

NHPD Status of Submissions Report

September 2007

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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.

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Withdrawn	File removed from the submission review process by the applicant

PRODUCT LICENSING STATISTICS

Note – Statistics for this report were generated on September 11, 2007

Chart 1.0 - Product Licence Applications Received and Completed since September 2006.

NOTE – “completed” includes the number of licences issued as well as those that were refused by the NHPD and those withdrawn by the applicant.

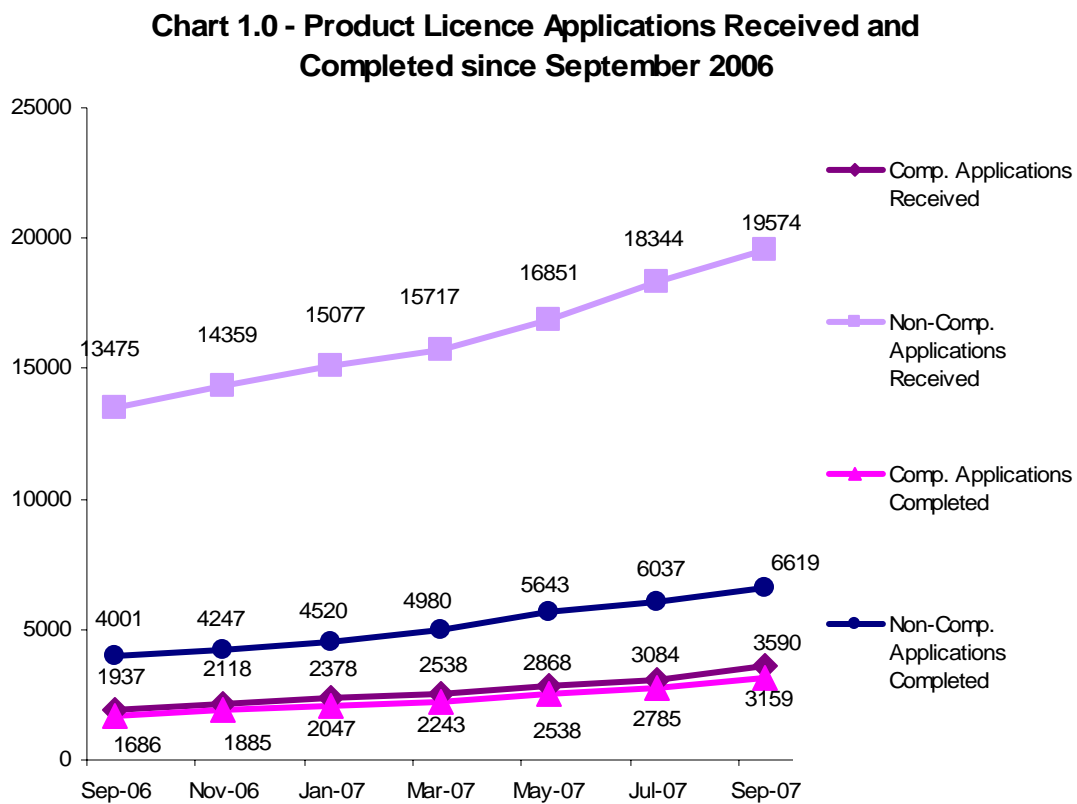


Chart 2.0 - Product Licence Applications Completed (i.e. Licensed and Withdrawn/Refused) since September 2006.

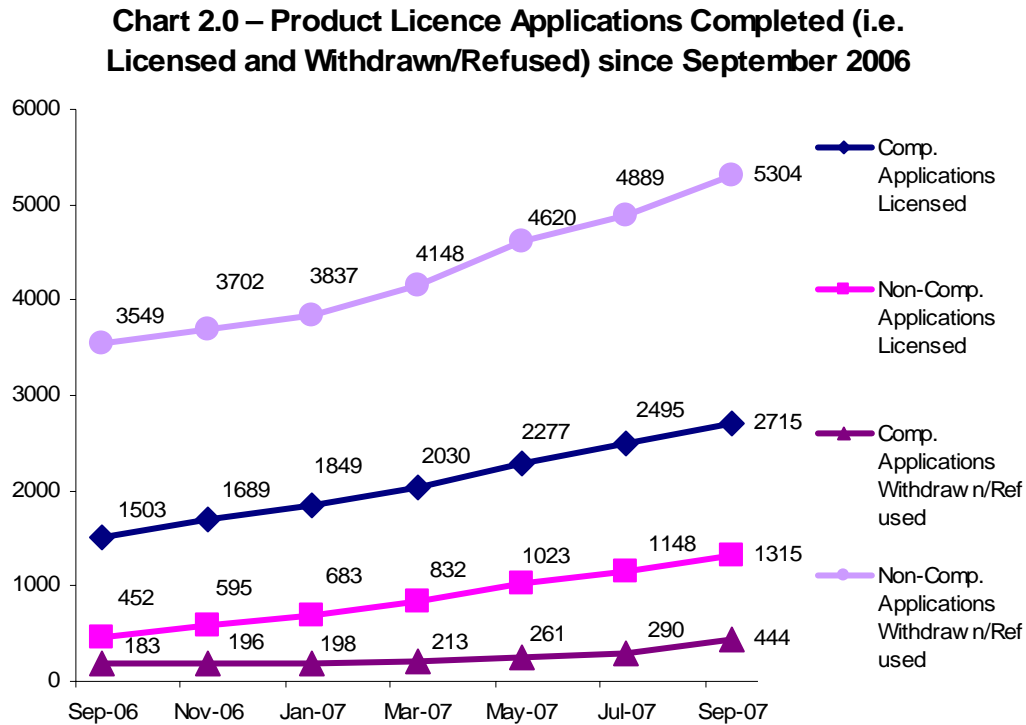


Chart 3.0 - Distribution by Level of Compendial Product Licence Applications Currently Being Worked On.

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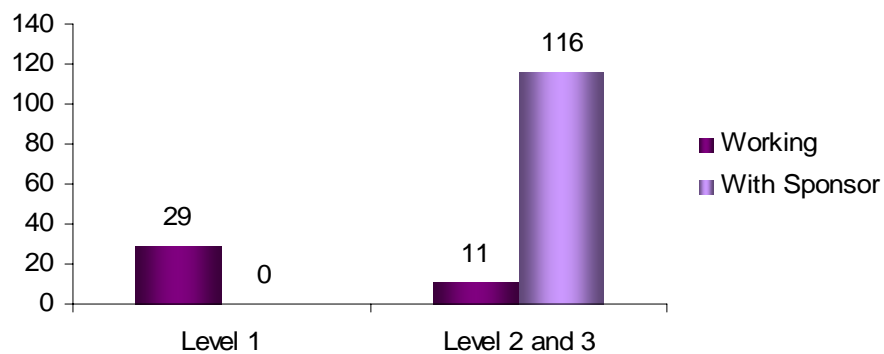


Table 3.1 – Breakdown Within Each Level of Compendial Product Licence Applications Currently Being Worked On		
	Level 1	Levels 2 and 3
In Queue	0	174
Working	29	111
With Sponsor	0	116
Halted	0	0
PC Pending	1	0

Chart 4.0 – Homeopathic Medicine (HM) Product Licence Applications Received and Completed since September 2006.

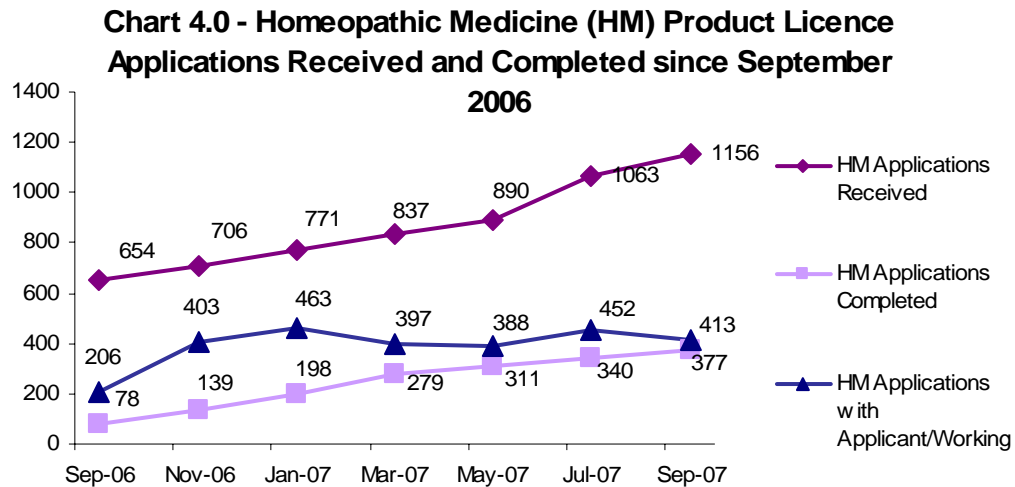


Table 4.1 – Breakdown Within Each Level of Homeopathic Medicine (HM) Product Licence Applications Currently Being Worked On			
	Level 1	Level 2	Level 3
In Queue	0	0	366
Working	84	1	293
With Sponsor	0	0	35
Halted	0	0	0
PC Pending	0	0	0

Chart 5.0 – Non-Traditional Product Licence Applications Received and Completed since September 2006.

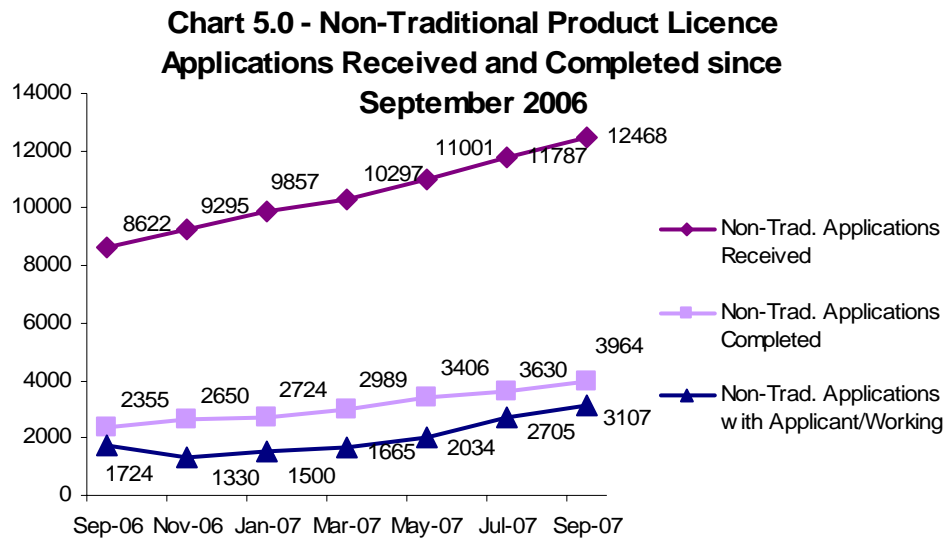
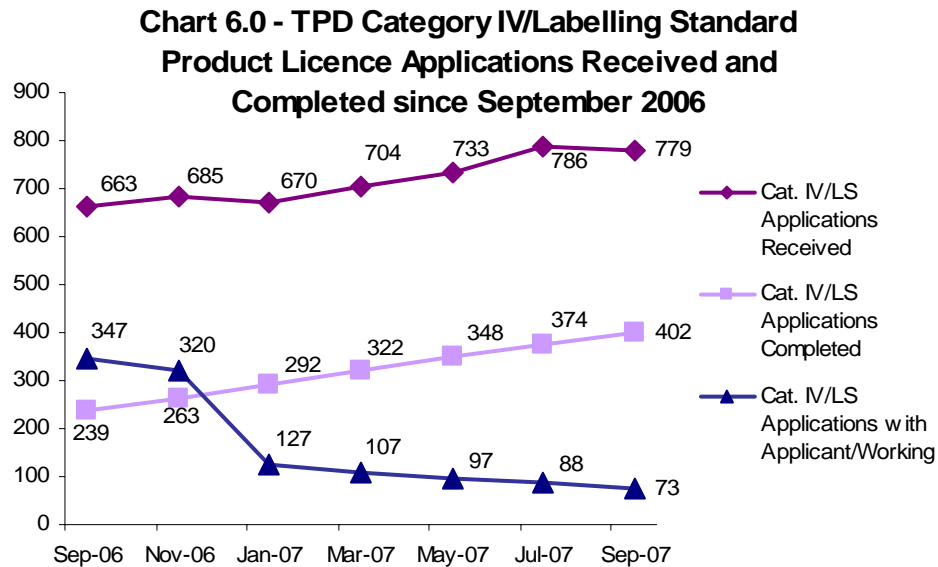


Table 5.1 – Breakdown Within Each Level of Non-Traditional Product Licence Applications Currently Being Worked On

	Level 1	Level 2	Level 3
In Queue	0	0	5370
Working	546	36	1701
With Sponsor	22	41	761
Halted	0	0	0
PC Pending	23	0	0

Chart 6.0 – TPD Category IV / Labelling Standard Product Licence Applications Received and Completed since September 2006.



**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	300
Working	8	1	41
With Sponsor	0	1	22
Halted	0	0	0
PC Pending	4	0	0

Chart 7.0 – Traditional Product Licence Applications Received and Completed since September 2006.

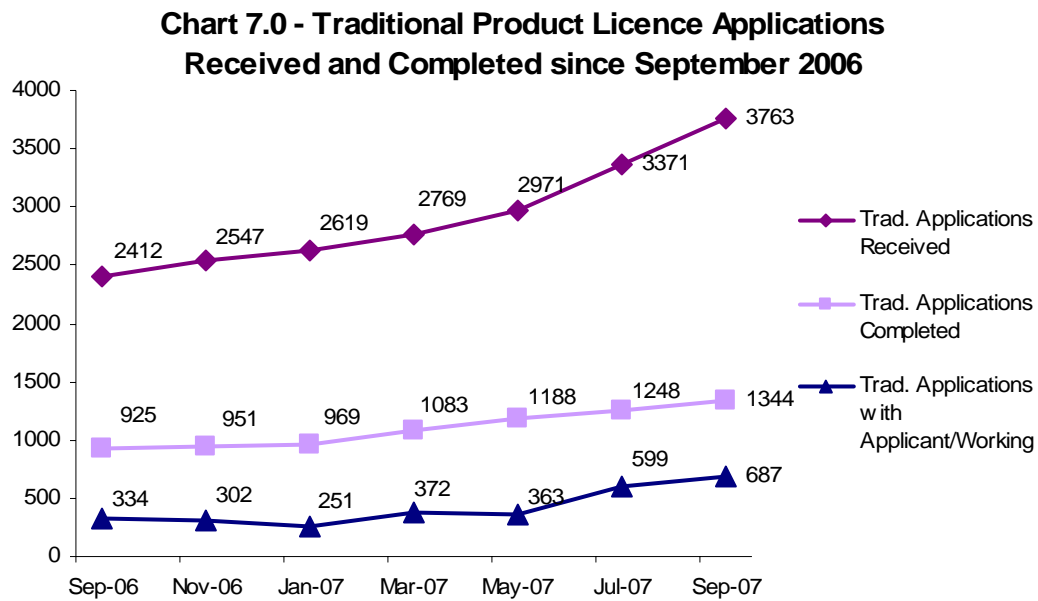


Table 7.1 – Breakdown Within Each Level of Traditional Product Licence Applications Currently Being Worked On

	Level 1	Level 2	Level 3
In Queue	0	0	1725
Working	249	37	237
With Sponsor	19	2	143
Halted	0	0	0
PC Pending	5	0	0

Chart 8.0 – Transitional DIN Product Licence Applications Received and Completed since September 2006.

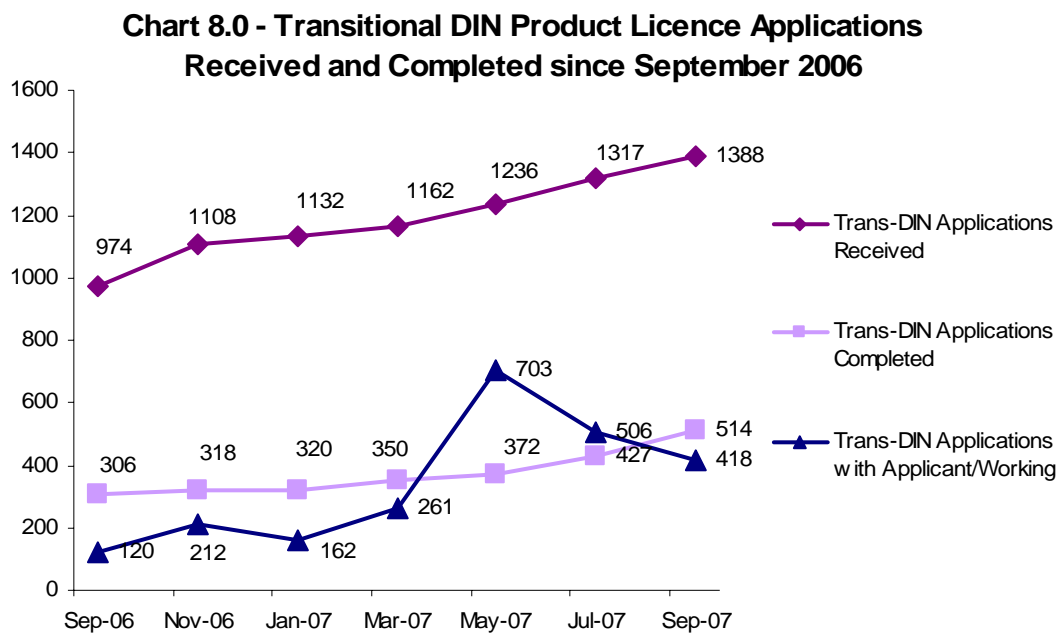


Table 8.1 – Breakdown Within Each Level of Transitional DIN Product Licence Applications Currently Being Worked On

	Level 1	Level 2	Level 3
In Queue	0	0	455
Working	23	145	171
With Sponsor	0	37	42
Halted	0	0	0
PC Pending	1	0	0

SITE LICENSING STATISTICS

Note – Statistics for this report were generated on September 11, 2007

Chart 9.0 - Site Licence Applications Received and Completed since September 2006.

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

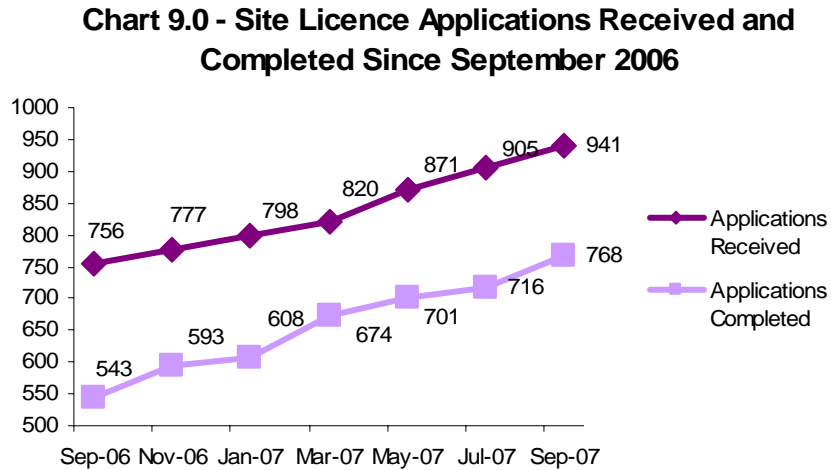


Chart 10.0 - Site Licence Applications Completed (i.e. Licensed and Withdrawn/Refused) since September 2006.

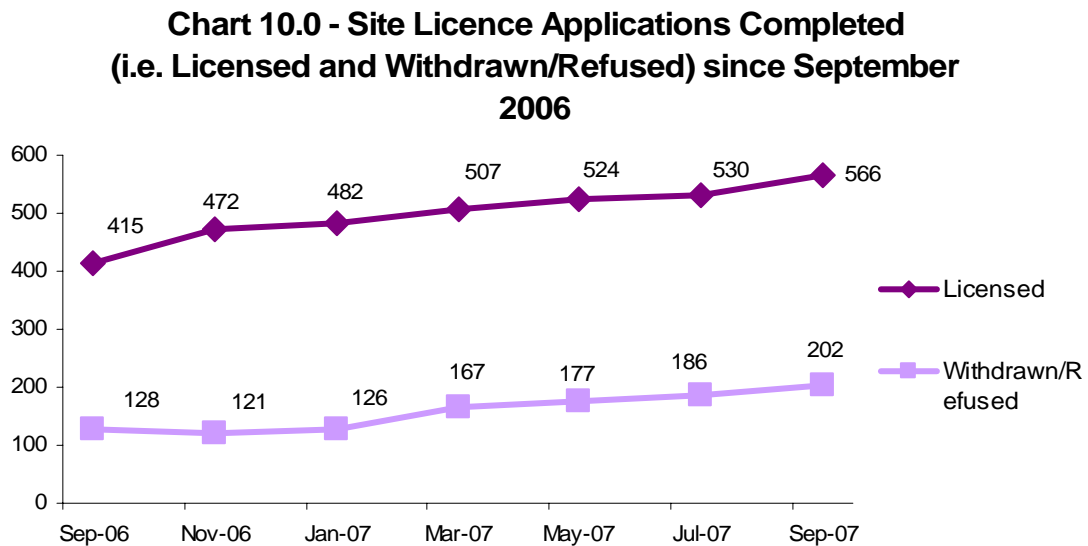


Chart 11.0 - Distribution by Level of Site Licence Applications Currently Being Worked On.

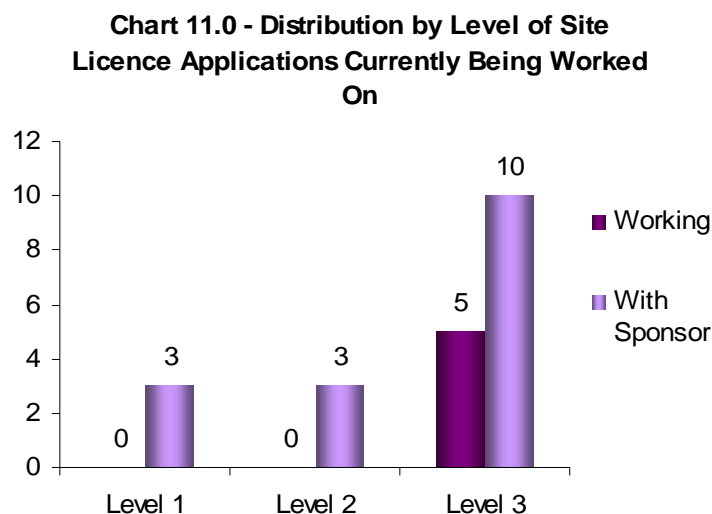


Table 11.1 – Breakdown Within Each Level of Site Licence Applications Currently Being Worked On

	Level 1	Level 2	Level 3
In Queue	2	2	1
Working	1	1	2
With Sponsor	5	11	2

AMMENDMENTS, NOTIFICATIONS, and RENEWALS STATISTICS

Note – Statistics for this report were generated on September 11, 2007

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 September 2006.

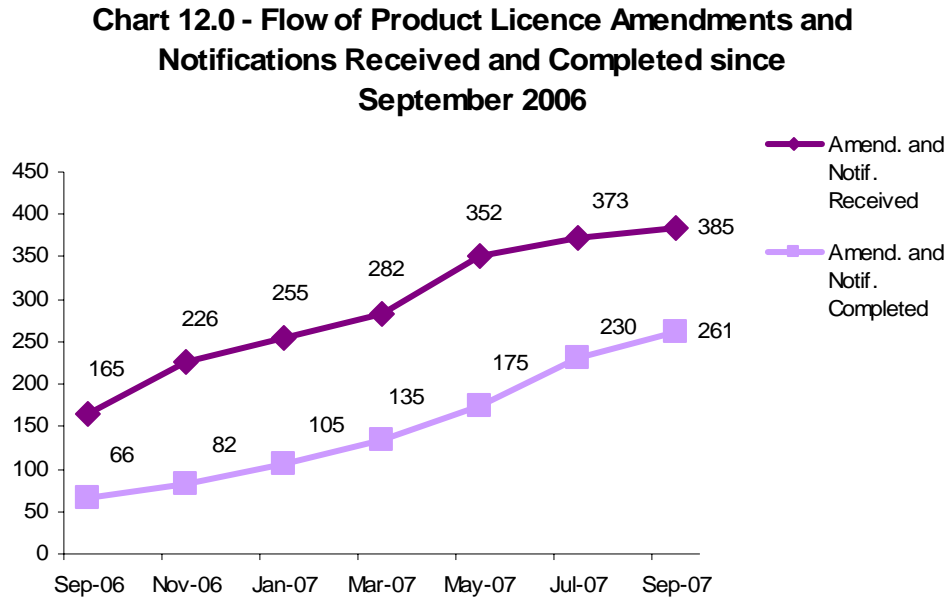


Chart 13.0 - Distribution by Level of Product Licence Amendments and Notifications Currently Being Worked On.

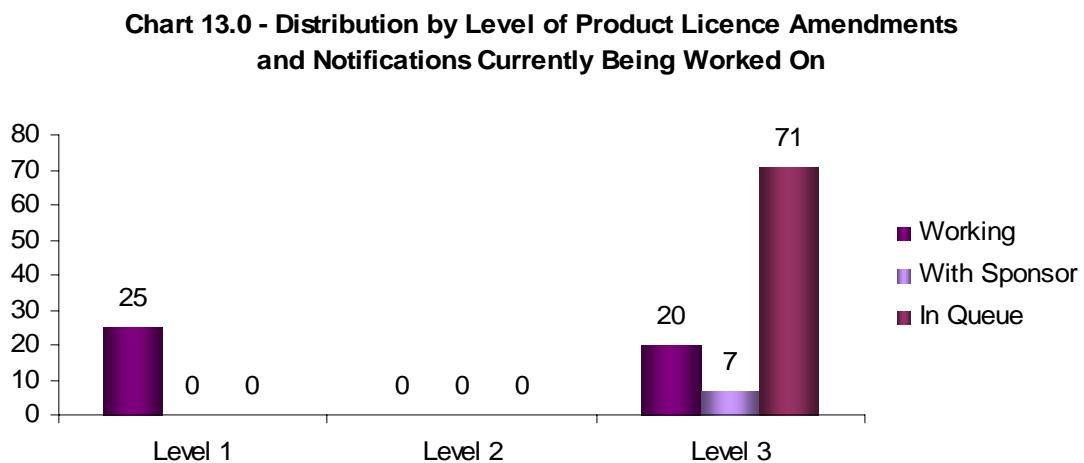


Chart 14.0 - Flow of Site Licence Amendments, Notifications and Renewals Received and Completed since September 2006.

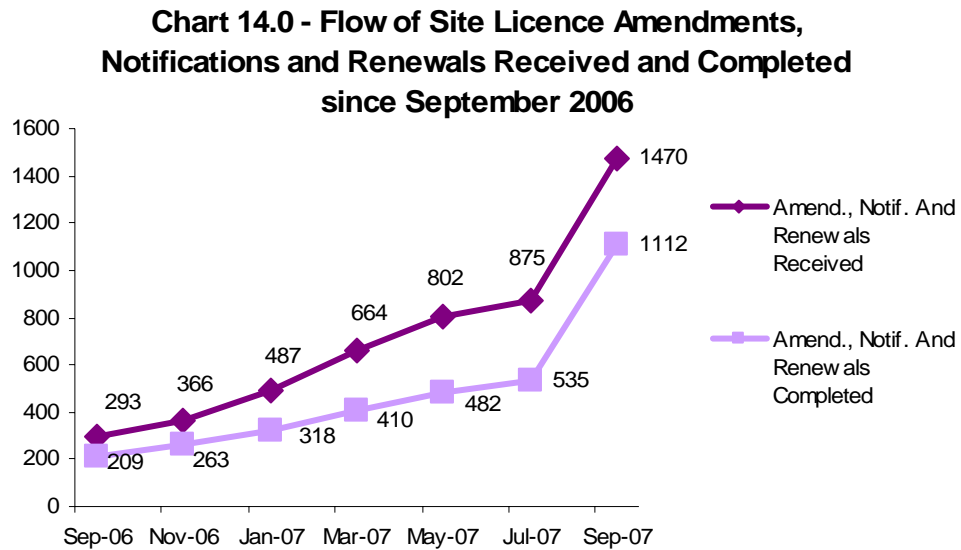


Chart 15.0 - Distribution by Level of Site Licence Amendments, Notifications and Renewals Currently Being Worked On.

