafter "DIGEMAPS"), through Decree number 82-15, dated April 6, 2015, a regulatory framework was established to effectively ensure the "safety and efficacy of drugs, foods and sanitary products, national and/or foreign, that guarantee the population access to quality medicines," within the lines of action of the National Development Strategy. This responsibility is under the direction of the Ministry of Public Health and Social Assistance (hereinafter "MISPAS") as the planning, direction, coordination and execution body of the administrative function of the State, as established by the Organic Law of Public Administration, and that this Decree has come to organize, transferring the duties of the Department of Drugs and Pharmacy and the Department of Foods and Beverages of the MISPAS to the DIGEMAPS, the new body created by the referred Decree, and which has among its obligations "to define and propose the classification of new registration and renewal processes through a simplified procedure ...". And it is this regulatory framework that supplements for the registries, the procedure of simplified sanitary registries, and with the new Decree number 117-18, dated March 7 of the current year, the automatic renewals of those registries.

The renewal regulated by Decree number 117-18 is the one concerning the sanitary registry of foods, drugs, sanitary, cosmetic and hygiene products, provided that they maintain the authorized conditions of the registry to be renewed.

The renewal will be automatic, after submission of the renewal request<sup>1</sup> with at least the following documents:

1. A request form corresponding to the type of product to be renewed, which must be duly signed.
2. A sworn statement of registry from the owner or applicant (legal representative or manufacturer) stating that the approved product has not changed.
3. The payment of fees for services.

For each type of registration the required documents will be submitted, which are contemplated in the aforementioned Decree number 117-18, and which must be deposited in a system and physically at the DIGEMAPS, with this Directorate having 30 business days to evaluate said documentation, upon receipt of the physical and original documents of the product in question<sup>2</sup>, and if they are correct, the registry is automatically renewed<sup>3</sup>. If the request is incomplete or is not in accordance with Decree number 117-18, a non-extendable period of six (6) months will be granted from the submission of the renewal request for such purposes<sup>4</sup>. And if within that period the requirements are not met, DIGEMAPS will cancel the registry.

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<sup>1</sup> Article 1 of Decree No. 117-18.

<sup>2</sup> Article 5 of Decree No. 117-18.

<sup>3</sup> Article 1 of Decree No. 117-18.

<sup>4</sup> It is not indicated if this period starts upon submission in the system or in physical. However, our interpretation, considering that the decree in its article 4 establishes that the physical submission is assumed as the initial date of the process, is that said 6 month period will start upon physical submission. Nevertheless, it is important that DIGEMAPS confirm this interpretation.



The detailed procedure to obtain an automatic renewal is the following:

The request is made through the "system"<sup>5</sup> "at least 30 calendar days before the expiration of the sanitary registry to be renewed"<sup>6</sup>. Within a period of 30 calendar days from the virtual request through the system, the documents established for this purpose according to the product to be renewed must be deposited. It is from that moment that the request for renewal is formalized and the registry is renewed automatically, if all the deposited documentation is complete and in accordance with the requirements.

The DIGEMAPS will have a period of 30 business days to evaluate the request and ask the applicant for any correction or supplement, without having to return the file or issue the certificate of renewal, if everything is in order<sup>7</sup>. That is, if you make a request through the system or the web site created for that purpose and do not deposit the required documents but 20 days after that electronic request, it is clear that the 30-day period that the DIGEMAPS has for evaluation and request of adequacy or correction that is appropriate, if any, will start from the submission of the physical, original and legalized documents, given the electronic request.

If the file is not complete or the deposited documents are not correct, DIGEMAPS may grant a period of no more than six (6) months to the applicant, counted from the date of submission, to proceed with the observed corrections and/or supplements<sup>8</sup>. After this period of six (6) months, if the applicant does not comply with the requirements, the registry to be renewed will be canceled, with the applicant having to withdraw the existing products from the market<sup>9</sup> and, if so considered, the applicant must proceed to formalize a new registration request, as if it were a new product, to be able to market and/or commercialize it, as established in the law.

The Decree Number 117-18 does not establish any deadline for DIGEMAPS to respond to the applicant if the deposited documentation satisfies the request, or if the applicant must wait indefinitely to know if the registry has been renewed and then receive the certificate of renewal<sup>10</sup>. It is understood that, if there is no news from DIGEMAPS after six (6) months,<sup>11</sup> counted from the date of submission of the application and after the corrections have been deposited, the registry has been renewed. Neither is it seen in the Decree number 117-18, if after this period has passed and the documents are not correct, and the renewal has not been granted, if DIGEMAPS has the obligation to inform the applicants, so that their products are not on the market without the protection of a sanitary registry, as it should be. Especially when the aforementioned Decree establishes that DIGEMAPS may grant a period of no more than six (6)

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<sup>5</sup> We assume "system" is the web platform of the DIGEMAS. It is mentioned, but not defined, for the first time in Decree No. 117-18 in Paragraph II of Article 1.

<sup>6</sup> Paragraph II of Article 1 of Decree No. 117-18.

<sup>7</sup> Article 5 of Decree No. 117-18.

<sup>8</sup> Paragraph I of Article 1 of Decree No. 117-18.

<sup>9</sup> Paragraph III of Article 5 of Decree No. 117-18.

<sup>10</sup> It could be assumed that this information would be available in the "system" but we must wait for the implementation to see how it will work.

<sup>11</sup> Note that the start of all the deadlines for supplementation and corrections initiate from the date of submission of the request, NOT from the date of the request for correction or supplementation that DIGEMAPS would make. Consequently, if DIGEMAPS does not issue or notify the applicant of the evaluations within the period of 30 business days, indicated by the Decree, this could affect the file and even expire it.



months, at the request of the interested party, for withdrawing the inventory from commerce, if the renewal has been denied<sup>12</sup>.

The Decree establishes the documents that must be deposited for each of the products in the registry. In this sense it states that;

A. For the renewals of **foods**, the following must be deposited:

1. Labels and packaging material according to the applicable and current guidelines of NORDOM. It is not necessary to deposit physical samples and it is only applicable upon the first renewal;
  - In case the product is of national origin, the applicant must deposit: (i) a copy of the sanitary license or permit of the establishment or the manufacturer's place; (ii) in case of a maquila, a copy of the license or permit of the establishment of the maquiladora, and (iii) a certificate of manufacture in which the product is manufactured under the same registered name.
  - In case the product is imported, in addition to the above, the following must be deposited: (i) a free sale certificate; (ii) in case of a maquila, a certificate of manufacture.

NOTE: Sanitary registries issued and renewed before 2017,

B. For the renewal of sanitary registries for **drugs**, it is necessary to deposit in original and legalized:

1. A real-time feasibility study signed by the person responsible for the quality control corresponding to the requested product, if it has not been previously deposited.
2. Proof of deposit of the pharmacovigilance of the deposited product, which can be done in the aforementioned sworn statement of renewal explicitly, or by declaring the entry number or by putting said procedure number in the request form.
3. Insert, labels, lettering, blisters and any other type of packaging material as authorized. This requirement does not include a physical sample and only applies the first time the automatic renewal is made;
  - If the product is of imported origin, in addition to the aforementioned documents, the following must be deposited: (i) a free sale certificate; (ii) a certificate of good manufacturing practices, and (iii) in case of a maquila, it must comply with a certificate of manufacture.

C. For **cosmetics** and **hygiene** products, the following will be required:

1. Insert, label, lettering, blister and any other type of packaging material as authorized. It is not necessary to deposit physical samples;

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<sup>12</sup> In this case, it could also be assumed that this information would be available in the "system" but we must wait for the implementation to see how it will work.



- If the product is of imported origin, the following must also be deposited: (i) a certificate of free sale; (ii) a certificate of good manufacturing practices or certificate of the quality system used corresponding to the classification of the product; and (iii) in case of a maquila, it must comply with a certificate of manufacture.

D. For **sanitary products**:

1. Instructions for use, insert, labels, lettering, blister and any other type of packaging material as authorized. This only applies for the first automatic renewal<sup>13</sup>.
2. When the registry consists of different codes, if it is a generic labeling, it will be possible to load the image of a sample and attach a communication declaring the fact;
3. If there is variation in the designs of the different codes, it will be necessary to load the image of each one of them. (literals a and b of article 9).

If the product is of imported origin, the following must be deposited in addition: (i) the certificate of free sale; certificate of good manufacturing practices, or quality system used according to the corresponding classification; and, in case of a maquila, it must comply with the certificate of manufacture.

The Decree also contemplates general requirements that apply to all renewals, including:

1. A request form corresponding to the type of product to be renewed, which must be duly signed.
2. A sworn statement from the registrant indicating that the approved product has not changed.
3. The payment of fees for services.
4. The qualitative and quantitative composition, if and only if it is not currently in the file of DIGEMAPS.
  - a. A power of representation on behalf of the manufacturer or legal representative in which the renewal and/or commercialization is authorized, or a copy of the distribution agreement signed with the manufacturer.
  - b. The deposited documents must be in Spanish or translated by a judicial interpreter.
  - c. They must be original or certified.
  - d. They must be legalized, notarized or apostilled, as appropriate.

As for the Sworn Statement, it must be done in compliance with express provisions which are indicated in the Decree, such as that:

1. The product to be renewed maintains the conditions previously authorized by MISPAS;

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<sup>13</sup> NOTE: according to article 9 of the Decree: "When the registry consists of different codes, it will be possible to load the image of a sample and annex a communication declaring the fact; if, on the other hand, there is variation in the different codes, if it is a generic labeling, it will be possible to load the image of each one of them.



2. When said statement is issued by the owner of the sanitary registry and the technical director, manufacturer, or legal representative or attorney; and also,
3. It has the number of the sanitary registry to be renewed.

In the same way, the certificates of free sale, whether for drugs, foods, sanitary products and cosmetics and hygiene products, must be issued following specific requirements indicated in the Decree. The same holds for the certificates of manufacture or fabrication in case of a maquila; the certificate of the quality system used, as well as the requirements to fulfil when there is a difference in the product name with respect to how it is marketed in the country of origin, which can be done explicitly in the Sworn Statement presented for the renewal or in an additional statement.

Now, what is the difference between the ordinary renewals known and regulated until March 7, 2018, in relation to the automatic renewals of sanitary registries? If we compare the requirements demanded so far by DIGEMAPS with those included in Decree 117-18, we will see that, for example, the documents or requirements to be fulfilled to renew a sanitary registry for drugs were 20 and now they are 6. For the renewals of foods and beverages there were 12, each of those requirements had subtitles of steps to fulfill, which made them really long, now with the Decree the requirements are 8<sup>14</sup> having been included only the necessary ones. For the registry of cosmetics and hygiene products there were 16, now they would only be 4. All this includes the variants that are presented if the product is imported or of national production.

Another variant that we must take into consideration is the time it currently takes for the renewal of a product, which nowadays varies if it is a drug, a hygiene, sanitary or cosmetic product, or foods and beverages. That is, before Decree 117-18 enters into force.

The former take almost the same time, and in some cases, more than a first time registry. MISPAS says that from 6 months to a year, but in practice it takes more than a year to renew. The food products are the ones that take less time and in general, they take between 4 to 6 months to be renewed. This is without counting the additional time it takes for MISPAS to deliver the corresponding physical renewal certificate.

As indicated in the analyzed Decree, the renewal of any of these products should not take more than seven (7) months, including the initial submission through the electronic system, the maximum time period to present the physical file and the single time period of six (6) months, counted from the referred physical submission, that the applicant has for corrections or supplementations. Consequently, the Decree promises that in less than (8) months and without returning the file, DIGEMAPS will issue the Certificate of Renewal.

In case the required documents submitted to DIGEMAPS were incorrect, after this period of 6 months, without the requested correction being made, all deadlines expire and the renewal is not possible. In that case, the interested party will have to request a new registry if still interested in it, assuming the corresponding consequences.

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<sup>14</sup> Note that this applies for the first renewal, since certain requirements such as the formula and the packaging material are not required in subsequent renovations.



According to the Decree, in the best of cases, the time period has been reduced to 30 business days from the deposit of the request and the documentation, if everything is correct, to receive the renewal certificate. There is no deadline for this nor a way for the applicant to find out if the renewal has been approved and the certificate of renewal issued, unless DIGEMAPS requires some correction or supplementation in the documentation. It only says that within a period of 30 business days from the request, the renewal is automatic.<sup>15</sup> Therefore we understand that there is a tacit presumption of renewal if after these 30 days there is no requirement from DIGEMAPS to complete or modify the documentation required for each type of renewal. If this supplementation is required, and if within 6 months after the 30 days of the deposit the supplementary documents are not deposited, the renewal application will perish and a renewal cannot be requested but a new registry, as established in the ordinary regulations currently in force.

We assume that in the platform that DIGEMAPS will have organized, this and other aspects will be regulated.

Prior to receiving renewal requests, the Decree 117-18 grants a period of 30 business days<sup>16</sup> to MISPAS to "develop the corresponding procedures and put the web platform into operation" through which the renewal requests will be processed. This, of course, once said Decree enters into force.

The Decree also establishes that its provisions will enter into force once "the terms established in the law have elapsed as of its publication in the Official Gazette". That is, as established in Article 1 of the Dominican Civil Code, the day after its publication in a newspaper of national circulation for the National District, and the second day in all provinces of the national territory.

This is important to take into consideration because so far we have not seen the official publication of said Decree, so the deadlines to which it refers have not started and, therefore, the Regulation No. 246-06 of June 9, 2006, continues in force regarding the articles to repeal on renewal.

It is obvious that the first of the time periods granted by the decree is to MISPAS to develop and put into operation the web platform, after this period will be when applications can be submitted electronically and subsequently the deposit of said request can be made in physical, accompanied by the corresponding documentation in accordance with the requirements for renewal of the product in question.

We hope that this works and that it does not just amount to advertising, considering that this Decree brings with it not only a reduction of the documents to be deposited in DIGEMAPS, which is considerable, but also a reduction in the time in which a renewal could be obtained. The registry, if everything is correct, according to the product to be renewed, can be renewed 30 days after depositing the aforementioned documentation. Until now a renewal could take more

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<sup>15</sup> We say this because 30 business days is the evaluation period. However, this statement seems to contradict Article 1 of the Decree which expresses that an automatic renewal takes place from the submission of the request with the minimum requirements.

<sup>16</sup> Note that all the time periods granted by the Decree to the applicants to meet their obligations are "calendar" while those granted to DIGEMAPS are "business".



than a year, with the economic consequences that this entails. We reiterate that the Decree does not establish a deadline for DIGEMAPS to issue and deliver the registry certificate. Here, the maximum "No news, good news" will govern, if there have been no additional requirements to the applicant.

At the time of making these notes, we have not seen the official publication of the Decree 117-18, so it is not in force. We have not had any information either from MISPAS that "the system" to which this Decree refers to is in the structuring process; therefore, automatic renewals are not yet in force.

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