Chemical Medicines Update

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### Currently Official Monographs

<table>
<thead>
<tr>
<th>Expert Committees</th>
<th>Therapeutic Category</th>
<th>Number of Official Monographs</th>
<th>Number of F-lots</th>
<th>Number of R/C-lots</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Medicines 1</td>
<td>Antiviral, Antimicrobials &amp; Antibiotics</td>
<td>608</td>
<td>26</td>
<td>295</td>
</tr>
<tr>
<td>Chemical Medicines 2</td>
<td>Cardiovascular, Cough, Cold, &amp; Analgesic</td>
<td>563</td>
<td>93</td>
<td>247</td>
</tr>
<tr>
<td>Chemical Medicines 3</td>
<td>Gastrointestinal, Renal, Endocrine and Ophthalmology, Oncology, Dermatology &amp; Veterinary</td>
<td>489</td>
<td>75</td>
<td>369</td>
</tr>
<tr>
<td>Chemical Medicines 4</td>
<td>Psychiatric, Psychoactive, Neuromuscular, Aerosol, &amp; Imaging Drugs</td>
<td>585</td>
<td>69</td>
<td>279</td>
</tr>
<tr>
<td>Chemical Medicines 5</td>
<td>Pulmonary &amp; Steroids</td>
<td>470</td>
<td>51</td>
<td>165</td>
</tr>
<tr>
<td>Chemical Medicines 6</td>
<td>Over the Counter (OTC)</td>
<td>458</td>
<td>13</td>
<td>96</td>
</tr>
</tbody>
</table>

Extracted from Tableau on 10-17-2019


# Chemical Medicines – 2015-2020 Cycle Submissions

<table>
<thead>
<tr>
<th>Expert Committees</th>
<th>New</th>
<th>Modernizations</th>
<th>*Revisions</th>
<th>Omissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Medicines 1</td>
<td>33</td>
<td>142</td>
<td>84</td>
<td>111</td>
</tr>
<tr>
<td>Chemical Medicines 2</td>
<td>54</td>
<td>182</td>
<td>97</td>
<td>52</td>
</tr>
<tr>
<td>Chemical Medicines 3</td>
<td>51</td>
<td>111</td>
<td>76</td>
<td>51</td>
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<tr>
<td>Chemical Medicines 4</td>
<td>40</td>
<td>158</td>
<td>156</td>
<td>115</td>
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<tr>
<td>Chemical Medicines 5</td>
<td>17</td>
<td>122</td>
<td>60</td>
<td>72</td>
</tr>
<tr>
<td>Chemical Medicines 6</td>
<td>19</td>
<td>114</td>
<td>31</td>
<td>11</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>214</td>
<td>829</td>
<td>504</td>
<td>412</td>
</tr>
</tbody>
</table>

*Note: Approximately 76% of Revisions are Accelerated

Extracted from Tableau on 10-17-2019
Topics Update – Chem Meds EC 2 & 6 and Chem Info

- Modernization of opioids monographs
- OTC Product Standards
- Development of Global Substance Registration System (GSRS)
Oct 2018, FDA requested USP to modernize a list of priority opioid monographs

• Out of date monographs with titration assays, only single ID tests, etc.
• Upgrading to modern analytical methods for better control of ID, assay, impurities, etc.

USP has prioritized modernization of these monographs

1. Butorphanol Tartrate
2. Codeine
3. Codeine Phosphate
4. Dihydrocodeine Bitartrate
5. Diphenoxylate Hydrochloride
6. Fentanyl Citrate
7. Aspirin, Caffeine and Dihydrocodeine Bitartrate Capsules
8. Hydromorphone Hydrochloride
9. Levorphanol Tartrate
10. Methadone Hydrochloride
11. Oxymorphone Hydrochloride
12. Pentazocine
13. Pentazocine Hydrochloride
Challenge:
- Slow progress obtaining sponsors and sourcing samples/reference stds.

Good progress modernizing the FDA priority list
- 3 modernized and official
- 4 modernized/published in PF
- 3 Currently in revision
- 2 Currently under Internal development
- 1 Pending sponsor donation or sample procurement for internal devel.

Remaining USP opioid portfolio prioritized for modernization
- About 40 monographs total in need of modernization
- Lacking organic impurity methods, secondary ID tests, etc.
Developing OTC Product Standards

- USP is committed to developing a suitable framework to facilitate public quality standards for finished OTC products
  - longstanding science, policy and compliance issues to overcome

- USP hosted 4th OTC Round Table - 17 Oct 2019
  - CHPA, FDA and USP
  - Agreements to date to be published in Stim Article

- Chem Meds 6 Expert Committee face-to-face meeting – 18 Oct 2019
  - New USP strategy for Chem Meds 6 EC in the next cycle (2020-25)
Global Substance Registration System (GSRS)

- Software system being developed by National Center for Advancing Translational Sciences (NCATS) for FDA
- Designed to be a repository for information on substances of interest to regulatory agencies throughout the world
- GSRS is freely distributable
- Allows USP to host and develop its own substance registration system for curation of USP Chemical Information
Thank You

Empowering a healthy tomorrow