

# NHPD Status of Submissions Report

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January 2008

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The *NHPD Status of Submissions Report* is a publication of Health Canada's Natural Health Products Directorate (NHPD), the federal department responsible for the regulation of natural health products sold in Canada. Its purpose is to provide the Canadian public with statistical data on the product and site licence applications received and processed by the NHPD.

The *NHPD Status of Submissions Report* is released to the Canadian public every two months via the NHPD's electronic bulletin. Subscribe to the NHPD e-bulletin: [http://www.hc-sc.gc.ca/dhp-mps/prodnatur/activit/education/list/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/activit/education/list/index_e.html).

**Questions, comments or feedback** regarding the content of the *NHPD Status of Submissions Report* may be addressed to **NHPD\_DPSN@hc-sc.gc.ca**.

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## GLOSSARY OF TERMS

The following is a glossary of terms encountered throughout the report

| Term         | Definition   |
|--------------|--|
| In Queue     | File awaiting assignment to a coordinator/assessor                                     |
| Working      | File has been assigned and is being worked on  |
| With Sponsor | File is awaiting the applicant's response to a PDN or IRN                              |
| Halted       | File on hold pending an internal decision  |
| PC Pending   | File pending a product classification (PC)   |
| Refused      | File has been refused by the NHPD due to deficiencies and is no longer being processed |
| Withdrawn    | File removed from the submission review process by the applicant                       |

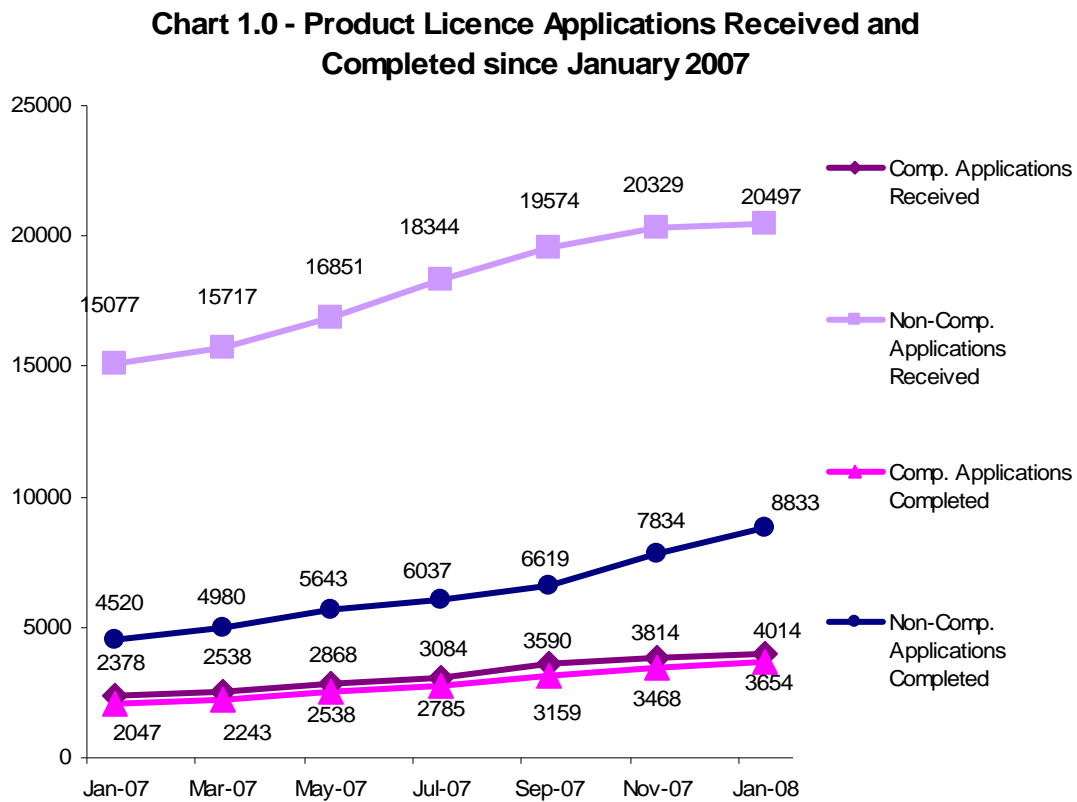
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## PRODUCT LICENSING STATISTICS

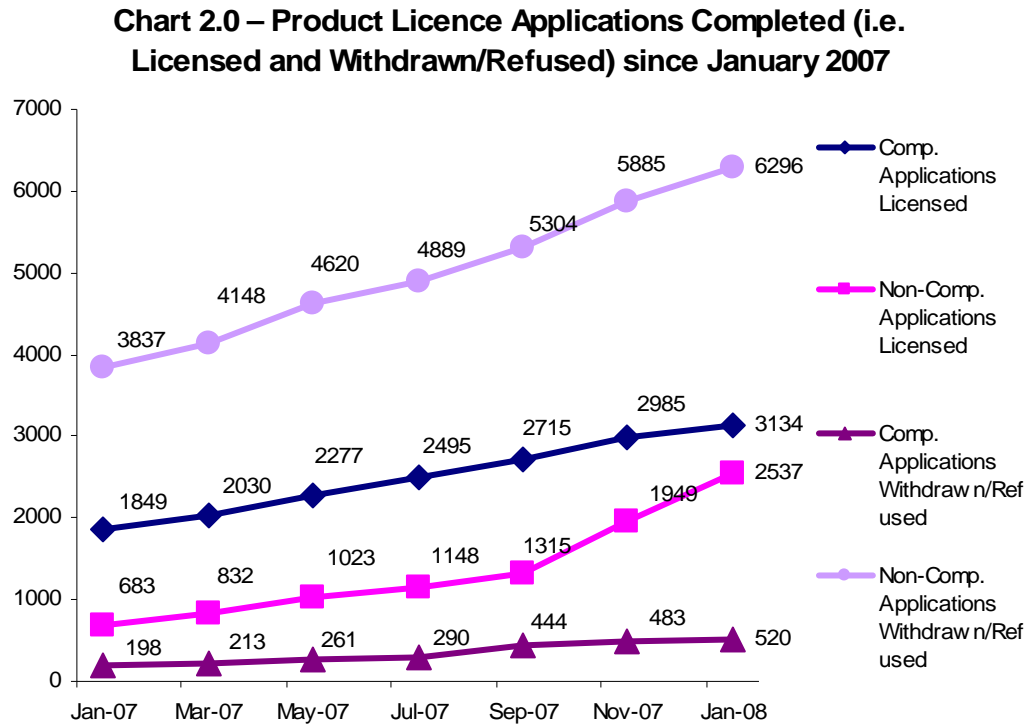
*Note – Statistics for this report were generated on January 4, 2008*

**Chart 1.0 - Product Licence Applications Received and Completed since January 2007.**

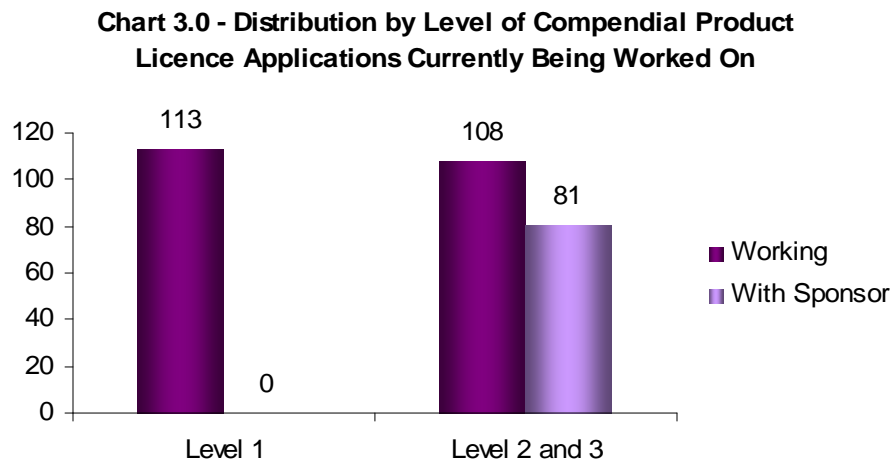
NOTE – “completed” includes the number of licences issued as well as those that were refused by the NHPD and those withdrawn by the applicant.



**Chart 2.0 - Product Licence Applications Completed (i.e. Licensed and Withdrawn/Refused) since January 2007.**

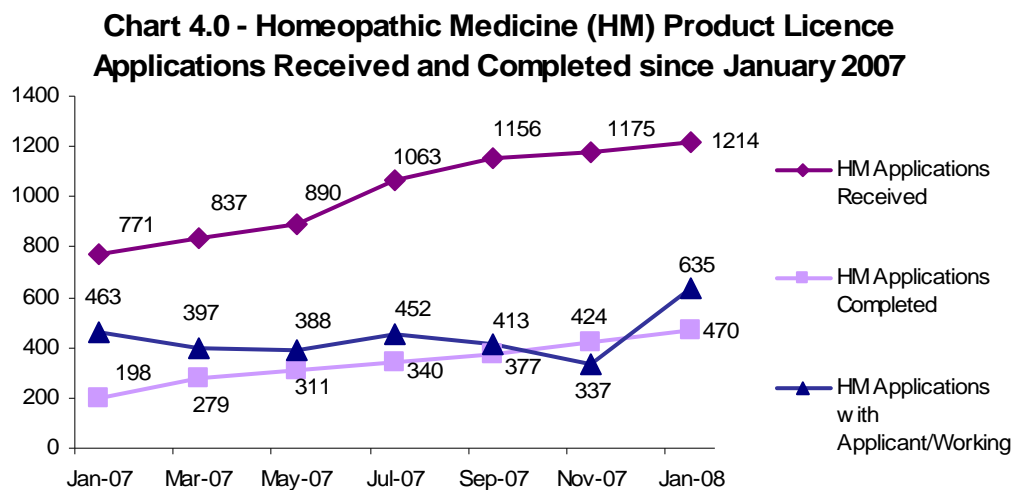


**Chart 3.0 - Distribution by Level of Compdial Product Licence Applications Currently Being Worked On.**



| Table 3.1 – Breakdown Within Each Level of<br>Compendial Product Licence Applications Currently<br>Being Worked On |            |                |
|--|------------|----------------|
|  | Level 1    | Levels 2 and 3 |
| In Queue   | 0          | 57             |
| <b>Working</b>   | <b>113</b> | <b>108</b>     |
| <b>With Sponsor</b>  | <b>0</b>   | <b>81</b>      |
| Halted   | 0          | 0              |
| PC Pending   | 1          | 0              |

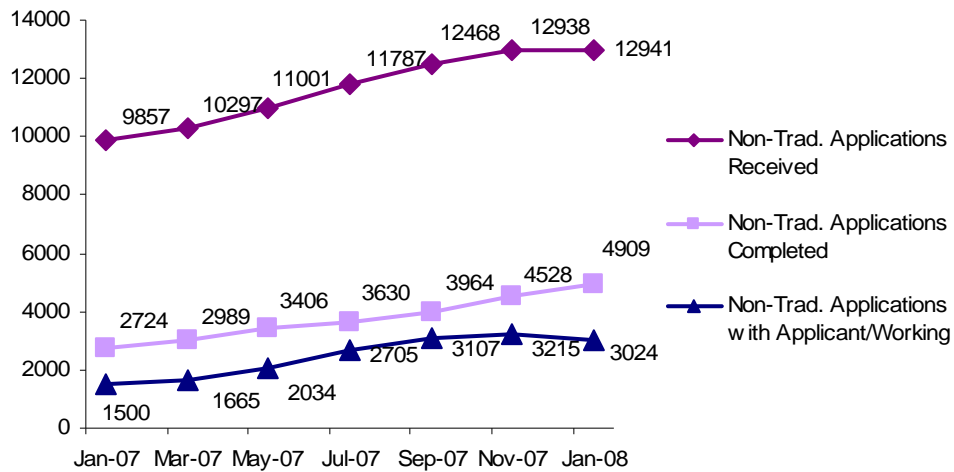
**Chart 4.0 – Homeopathic Medicine (HM) Product Licence Applications Received and Completed since January 2007.**



| Table 4.1 – Breakdown Within Each Level of<br>Homeopathic Medicine (HM) Product Licence<br>Applications Currently Being Worked On |           |          |            |
|---|-----------|----------|------------|
|   | Level 1   | Level 2  | Level 3    |
| In Queue  | 0         | 0        | 379        |
| <b>Working</b>  | <b>83</b> | <b>0</b> | <b>228</b> |
| <b>With Sponsor</b>   | <b>0</b>  | <b>0</b> | <b>54</b>  |
| Halted  | 0         | 0        | 0          |
| PC Pending  | 0         | 0        | 0          |

**Chart 5.0 – Non-Traditional Product Licence Applications Received and Completed since January 2007.**

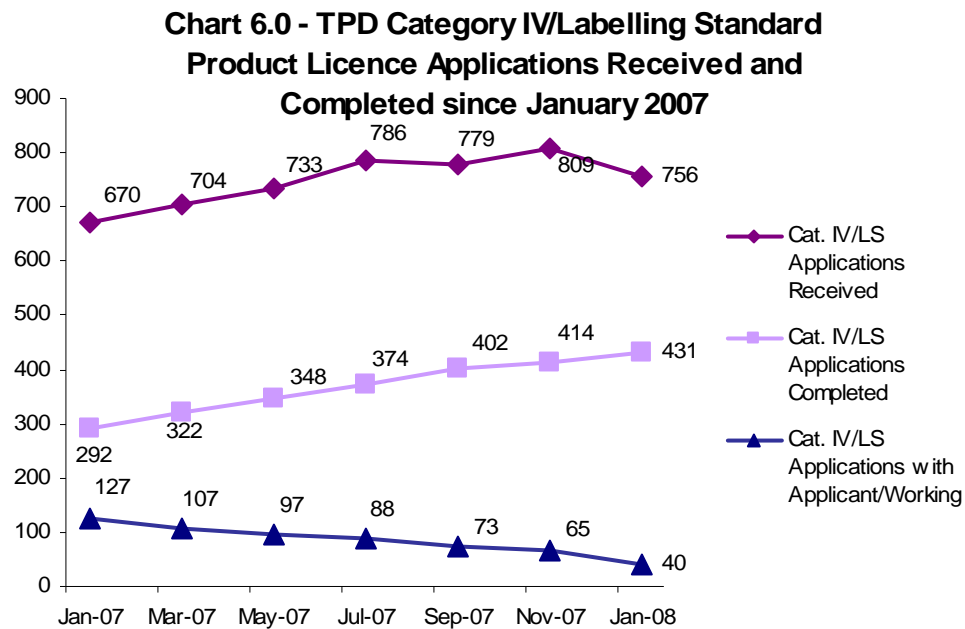
**Chart 5.0 - Non-Traditional Product Licence Applications Received and Completed since January 2007**



**Table 5.1 – Breakdown Within Each Level of Non-Traditional Product Licence Applications Currently Being Worked On**

|                     | Level 1    | Level 2  | Level 3     |
|---------------------|------------|----------|-------------|
| In Queue            | 0          | 1        | 4997        |
| <b>Working</b>      | <b>977</b> | <b>0</b> | <b>1471</b> |
| <b>With Sponsor</b> | <b>9</b>   | <b>1</b> | <b>566</b>  |
| Halted              | 0          | 0        | 0           |
| PC Pending          | 10         | 0        | 0           |

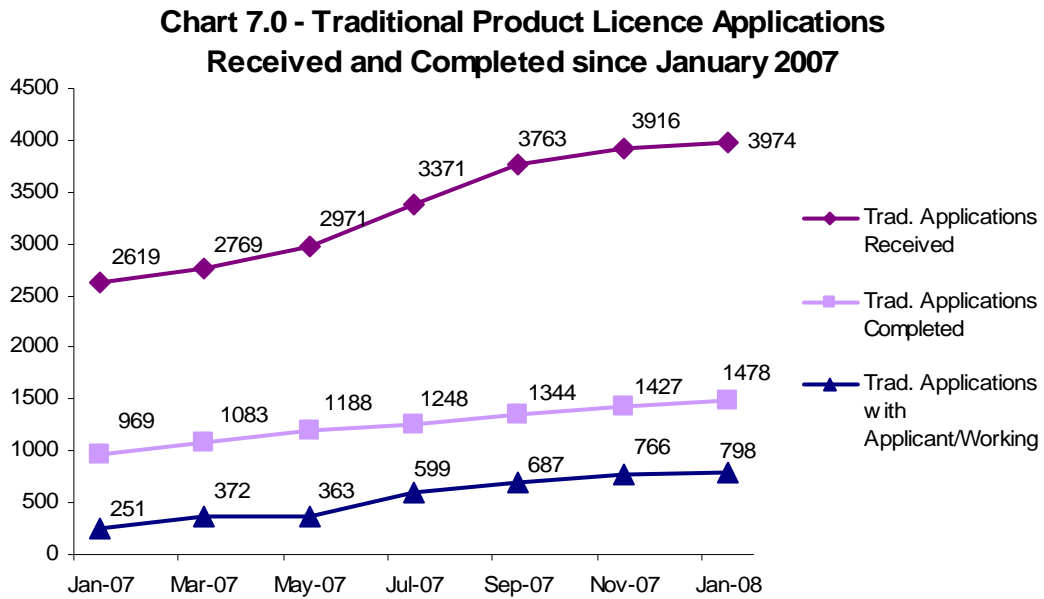
**Chart 6.0 – TPD Category IV / Labelling Standard Product Licence Applications Received and Completed since January 2007.**



**Table 6.1 – Breakdown Within Each Level of TPD Category IV / Labelling Standard Product Licence Applications Currently Being Worked On**

|                     | Level 1   | Level 2  | Level 3   |
|---------------------|-----------|----------|-----------|
| In Queue            | 0         | 0        | 285       |
| <b>Working</b>      | <b>21</b> | <b>0</b> | <b>15</b> |
| <b>With Sponsor</b> | <b>0</b>  | <b>0</b> | <b>4</b>  |
| Halted              | 0         | 0        | 0         |
| PC Pending          | 0         | 0        | 0         |

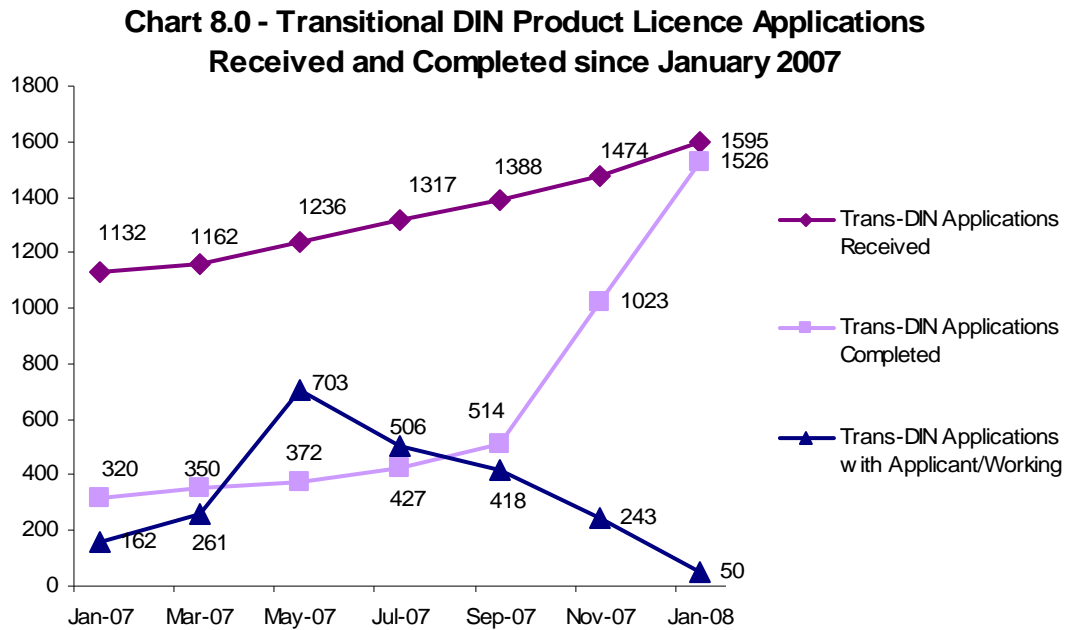
**Chart 7.0 – Traditional Product Licence Applications Received and Completed since January 2007.**



**Table 7.1 – Breakdown Within Each Level of Traditional Product Licence Applications Currently Being Worked On**

|                     | Level 1    | Level 2  | Level 3    |
|---------------------|------------|----------|------------|
| In Queue            | 0          | 0        | 1696       |
| <b>Working</b>      | <b>313</b> | <b>1</b> | <b>344</b> |
| <b>With Sponsor</b> | <b>5</b>   | <b>0</b> | <b>135</b> |
| Halted              | 0          | 0        | 0          |
| PC Pending          | 2          | 0        | 0          |

**Chart 8.0 – Transitional DIN Product Licence Applications Received and Completed since January 2007.**



**Table 8.1 – Breakdown Within Each Level of Transitional DIN Product Licence Applications Currently Being Worked On**

|                     | Level 1   | Level 2   | Level 3  |
|---------------------|-----------|-----------|----------|
| In Queue            | 0         | 0         | 16       |
| <b>Working</b>      | <b>27</b> | <b>2</b>  | <b>5</b> |
| <b>With Sponsor</b> | <b>0</b>  | <b>13</b> | <b>3</b> |
| Halted              | 0         | 0         | 0        |
| PC Pending          | 0         | 0         | 0        |

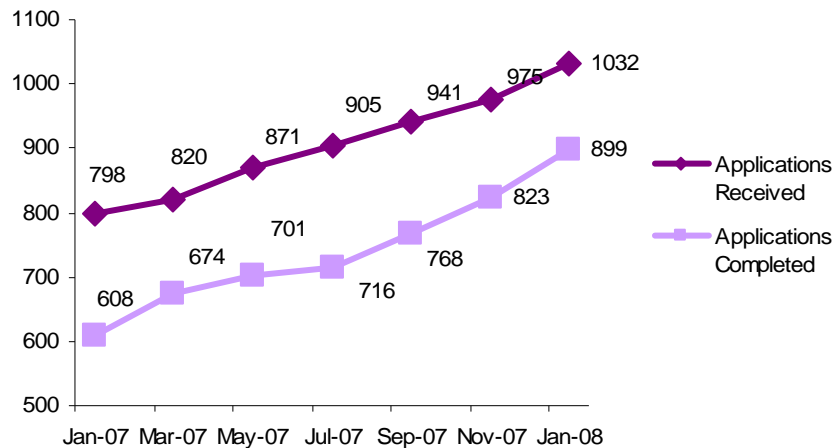
## SITE LICENSING STATISTICS

*Note – Statistics for this report were generated on January 4, 2008*

**Chart 9.0 - Site Licence Applications Received and Completed since January 2007.**

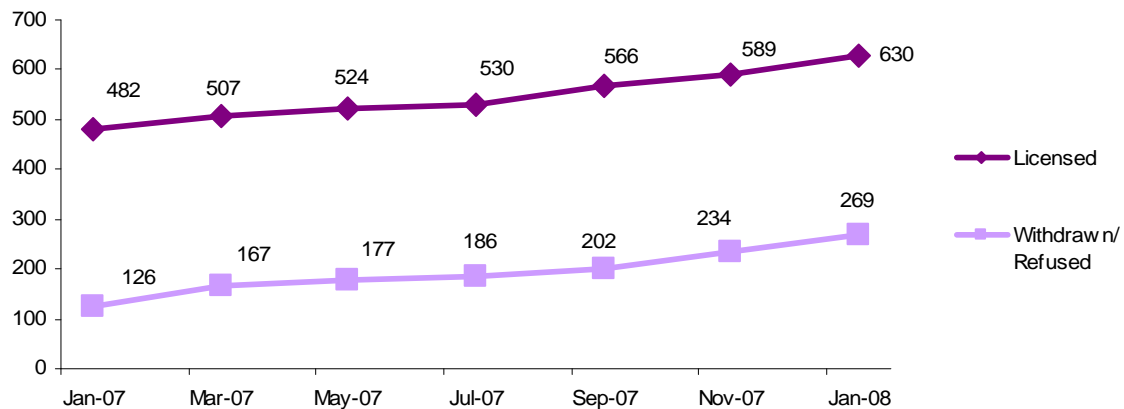
NOTE – “completed” includes the number of licences issued as well as those that were refused by the NHPD and those withdrawn by the applicant.

**Chart 9.0 - Site Licence Applications Received and Completed Since January 2007**

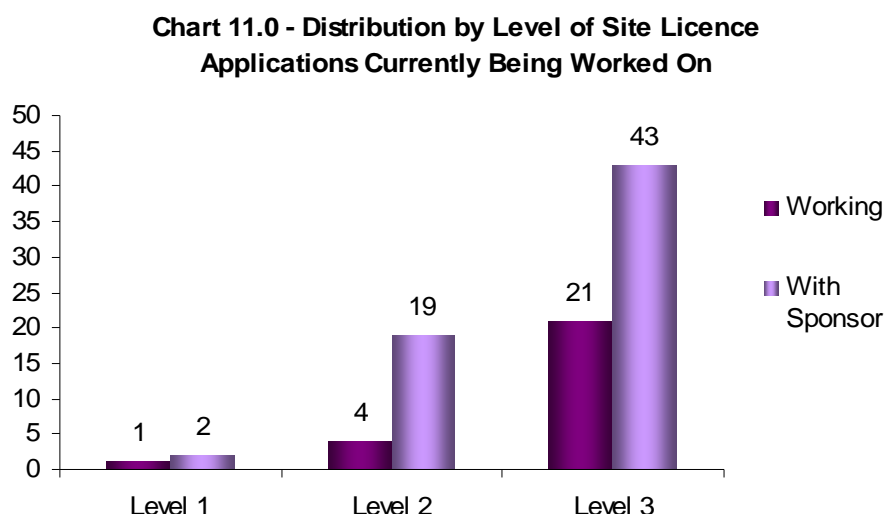


**Chart 10.0 - Site Licence Applications Completed (i.e. Licensed and Withdrawn/Refused) since January 2007.**

**Chart 10.0 - Site Licence Applications Completed (i.e. Licensed and Withdrawn/Refused) since January 2007**



**Chart 11.0 - Distribution by Level of Site Licence Applications Currently Being Worked On.**



**Table 11.1 – Breakdown Within Each Level of Site Licence Applications Currently Being Worked On**

|                     | Level 1  | Level 2   | Level 3   |
|---------------------|----------|-----------|-----------|
| In Queue            | 1        | 13        | 21        |
| <b>Working</b>      | <b>1</b> | <b>4</b>  | <b>22</b> |
| <b>With Sponsor</b> | <b>2</b> | <b>19</b> | <b>43</b> |

## AMENDMENTS, NOTIFICATIONS, and RENEWALS STATISTICS

*Note – Statistics for this report were generated on January 4, 2008*

**Amendments and Notifications:** Holders of product and/or site licences are required to notify the NHPD of any changes they make to their product or site licence. Depending on the change, the holder must either submit an amendment or a notification.

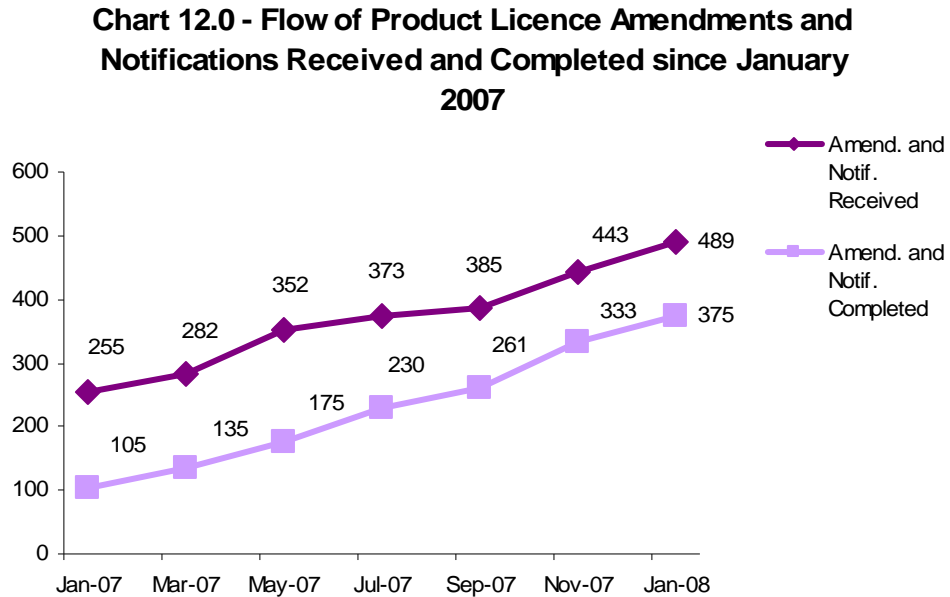
**Renewals:** Holders of site licences are required to renew their licences in accordance with a specific renewal schedule.

Further information on amendments, notifications and renewals is available at the following guidance documents:

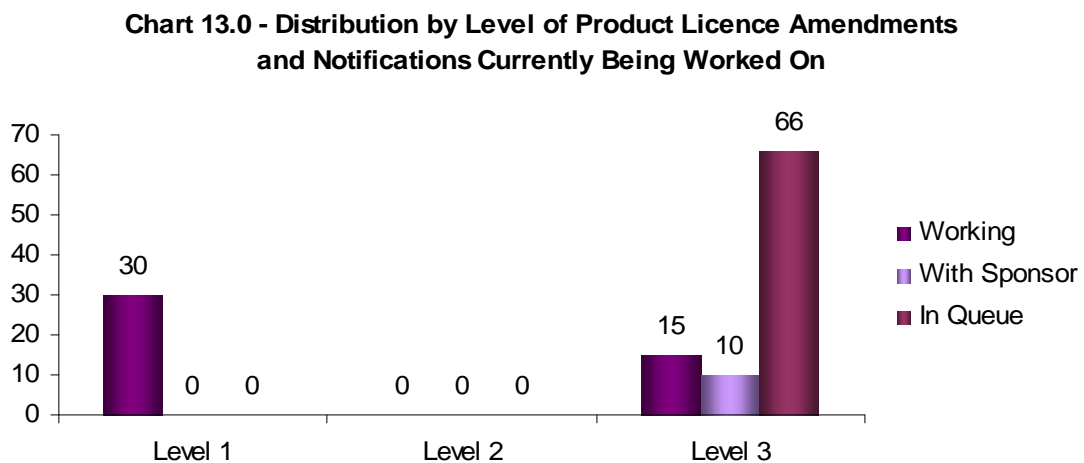
- Amendments and Notifications for Product Licences: Refer to the Guide for Completing the Product Licence Application Form, which is included at the end of the PLA-FORM.

- Amendments, Notifications and Renewals for Site Licences: Refer to Chapter 5 “Obligations of Licencees” of the *Site Licensing Guidance Document*.

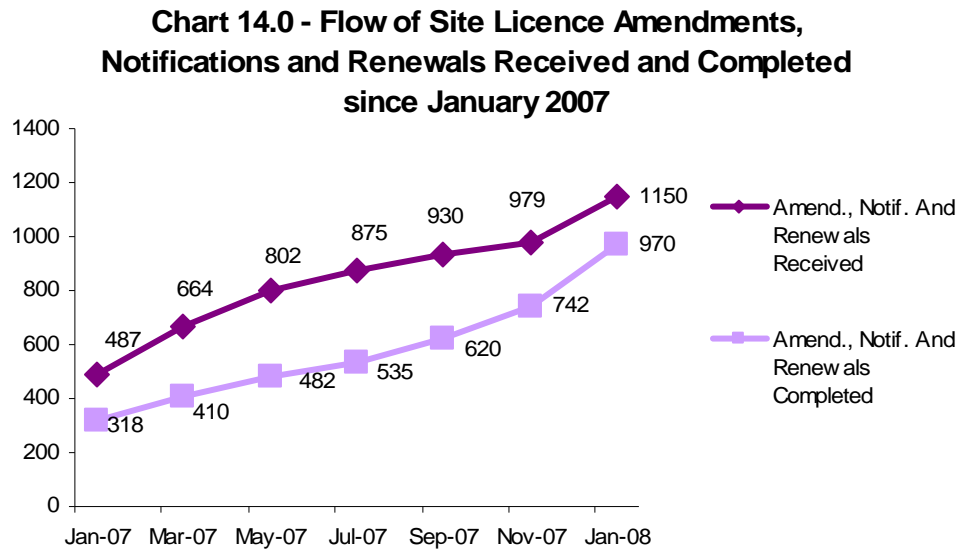
**Chart 12.0 - Flow of Product Licence Amendments and Notifications Received and Completed since January 2007.**



**Chart 13.0 - Distribution by Level of Product Licence Amendments and Notifications Currently Being Worked On.**



**Chart 14.0 - Flow of Site Licence Amendments, Notifications and Renewals Received and Completed since January 2007.**



**Chart 15.0 - Distribution by Level of Site Licence Amendments, Notifications and Renewals Currently Being Worked On.**

