New Brazilian rules for herbal medicines

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Abstract
Brazil has republished several normative instructions for the last months related to medicinal plants and herbal medicines in accordance to public policies which encourage the use of herbal medicines that present safety, efficacy, and quality patterns. This article reports the last published rules and their major changes comparing to the previous ones.

Keywords: phytotherapy, herbal medicine, medicinal plants, regulation

Resumen
Brasil acaba de publicar varias normas relacionadas con las plantas medicinales y fitoterápicos con el fin de satisfacer las demandas de las políticas públicas vigentes en el país y fomentar la entrada de medicamentos a base de hierbas con la seguridad, eficacia y calidad para la población. Este artículo presenta las normas recientemente publicadas y presenta los cambios más importantes.

Palabras Clave: fitoterápico, medicamento herbolario, plantas medicinales, regulación.

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Since 1967, Brazilian health policies have recognized the role of medicinal plants in the Public Health scenario, publishing specific regulations for herbal medicines regarding certain aspects such as safety, quality, and efficacy (BRASIL, 1967). Table 1 summarizes the most important Brazilian published documents.

### Table 1. Mainly Brazilian specific guidelines about medicinal plants regulation

<table>
<thead>
<tr>
<th>Category</th>
<th>Legal Basis</th>
<th>Main features</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicinal Plants</td>
<td>Law 5991/1973</td>
<td>Controls medicines trade, pharmaceuticals and related supplies</td>
<td><a href="http://www.anvisa.gov.br/legis/consolidada/lei_5991_73.htm">http://www.anvisa.gov.br/legis/consolidada/lei_5991_73.htm</a></td>
</tr>
<tr>
<td>Medicinal Plants; Herbal medicines</td>
<td>MS/GM 971/2006</td>
<td>Approves the national policy of complementary practices</td>
<td><a href="http://portal.saude.gov.br/portal/arquivos/pdf/PNPIC.pdf">http://portal.saude.gov.br/portal/arquivos/pdf/PNPIC.pdf</a></td>
</tr>
<tr>
<td>Herbal medicines</td>
<td>IN 05/2010</td>
<td>List of references to evaluate safety and efficacy of herbal medicines</td>
<td><a href="http://www.in.gov.br/impressa/visualiza/index.jsp?data=05/04/2010&amp;jornal=1&amp;pagina=91&amp;totalArquivos=160">http://www.in.gov.br/impressa/visualiza/index.jsp?data=05/04/2010&amp;jornal=1&amp;pagina=91&amp;totalArquivos=160</a></td>
</tr>
</tbody>
</table>

MS: Health Ministry; GM: ANVISA Pharmaceuticals Bureau; RDC: Resolution; IN: Normative Instruction; RE: Resolution from ANVISA Council

Therefore, the regulation of herbal medicine and medicinal plants largely evolved in the last decade, stimulated by the foundation of the Agência Nacional de Vigilância Sanitária - ANVISA, and by the implementation of the National Policy of Integrative and Complementary Practice and National Policy of Medicinal Plants and Herbal Medicines (BRASIL, 2006a, 2006b; Carvalho et al., 2007; Carvalho et al., 2008). One of the most recent regulations is the RDC number 14, published on April 05th, 2010 (BRASIL, 2010d), which updated the technical requirements for industrialized herbal medicine registration. Indeed, few changes can be noted when comparing the latter to the previous guideline (RDC 48/2004) (BRASIL, 2004) concerning the requirements to prove efficacy and safety patterns. The demand on safety and efficacy patterns still remains and they must be preceded by pre-clinical and clinical tests. The results must also be supported by scientific literature or traditional use of the plant species. A list of references that support the plant’s safety and efficacy patterns was published again as IN 05/10 (BRASIL, 2010c).

However, the new document includes innovations in the requirements for quality control. The Biological control is a new alternative to replace the chemical marker control for in vivo, ex vivo or in vitro validated tests, controlling the activity of the herbal medicine. Other inclusions refer to the need to evaluate the aflatoxins as recommended by the WHO magazine reports (WHO, 2007).
One innovative inclusion is the requirement to register alga and multicellular fungus based products as ANVISA is defining the specific guidelines for this purpose. There was a lack of requirements in order to register these sorts of products and the RDC 14/2010 filled in this gap. Another innovation is the possibility for an herbal drug to become the active substance in the herbal medicine, if its efficacy can be clinically tested and proved. Herbal drug registration was prohibited by the preceding rule (RDC 48/2004).

One of the several aspects that show the evolution of the Brazilian regulation in this field is the obligation to present pharmacologic surveillance reports for renewing herbal medicine registration in order to monitor adverse effects related to the herbal medicine in question.

The new regulation norms also affect imported herbal medicines. The authorization to import samples of herbal medicines can be done prior to their registration in order to process batch-to-batch quality analyses and clinical tests. Such analyses can be done by a third party Quality Control laboratory in Brazil instead of by a laboratory from the samples’ home country as long as the laboratory hired to perform these tests has herbal medicine certifications from Good Laboratory Practices – GLP and Good Manufacturing Practices - GMP (BRASIL, 2010b). Good Manufacturing Practices guideline was also updated on April 19th by RDC number 17/2010. This guideline brings specific requirements for herbal medicine industries. The normative requires technical qualification on herbal medicine aspects for all those involved in the manufacturing/inspection/liberation of these products. Other innovations added to this guideline are the mandatory control of pesticides and fumigant residues in final products and the rules about genetically modified herbal drug manufacturing (BRASIL, 2010a).

Two other guidelines were recently published. The RDC 47/2009 defines the rules on elaborating, harmonizing, improving, and publishing literature to inform patients and health professionals about herbal medicines and their rational use (BRASIL, 2009a). The other guideline, RDC 71/2009, defines the requirements of labeling all pharmaceutical products that are registered and sold. The labels must also be written in Braille and must have a tracking system, along with other requirements (BRASIL, 2009c).

Another newly published regulation, the RDC 10/2010, from March 10th, deals with herbal drugs that are used in medicinal teas and has, therefore, filled in another gap in the Brazilian regulation. With this norm, the industries can now register their herbal drug productions based on a list of 66 traditionally recognized as efficient and safe herbal species (BRASIL, 2010b).

CONCLUSIONS

All these new rules present an evolution to the Brazilian Regulation. However, even though the innovated sanitary regulation meets the Public Health Policies for Industries it is mandatory to carry on researches in order to appraise the Brazilian medicinal plants accordingly, as established by the Relação Nacional de Plantas de Interesse para o Sistema Único de Saúde (RENISUS) (BRASIL, 2009b).

REFERENCES


