

Original Article

## Characterization of Potentized (Homeopathic, Anthroposophical and Antihomotoxic) Medicines Registered and Notified In Brazil

Robelma France de Oliveira Marques<sup>1\*</sup>, Ana Cecília Bezerra Carvalho<sup>2</sup>, Marco Antônio Costa<sup>3</sup>

<sup>1</sup>Agência Nacional de Vigilância Sanitária (ANVISA). Coordenação de Inspeção de Medicamentos (Coordination of Medicines Inspection). Brazil, [www.anvisa.gov.br](http://www.anvisa.gov.br); Email: [robelma.marques@gmail.com](mailto:robelma.marques@gmail.com); link to curriculum vitae: <http://bit.ly/1OTbn6Y>

<sup>2</sup>Agência Nacional de Vigilância Sanitária (ANVISA). Coordenação de Medicamentos Fitoterápicos e Dinamizados, Brazil, [www.anvisa.gov.br](http://www.anvisa.gov.br); Email: [anacecijp@yahoo.com.br](mailto:anacecijp@yahoo.com.br); link to curriculum vitae: <http://bit.ly/1G3I5Lx>

<sup>3</sup>Universidade Estadual de Maringá. Departamento de Farmácia. Centro de Ciências da Saúde. Maringá, Brazil, [www.uem.br](http://www.uem.br); Email: [macosta@uem.br](mailto:macosta@uem.br); link to curriculum vitae <http://bit.ly/1OvkFqv>

### Abstract

**Background:** Potentized medicines include, according to the Brazilian legislation, homeopathic, anthroposophic, and antihomotoxic medicine and are regulated by the Brazilian Health Surveillance Agency (ANVISA).

**Aim:** This study aims to analyze and describe a profile of potentized medicines manufactured in Brazil, either registered or notified.

**Methodology:** Information was obtained by data analysis related to ANVISA's electronic medicine registration system.

**Results:** The results, obtained as of September 2012, showed that 106 potentized medicines were registered and 519 were notified. Among the registered medicines, 92.0% were combined and 100.0% of the notified were simple medicines. For registered medicines, there were equivalent manufacturing scales among them, whereas for notified medicines, there was a predominance of centesimal scales. Active pharmaceutical ingredients (API's) of vegetal origin were the most commonly used for potentized medicine manufacturing processes; the oral route was the most common form of administration. Potentized medicines manufacturing units are more often located in southeast region of Brazil. In addition, homeopathic medicines prevail as registered or notified medicines, followed by anthroposophic medicines.

**Conclusions:** The results of the study are expected to be useful as reference material for ANVISA to improve its regulatory activity as well the industry sector and other stakeholders.

**Keywords:** Homeopathy, Anthroposophic medicine, Antihomotoxic medicine, Drug surveillance, ANVISA, Potentized medicine



## **Introduction**

The World Health Organization (WHO), in spite of great advances in public policies over the past 30 years still estimates that a substantial part of the population has no access to either conventional health care services or to affordable, essential medicinal products, most of them are located in developed countries.<sup>1</sup> In these countries, primary health care uses traditional or popular treatments such as acupuncture, herbal medicine, and homeopathy.<sup>2-5</sup>

Homeopathic therapeutics is based on the premise of bringing vital energy to a state of balance, restores body homeostasis, and to “cure the similar by the similar,” by comparing potentized medicine’s principle of action to the patient’s symptoms.<sup>2,5-7</sup> The efficacy of Homeopathy has been proved by biological tests, and its utilization has increased all around the world in past few decades.<sup>8-11</sup> It is also clear that benefit-to-cost ratio of this therapy is satisfactory, especially if compared to high costs of modern medicine practices.<sup>2</sup> It is also considered an easily administered, safe and affordable.<sup>7,11-13</sup>

According to Brazilian Health Ministry (HM) data (1986), only 14 countries held regulations for homeopathic medicines, rising to 83 countries in 2003. In mid-2009, there were 7000 homeopathic physicians practicing in 49 countries.<sup>4</sup> With homeopathic medicine products being well recognized in countries such as India, USA, France, and Germany, and with the continuing globalization process and easy access to information, this knowledge has spread worldwide.<sup>14</sup>

Homeopathy has already been included in the national health system of many countries, including Germany, Pakistan, India, Mexico, Cuba, and Brazil.<sup>4,15-18</sup> In Brazil, there are two licensing processes for potentized manufactured medicines issued by Agência Nacional de Vigilância Sanitária (ANVISA) according to the Collegiate Board Resolution - Resolução de Diretoria Colegiada (RDC) 26/2007: The medicine registration, which requires a longer and more detailed approval process, and the notification process, a marketing authorization that is simpler and faster. To register a potentized medicine, a company has to present documents and investigations related to quality, safety and efficacy of the medicine. It is necessary to present data to support the therapeutic claims. ANVISA evaluates all the documents and decide to accept or decline the license. The notification process is electronic and automated. If the company is authorized to manufacture medicines and follow pre-established patterns, the product may be immediately licensed by ANVISA and the suitability of the product is verified afterwards through audits of manufacturing companies. For registration or notification of a potentized medicine, the company can choose any of the 1,868 active substances available in the Normative Instruction (IN) No. 05/2007. In addition, for medicines subjected to registration, the company can also use active ingredients not included in this resolution, since it has to independently prove the safety and therapeutic efficacy of the substance, range and desired power. Compound medicines are not registered or notified at ANVISA. Its production is made in



authorized pharmacies according to a doctor's prescription.

All potentized manufactured products were registered in Brazil as homeopathic medicines until the beginning of 2007. In 2007, ANVISA issued the RDC 26/2007—including new categories of manufactured products: anthroposophic, antihomotoxic, and homeopathic, and named the group "potentized medicines".

<sup>19</sup> The translation for this term in the Brazilian legislation is "dinamizado". RDC 26/2007 is complemented by three normative instructions. First is IN 3/2007, which publishes a list of bibliographic references aimed at establishing an evaluation of safety and efficacy of potentized medicines. Second is IN 4/2007, a "Guide for promoting studies of stability for potentized medicine." Third is IN 5/2007, which regulates the limits for registration and notification of potentized medicines.<sup>19-22</sup>

RDC 26/2007 defines potentized manufactured medicines as any product whose preparation comes from substances derived from successive triturating processes and/or dilution, followed by succussion, crushing, or any other kind of rhythmical agitation, administered in accordance with homeopathic, homotoxicologic, and anthroposophic therapeutics, and with the aim of preventive or curative use.<sup>19</sup>

The difference between the three categories of potentized medicines is given on the basis of the principle followed, i.e. if the foundations and methodologies are grounded on homeopathic, anthroposophic, or antihomotoxic principles, then the

products will be homeopathic, anthroposophic, or antihomotoxic medicines, respectively.<sup>19</sup>

In the preparation of homeopathic medicines, the pharmaceutical technology mainly uses the decimal and centesimal scales according to the Hahnemannian or Korsakovian methods.<sup>23</sup>

Anthroposophic medicines are those manufactured according to the principles and processes of anthroposophy, which reflect the interrelationships between humans and nature, at physical, vital, psychic and spiritual levels and shows how these natures act in interrelation in a constant attempt to provide a dynamic balance.<sup>24-25</sup>

The antihomotoxic medicine acts by stimulating the immune system by activating the detoxification process of homotoxins and the stimulation of the organs.<sup>26-27</sup>

The Brazilian government implemented homeopathy treatment as a public health service in 1985, and in 1986 it became a part of medical specialties assistance in ambulatory care for the Brazilian population.<sup>28,29</sup> Acceptance was immediate, and since then it has been undergoing an increased expansion.<sup>2</sup> Homeopathy as a medical specialty is present in Brazil's public health services in 20 states of the country, 16 capitals of Brazilian states, and 158 towns.<sup>2</sup> In 2006, pursuant to Ordinance 971/2006 of HM, homeopathy specialty was included into the National Policy on Integrative and Complementary Practices - Política Nacional de Práticas Integrativas e Complementares (PNPIC) of Brazilian



Unified Health System - Sistema Único de Saúde (SUS).<sup>30</sup>

One of the guidelines of this policy is the provision of access of public production of homeopathic medicines. Homeopathy was included in the Policy to enrich and strengthen the public health system and improve the quality of life of the population and, therefore, has an important role in public health of the country.<sup>31</sup> ANVISA is a key part of PNPIC, because it aims to promote and protect Brazilian population's health, through medicine, by building up an effective regulatory control, health sanitary, vigilance on commercialization, dispensing and distribution of pharmaceutical products, and it rules on licensing and supervision of the manufacturing process.<sup>32</sup>

In Brazil, no manufactured medicinal product, including those imported, is allowed to be sold, or delivered for consumption before licensing by ANVISA. Medicine licensing is valid for five years, but this official sanction is renewable for successive periods. Revalidation processes are required in the first semester, in the final year of a five-year period, before ending the current official sanction.<sup>33</sup>

The Brazilian first resolution for homeopathic medicine was issued by the Brazilian National Organization for Medicine and Pharmacy Regulation—Serviço Nacional de Fiscalização da Medicina e Farmácia (SNFMMF)/MS Ordinance 17, dated 22th August 1966, which was about the manipulation, prescription, manufacturing, and sale of those products used for homeopathy. In

2003, it was published as a new resolution, named as RDC 139, dated 29th May, setting some specific rules for homeopathic medicines including registration and exemption of registration.<sup>34</sup>

From the start of licensing of potentized medicines by ANVISA, no survey about qualitative and quantitative monitoring of potentized medicines has been performed, so the aim of this study is to analyze and describe a profile of manufactured potentized medicines in Brazil, either registered or notified.

### **Materials and Methods**

A descriptive, retrospective, exploratory research including quantitative and qualitative data was conducted to evaluate potentized manufactured medicines under valid registration or notification according to Brazilian normative rules. The characterization for these medicines included the following variables: number of valid registered and notified medicines by company and API's; qualitative and quantitative products' composition; simple and combined products, their pharmaceutical form, as well geographical distribution of those companies responsible for registration or notification.

All information were gathered from primary data, through registers of expedient's evaluation and renewing for potentized medicines, as well through the system of potentized medicine notification, listed on DATAVISA, ANVISA's internal system.

Further each of the process was enquired in detail, aiming at developing, through the use of qualitative and quantitative



data, a profile of potentized medicine under valid registration, as of September 2012, in Brazil. Thus, among all these valid processes, information was collected about the register expiration time, the qualitative composition, pharmaceutical form, restriction for sale, and holding companies.

Based on the registered application in accordance with the ANVISA database, the medicines were classified as simple or combined medicines, and a survey about each API was performed on Biblioteca Nacional de Saúde (BVS) system - Virtual Health Library (VHL), available at: <http://decs.bvsalud.org/cgi-bin/wxis1660.exe/decsserver>, aimed at classification according to origin. This site categorizes substances into three origin types: plant, animal, or chemical origin.

Finally, the distribution of medicines' registration and notification per company was evaluated, the size of each was considered in accordance with framework adopted by ANVISA,<sup>35</sup> and according to the geographical location.

To include only valid registered medicines in the research, some exclusion criteria were adopted: (a) potentized manufactured medicine registered with DATAVISA system whose register, application, renewal, or notification was expired; (b) Registered applications of potentized medicine was not valid at time of survey.

Additionally, exclusion criteria was established to keep out any repeated potentized medicine application processes, because during this work, searches were performed by several

different subjects, whose searches could have found the same process number, i.e. the same medicine.

After this exploratory path, the collected contents were dealt with as quantitative data. Data analysis was performed using Microsoft Excel 2003 software. Tables and graphs are prepared to organize the frequency of variables as well to describe the profile of potentized medicine manufactured in Brazil.

In compliance with ethical issues, ANVISA's permission was obtained for data accessing (Memorandum 2880/2012—ASEGI/ANVISA). The names of involved companies and medicines were blanked out.

## **Results and Discussion**

### ***Survey of potentized manufactured registered medicine***

According to the matter concerned, "997-Registro de Medicamento Migra (Drug registration)," 354 processes for registered applications were found, but none of those referred to potentized medicine. However, when searched by subjects, "118-Registro de Nova Associação no País (New association)", "139-Registro de Medicamento Homeopático Novo (New registration)" and "1619-DINAMIZADO-Registro de Medicamento (Potentized medicine)", filed since the year 2000, there was a total of 213 application processes for potentized medicine registration.

Investigation by subject number, "159-DINAMIZADO—Renovação de Registro do Medicamento (Drug registration renewal)," found 299 applications (filed petitions) concerning a total of 189 potentized medicine registration

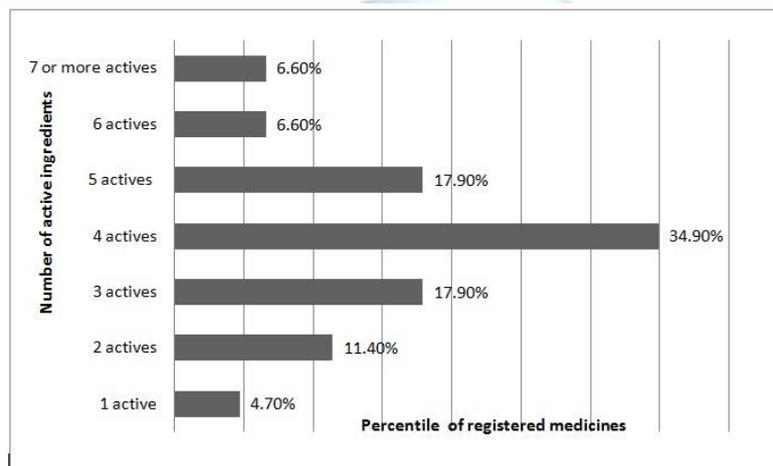


processes, and some of those processes were attached to more than one kind of registered application. Among the 189 registration processes, which were found by the search term “renovation,” nine of them were located neither on DATAVISA system nor physically incorporated on Arquivo (ANVISA documentation unity); the last one dated back to 1980. Thus, by terms such as “renovation” 180 registration processes for potentized medicines were found and included in the research.

The interpretation of data collected from the DATAVISA system found 106 potentized medicines under valid sanitary registration in Brazil. Moreover,

among these, only five (4.7%) of them were prepared from a single API.

With reference to combined APIs in registered potentized medicines: 34.9% were composed by four APIs; 17.9% for three, and also 17.9% including five APIs; 11.4%, two APIs, and 6.6% are composed by six APIs, in their formulations. Those products presenting higher quantity of APIs in their composition (from 7 to 22 API's) composed 6.6% of registered medicines. Therefore, there is a small amount (4.7%) of medicinal products whose preparation takes only one active ingredient, with a large majority of them (95.3%) resulting from a combination of substances (Graph-I).



**Graph - I: Percentage of potentized medicines with currently valid license, as of September 2012, by the number of APIs in the formulation.**

Thus, 95.3% of registered products are classified as combined *medicine*, whose safety and efficacy of combination were properly confirmed upon registration, according to current Brazilian resolutions. Because there is no limitation in the number of APIs in potentized medicines formulation in Brazil, the registration process for them has become a very interesting option and is a widely option by these companies. It was confirmed by the large number of

registered combined medicines, as well as by the number of APIs used in product manufacturing.

Potentized medicine companies, more often than not, have chosen a combination of substances, perhaps to draw distinction as an alternative, to differentiate themselves from a wide range of other notified or registered medicines, or from those medicines already in the market.

For those 464 times that APIs were used for potentized medicines under valid registration, it was possible to observe the distribution concerning the dilution and scales used. There was a certain

balance between the applied scales, since 47.7% of the potentized medicines registered were prepared by the decimal scale, and 51.9%, by centesimal one (Table - I).

AIDS	Number of medicines	Percentage
Mother tincture	2	0.4%
1 – 4x	131	28.2%
5 – 10x	56	12.1%
12 – 30x	22	4.8%
200x	7	1.5%
1000x	3	0.7%
1 – 4cH	126	27.1%
5 – 8cH	115	24.8%
200K	2	0.4%

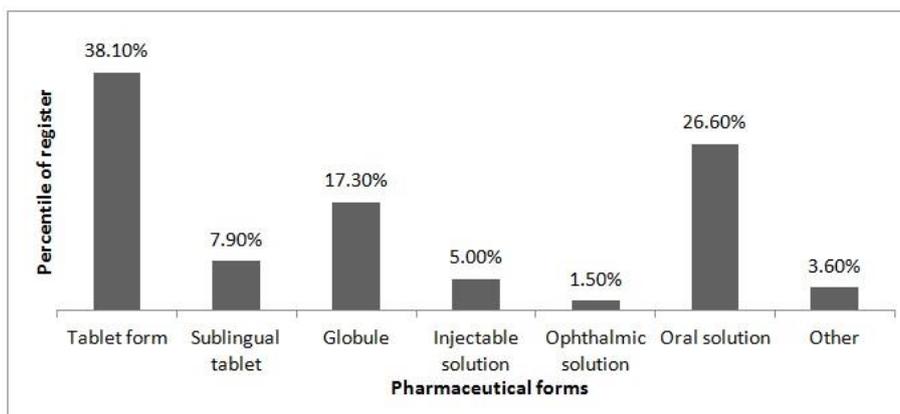
**Table - I: Active ingredient dilutions and scale/method (AIDS) of potentized medicines under valid register, as of September 2012.**

Regarding sales restriction for potentized medicines, 95 (89.6%) are classified as non-prescription products (over the counter).

in one pharmaceutical form, followed by 26.5% under two forms, and 1.8% under three or four dosage forms.

It shall be considered for pharmaceutical forms of registered potentized medicine that, independent of the APIs, a medicine may present more than one pharmaceutical form. Results showed that 106 registered potentized medicines resulted in 139 commercial presentations; 71.7% were only available

Múrias affirms that the oral route of administration is the most common for homeopathic medicine.<sup>14,28,36</sup> Likewise, majority of pharmaceutical forms, among 139 available commercial presentations of registered potentized medicines, were in tablet form (38.1%), oral solution (26.6%), globule (17.3%), and sublingual tablet (7.9%) (Graph - II).



**Graph - II: Commercial presentation of potentized medicines, valid as of September 2012, by pharmaceutical form.**



**Cite as:** Marques RFO, Carvalho ACB, Costa MA. Characterization of Potentized (Homeopathic, Anthroposophical and Antihomotoxic) Medicines Registered and Notified In Brazil. *Int J High Dilution Res.* 2015;14(3): 20-35.

It was verified that registered potentized medicines were prepared from 182 different substances following classification according to the origin, included 117 (64.3%) vegetable, 49 (26.9%) chemical, and 16 (8.8%) animal products. This is according to VHL database. According to Lajeunesse,<sup>11</sup> this datum confirms that majority of homeopathic medicines originate from herbal or mineral kingdoms. Múrias<sup>14</sup> also supports this finding and upholds that the herbal kingdom supplies most of the raw material for homeopathic medicine preparation, followed by the mineral kingdom; consequently, the animal kingdom provides the lowest amount of raw or starting material.

Among 182 APIs, 89 (48.9%) substances were used only once, alone, or in combination with another active ingredients for preparation of a medicine, compared to 51.1% of the APIs, which were used more than once, either for the same or different medicine formulations.

The diversity of APIs, used to manufacture registered potentized medicines, can be related to several possible associations, which is not possible for notified medicine products,

because they are authorized to use only one active ingredient in the manufacturing process. However, although registered potentized medicines present a wide variety of combined substances, generally they are available under fewer pharmaceutical forms, compared to notified medicines.

For the registration of potentized medicines, the company can avail itself of any of the 1868 listed substances from IN 5/2007, or even APIs not contained in this normative, since it may prove the safety and efficacy of the substance(s), respecting the intended scale and desired power. Then, on evaluating 182 APIs, which were a component part of those 106 registered products, it was found that 169 of these substances were listed by IN 5/2007. Therefore, registered potentized medicines used 9.0% of those APIs there were available in the referred normative. It can be inferred that there is an underutilization of APIs listed by IN 5/2007. The 13 APIs that were not included in the table have been licensed based on references as *Materia Medica*, or by specific studies.

The APIs that resulted in a larger amount of registered medicines are shown in Table - II

Active ingredients	Number of registered medicines
<i>Nux vomica</i>	17
<i>Viscum album</i> (Visco) - Mali	15
<i>Lycopodium clavatum</i>	11
<i>Atropa belladonna</i>	10
<i>Bryonia alba</i>	10
<i>Citrullus colocynthis</i>	10
<i>Aconitum napellus</i>	9
<i>Berberis vulgaris</i>	9
<i>Pulsatilla nigricans</i>	9

Table - II: The most commonly used APIs for manufacturing potentized medicine under valid registration, as of September 2012.

As of September 2012, there were six companies that had registered potentized manufactured medicines, which were geographically located in the southeast (66.7%) and south Brazil (33.3%).

Analyzing the number of registered potentized medicines, distributed by region where holder companies were from, the southeast region was highlighted by a majority of registered products (81.1%) and followed by South Brazil (18.9%). At the time of this research, the survey pointed that the holder company, which presented the largest amount of registered potentized medicines in Brazil had, by its own, almost half (45.3%) of all valid register applications.

Companies holding potentized medicines under valid registration were classified by ANVISA according to their size. Two of them were large sized companies, and four of them were medium-sized. Whereas stratification, by number of valid registration processes, found that 63.2% of all products belong to large sized companies, and just 36.8% to medium sized companies. Thus it can be said that large sized firms (two of them) have, on their own, almost two-thirds of the total registered potentized medicines.

Considering that each company produces just one kind of product, the following distribution for registered potentized medicines was obtained, according to the therapeutic category of medicinal products, 67.0% were homeopathic medicines, 17.9% were anthroposophic

medicinal products, and 15.1% were antihomotoxic.

### ***Survey of Potentized Manufactured Medicines under Notification***

Through surveys conducted using the DATAVISA system, it was found that there were a total of 519 potentized medicines under valid notification in Brazil, i.e., nearly five times more than the number of registered products. This may be because it is easier to license a medicine with ANVISA through notification process than through the registration process, despite limitations that exist for notified pharmaceutical product applications. Among these limitations, for example, it is not allowed to associate APIs, or to give commercial names to the medicine, and it is not allowed to write the therapeutic indications on the package or on advertising material.

The notification process of potentized medicines is a simplified marketing authorization, therefore, companies are exempted from submitting as many documents, including production reports as well as quality control and safety and efficacy reports. Companies are required to demonstrate Good Manufacturing Practices (GMP), presenting a certificate issued by ANVISA for the line (solid, liquids) of production in which the specific medicine pharmaceutical product will be manufactured, and industries also need to provide studies of product(s) stability.

It is mandatory that the APIs of notified products must be included under Annex I of IN 5/2007—Table of potencies for registration and notification of



potentized medicines. According to this investigation, only 12.6%, or 236 APIs of the list, were chosen to manufacture notified medicines.

According to the VHL database classification, amongst the notified manufactured medicines, 112 (47.5%) are from vegetable origin, 85 (36.0%) are from chemical origin, and 39 (16.5%) are from animal origin.

Among all these APIs, 34.3% were being used for manufacturing of just one medicinal product, compared with 65.7%

of APIs which were being used to manufacture more than one medicinal product.

Investigating scales and dilutions of APIs included in notified manufactured medicines, the results showed that the most used dilutions and scales are 1cH (63.2%), 20x (15.6%), 3cH (8.1%), 6cH (6.0%), and 1x (3.4%) (Table - III). It was found that the centesimal scale was the most commonly used for notified potentized medicines (79.7%), as well as for registered medicines.

AIDS	Number of medicines	Percentage
Mother tincture	1	0.2%
1x	18	3.4%
2x	3	0.6%
4x	1	0.2%
6x	1	0.2%
20x	81	15.6%
1cH	328	63.2%
2cH	7	1.3%
3cH	42	8.1%
4cH	5	1.0%
5cH	1	0.2%
6cH	31	6.0%

Table - III: AIDS of potentized medicines under valid notification, as of September 2012.

The APIs, which were included in a major amount of notified medicines, were the following: *Atropa belladonna* (included in 6 medicines), *Cinchona officinalis* (6), *Arnica montana* (5), *Matricaria chamomilla* (5), *Nux vomica* (5), *Silicea* (5) and *Sulphur* (5).

Each API, under specific scale, dilution and pharmaceutical form, during the notification process of potentized medicines, is a commercial presentation of a notified medicine. It was verified that 85 APIs were available in only one pharmaceutical form, i.e. available as 90 medicines; 58 APIs were available under

two pharmaceutical forms, or as 120 medicines; 89 substances were under three pharmaceutical forms that is in 290 medicines. Finally, four available substances under four pharmaceutical forms, resulting in 19 medicinal products, which totals up to 519 notified medicines (Table - IV).

It should be emphasized that, in this case, the number of available medicines is not proportional to the number of substances in pharmaceutical form because the same substance, under specific pharmaceutical forms, may be notified by more than one company.

Availability by pharmaceutical form	Number of active ingredients	Percentage of active ingredients	Number of medicines
1	85	36.0%	90
2	58	24.6%	120
3	89	37.7%	290
4	04	1.7%	19
<b>Total</b>	<b>236</b>	<b>100.0%</b>	<b>519</b>

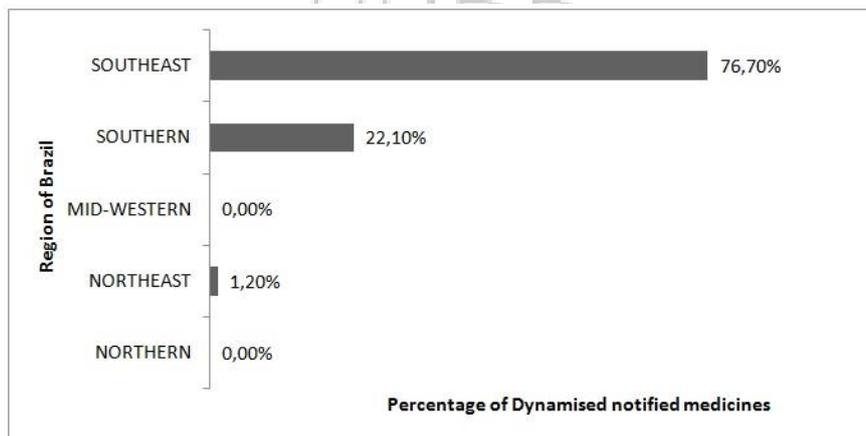
**Table - IV: Number of available APIs and potentized medicine products under valid notification, as of September 2012.**

The major pharmaceutical forms available for notified potentized medicines are: oral solution (194), pills (177), globules (142), oral powder (3), ointment (2), and ovule (1). It shall be emphasized that, according to RDC 26/2007, these notified potentized medicines shall not be made available in the injectable pharmaceutical form, which is allowed only for registered products.

There were nine companies with valid notification with ANVISA for potentized medicines. Those companies are

geographically distributed as follows: Northeast (45.0%), followed by the South (33.0%) and Southeast (22.0%) region.

However, when notified medicines were categorized by region of origin, it changed the overall framework, the Southeast region which has the least number of companies, presented the majority of potentized medicines under valid notification (77.0%). In contrast, the Northeast region of the country where a majority of companies are located, has only a small number of notified pharmaceutical products (1.0%) (Graph-III).



**Graph - III: Valid notifications of potentized medicines as of September 2012, by each region of Brazil.**

Companies, which held valid notification of potentized medicines, are classified with ANVISA according to their size, as

follows: small sized (33.4%), large sized (22.2%), medium sized (22.2%), and microenterprise (22.2%). Therefore, for



notified products, companies have a broader range in size than registered potentized medicines, whilst the companies, which have registered potentized medicines, are medium or large sized, companies holding notified medicines also include small sized as well microenterprises.

Considering stratification by size versus the number of potentized medicines notified, it was possible to verify that major companies own the majority (76.1%) of notified potentized medicines (Table - V).

After correlating the size of notified medicine companies to quantity of

products, it was assumed that there was no direct relationship between them, since there was a large variation in the number for notified potentized medicines. Large sized companies are completely different, considering that one of them owns 393 potentized notified medicines, and the other one owns only two products; among those different sized companies, which hold more potentized notified medicines, are a large sized company and microenterprise, respectively. In addition, the company that holds the highest number of notified potentized medicines in Brazil owns three-quarters (75.7%) of the total medicines under valid notification.

Company	The size of the company	Number of medicines	Percentage
A	Large sized - Group I	2	76.1%
B	Large sized - Group II	393	
C	Medium - Group III	5	2.1%
D	Medium - Group IV	6	
E	Small	1	1.6%
F	Small	2	
G	Small	5	
H	Micro	1	20.2%
I	Micro	104	

**Table - V: Number of potentized medicines under valid notification, as of September 2012, by company and size.**

Another major finding of the study was that, among the total of evaluated holding companies, only two owned both valid registration and valid notifications, and the largest registration holder is also the one that owns the highest number of notifications. This situation is indeed a matter for concern, because it might entail market centralization and may be a determining factor for higher prices of pharmaceutical products, it might

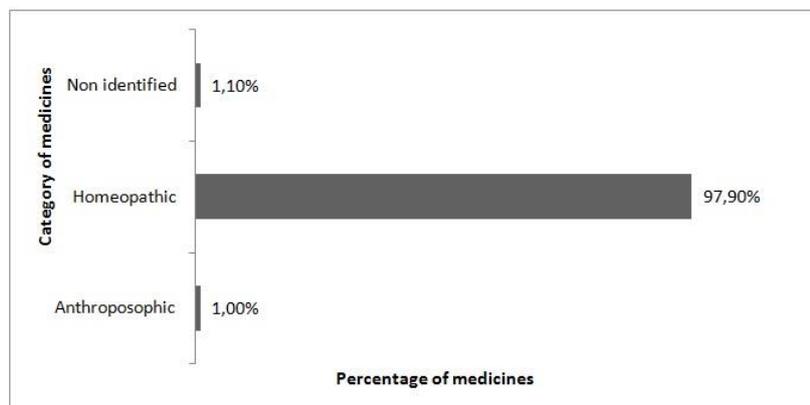
hamper competition, or promote the disappearance of small sized national companies.

As shown in Graph IV, the distribution per category of notified manufactured potentized medicines is: four companies manufacture homeopathic medicines (508 products) and one company manufactures anthroposophic medicines (five products). It was not possible to



identify product subcategories from four companies, which together are

responsible for six notified potentized medicines.



**Graph - IV: Distribution of potentized medicines under valid notification, as of September 2012, according to the specific category.**

Therefore, regarding categories of potentized medicines, homeopathic medicines predominate among them, either registered (67.0%) or notified ones (97.9%), followed by anthroposophic medicines.

## Conclusion

This research indicates that there are a small number of potentized manufactured medicines under valid registration or notification in Brazil. As of September 2012, there were only 106 registered medicines and 519 notified medicines. Despite licensed in accordance with ANVISA, these are not necessarily available on the market for the population.

Most licensed drugs (95.3%) are obtained from the combination of substances, i.e. associations, which does not occur with the notified drugs that necessarily consist of only one active substance. Also, it was observed that while there are only six companies holding registered medicines, nine

companies have notified medicines, which may be due to the fact of the notification process is faster and less expensive than the registration of medicines. However, there are some similarities between the two classes of potentized medicines like the oral route of administration which is the most prevalent in both cases.

This study presented the potentized medicines' market situation in Brazil and these results may be used for planning Brazilian regulatory processes and medicine policies and also to guide the market for new medicine registration or notification.

**Conflict of Interest:** None declared.

## References

1. WHO. Informe sobre la salud en el mundo 2008: La atención primaria de salud, más necesaria que nunca [Book online]. Geneva (Switzerland): WHO; 2008 [cited

- 2013 Jan 22] 154 p. Available from <http://bit.ly/1KPLp2o>
2. Marino R. Homeopatia em saúde coletiva: contribuição ao estudo das epidemias [Dissertation]. São José do Rio Preto (Brazil): Ciências da Saúde; Faculdade de Medicina de São José do Rio Preto; 2006. 73p. [Portuguese]
  3. Spadacio C, Barros NF. Uso de medicinas alternativas e complementares por pacientes com câncer: Revisão sistemática. *Rev. Saúde Pública* 2008;42(1): 158-64. [Portuguese]
  4. Brasil. Relatório do 1º Seminário internacional de práticas integrativas e complementares em saúde – PNPIC [Book online]. Brasília (Brasil): Ministério da Saúde; 2009 [cited 2013 Feb 23] 196 p. Available from: <http://bit.ly/1iMkR83> [Portuguese]
  5. Teixeira MZ. Homeopatia nas doenças epidêmicas: conceitos, evidências e propostas. *Rev. Homeop.* 2010; 73 (1/2): 36-56. [Portuguese]
  6. Teixeira MZ. Pesquisa clínica em homeopatia: evidências, limitações e projetos. *Pediatrics* 2008; 30 (1): 27-40. [Portuguese]
  7. De Lima AC, Bem PNI. Tratamento homeopático da asma infantil. *Rev. Pesq. Inov. Farmac* Jan/Jul 2010;2(1):62-71. [Portuguese]
  8. Milgrom L. Homeopathy UK: ‘The Sick Man of Europe’? *Forsch Komplementmed* 2012;19(3): 120-22
  9. Mohammad I. Homeopathy – a synergistic approach to clinical medicine? *InnovAiT: Education and inspiration for general practice* 2013;6 (2):108-10.
  10. Teixeira MZ. Evidências científicas da episteme homeopática. *Rev. de Homeop.* 2011;74 (1/2):33-56.
  11. Lajeunesse ME. Homeopathic medicines for children. *Arch. Dis. Child.* 2012; 97:135-38.
  12. Callejas NCP, Ruíz IO, Callejas LP. Homeopatía, ciencia milenaria útil en edad pediátrica. *MediCiego* [serial online]. 2004 (cited 2013 Feb 20); 10 (2). Available from: <http://bit.ly/1R09OmM> [Spanish]
  13. Ghosh AK. A short history of the development of homeopathy in India. *Homeopathy* 2010; 99:130-36.
  14. Múrias IAS. Homeopatia – um estudo sobre os seus conceitos científicos, médicos e farmacêuticos [monograph]. Porto (Portugal): Instituto de Ciências Farmacêuticas, Universidade Fernando Pessoa; 2009. 80 p. [Portuguese]
  15. Poitevin B. Integrating homoeopathy in health systems. *Bull World Health Organ.* 1999; 77 (2): 160-66.
  16. Priven SW. History of homeopathy and social history of medicine: the story of a successful marriage. *Int J High Dil Res.* 2009; 8 (28): 128-40.
  17. Di Sarsina PR, Iseppato I. Traditional and non-conventional medicines: the socio-anthropological and bioethical paradigms for person-centered



- medicine, the Italian context. *EPMA J.* 2011; 2: 439-49.
18. Gonçalves MMR. Medicina tradicional, complementar e alternativa no mundo: o processo de regulamentação em Portugal — o caso da Acupuntura [monograph]. Porto (Portugal): Instituto Português de Naturologia; 2011. 94p. [Portuguese]
19. Brasil. Resolução RDC 26, de 30 de março de 2007. Dispõe sobre o registro de medicamentos dinamizados industrializados homeopáticos, antroposóficos e anti-homotóxicos [online]. Brasília:DOU. 2007; [cited 2007 Apr 02]. Available from <http://bit.ly/1Fv8qr8> [Portuguese]
20. Brasil. Instrução Normativa 3, de 11 de abril de 2007. Dispõe sobre a “Lista de referências bibliográficas para avaliação de segurança e eficácia de medicamentos dinamizados” [online]. Brasília:DOU. 2007; [cited 2007 Apr 13]. Available from: <http://bit.ly/1YCdfol> [Portuguese]
21. Brasil. Instrução Normativa 4, de 11 de abril de 2007. Dispõe sobre o “Guia para a Realização de Estudos de Estabilidade para Medicamentos Dinamizados” [online]. Brasília: DOU. 2007; [cited 2007 Apr 13]. Available from: <http://bit.ly/1KClEiF> [Portuguese]
22. Brasil. Instrução Normativa 5, de 11 de abril de 2007. Dispõe sobre os “Limites de potência para registro e notificação de medicamentos dinamizados” [online]. Brasília: DOU. 2007; [cited 2007 Apr 13]. Available from: <http://bit.ly/1Kw3Bga> [Portuguese]
23. Santos R, De Sá FMP. Homeopatia: histórico e fundamentos. *Rev. Científica da Faculdade de Educação e Meio Ambiente.* Jan./Jun. 2014; 5(1): 60-78. [Portuguese]
24. Follador ECR. Medicina antroposófica: um novo paradigma para as questões da medicina moderna. *Rev. Med.* (São Paulo). Jul-Sep 2013; 92(3):166-72.[Portuguese]
25. Wenceslau LD, Röhr F, Tesser CD. Contribuições da medicina antroposófica à integralidade na educação médica: uma aproximação hermenêutica. *Rev. Interface: comunicação, saúde e educação.* 2014; 18(48):127-38. [Portuguese]
26. Bella FA, Acedo DMG. Homotoxicología aplicada en el entorno quirúrgico. *Rev. Int. Ciencias Podológicas.* 2009; 3 (2): 51-62. [Spanish]
27. Garcia DA, Patino L, Rueda G. Medición de la citotoxicidad y producción de citocinas en fibroblastos gingivales humanos estimulados con Mercurius-Heel®S: Un estudio piloto. *Univ. Sci. Bogotá* Sept./Dec. 2014; 19 (3): 225-32. [Spanish]
28. Cesar, AT. O medicamento homeopático nos serviços de saúde [thesis online]. São Paulo (Brasil): Faculdade de Saúde Pública da USP. Universidade de São Paulo; 1999 [cited 2013 Feb

- 19]. 172 p. Available from:  
<http://bit.ly/1JqJHPO>  
[Portuguese]
29. Brasil. Política nacional de práticas integrativas e complementares no SUS - PNPIC-SUS [online]. Brasília: DOU; 2006 [cited 2013 Feb. 24]. Available from: <http://bit.ly/1MJSGN9> [Portuguese]
30. Brasil. Portaria 971, de 03 de maio de 2006. Aprova a política nacional de práticas integrativas e complementares (PNPIC) no Sistema Único de Saúde[online]. Brasília: DOU; 2006 [cited 2013 Feb 5]. Available from: <http://bit.ly/1JqJNXB> [Portuguese]
31. Lemonica R. Compreendendo o impacto das diretrizes propostas pela Política Nacional de Práticas Integrativas e Complementares em serviços de homeopatia do Sistema Único de Saúde [monograph]. Botucatu (São Paulo): Universidade Estadual Paulista "Júlio de Mesquita Filho"; 2014. 174p. [Portuguese]
32. Brasil. Lei 9.782, de 26 de janeiro de 1999. Define o Sistema nacional de vigilância sanitária, cria a Agência nacional de vigilância sanitária, e dá outras providências[online]. Brasília: DOU; 1999 [cited 2013 Feb 19]. Available from:
- <http://bit.ly/1WjDXR7>  
[Portuguese]
33. Brasil. Lei 6.360, de 23 de setembro de 1976. Dispõe sobre a vigilância sanitária a que ficam sujeitos os medicamentos, as drogas, insumos farmacêuticos e correlatos, cosméticos, saneantes e outros produtos, e dá outras providências [online]. Brasília: DOU; 1976 [cited 2013 Jan 27]. Available from <http://bit.ly/1OvjaIM> [Portuguese]
34. Brasil. Resolução RDC 139, de 29 de maio de 2003. Dispõe sobre o registro e a isenção de registro de medicamentos homeopáticos industrializados [online]. Brasília: DOU; 2003 [cited 2013 Feb 7]. Available from: <http://bit.ly/1KCmqfF> [Portuguese]
35. Brasil. Enquadramento de porte de empresa. Agência nacional de vigilância sanitária [online]. Brasília: DOU; 2013 [cited 2013 Feb 14]. Available from: <http://bit.ly/1R12pna> Access 2013 Feb. [Portuguese]
36. De Sá FMP, Alves E. Estudo comparativo dos métodos da simples e tríplice impregnação de glóbulos empregados em homeopatia. Rev. Científica da Faculdade de Educação e Meio Ambiente. Jul./Dez. 2012; 3(2):1-8. [Portuguese]

Received: October 21 2014. Accepted: August 15 2015.

© International Journal of High Dilution Research.  
Not for commercial purposes.

