Herbal Medicines Regulation - Brazil

National Health Surveillance Agency – ANVISA
General Office of Drugs – GGMED
Office of Specifics, Phytotherapics and Homeopathics Drugs – GMEFH

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Making clear the terms:

• Herbal medicines – a pharmaceutical products made by GMP-certified industry; active ingredients, must be plant extracts, tinctures, oils, or so; require licensing; in Brazil is more common to call them “phytotherapics”

• Traditional herbal product – a product made with plants, used therapeutically; not licensed; still not regulated;

• Medicinal plant – plant in natura, fresh or dry, desagregated or not, used therapeutically; not licensed;
Summary

- Brasil have effective regulation of herbal products since 2000, and it was updated in 2004 (minimal changes)
- Only herbal medicines are regulated
- Herbal medicines have the same status as any other medicines
- Can be produced only by pharmaceutical industries, and these must be GMP-certified
- Efficacy an safety can be demonstrated by literature data, clinical and pre-clinical tests, and to some extent by tradition of use
Medicinal Plants

- Can be sold in pharmacies and herbal shops
- Labeling cannot exhibit therapeutic claims
- Sold as fragmented or powdered material, for making infusions, and for external use
- powdered plants in capsules or tablets are not permitted

** a new regulation is in progress, will be effective probably in 2009; some pre-approved therapeutic claims will be permitted in the packages.

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• They have the full status of medicines.
• They have to be licensed as medicines to be sold.
• Can be OTC or may need a prescription.
• Can be produced only by pharmaceutical industries.
• Producers must have GMP certification.
HERBAL MEDICINES IN BRAZIL

• Products must use only **standardized extraction derivatives** (extracts, tinctures, oils, and others) as active ingredients; cannot use raw plant material, nor isolated substances, even if extracted from plants.

• Products that use more than one plant species have to demonstrate **safety and efficacy for the product** - it is not acceptable to make assumptions based on the safety and efficacy of the individual components.
Herbal Medicines - Licensing

To get a license, herbal medicines must have:

- Evidence of efficacy
- Evidence of safety
- Quality standards (standardized extracts, with chromatographic fingerprints and chemical markers)
Herbal Medicines - Licensing

Efficacy and safety can be demonstrated by:

- scientific literature (e.g. WHO and ESCOP monographs, Commission E, other considered as reference books)
- pre-clinical and clinical studies
- extensive ethnopharmacological research data that can be used to help evaluate safety and efficacy

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Herbal medicines market numbers – March 2008

- 512 licensed herbal medicines
- 432 - use one plant extract
- 80 – use two or more plant extracts
- 119 industries have at least one licensed herbal medicine
- Annual sales estimated – US$ 160 M

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**Most licensed herbal medicines in Brazil – March 2008**

<table>
<thead>
<tr>
<th>Plant</th>
<th>Number of products</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Ginkgo biloba</em></td>
<td>33</td>
</tr>
<tr>
<td><em>Aesculus hippocastanum</em></td>
<td>29</td>
</tr>
<tr>
<td><em>Cynara scolymus</em></td>
<td>21</td>
</tr>
<tr>
<td><em>Hypericum perforatum</em></td>
<td>20</td>
</tr>
<tr>
<td><em>Glycine max</em></td>
<td>20</td>
</tr>
<tr>
<td><em>Valeriana officinalis</em></td>
<td>20</td>
</tr>
<tr>
<td><em>Panax ginseng</em></td>
<td>17</td>
</tr>
<tr>
<td><em>Cassia angustifolia, Cassia senna, Senna alexandrina</em></td>
<td>14</td>
</tr>
<tr>
<td><em>Cimicifuga racemosa</em></td>
<td>14</td>
</tr>
<tr>
<td><em>Mikania glomerata</em></td>
<td>14</td>
</tr>
<tr>
<td><em>Maytenus ilicifolia</em></td>
<td>13</td>
</tr>
<tr>
<td><em>Peumus boldus</em></td>
<td>13</td>
</tr>
</tbody>
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New Situation

• Since 2006, Brasil have a National Policy on medicinal plants and herbal medicines

• Traditional herbal products will be adopted by the government health program, for primary health care

• Traditional herbal products must have their own licensing rules
  1. medicines ?
  2. Supplements ?
  3. “in-between” ?

Still evaluating the rules for these products...

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THANK YOU!!

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