

# NHPD Status of Submissions Report

**July 2007** 

# **NHPD Status of Submissions Report**

# July 2007

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.

### TABLE OF CONTENT:

GLOSSA	RY OF TERMS4
PRODU	CT LICENSING STATISTICS5
•	Chart 1.0 - Product Licence Applications Received and Completed
	since September 2006
•	Chart 2.0 - Product Licence Applications Completed (i.e. Licensed and
	Withdrawn/Refused) since September 2006 6
•	Chart 3.0 - Distribution by Level of Compendial Product Licence
	Applications Currently Being Worked On
•	Table 3.1 - Breakdown Within Each Level of Compendial Product
	Licence Applications Currently Being Worked On
•	Chart 4.0 - Homeopathic Medicine (HM) Product Licence Applications
	Received and Completed since September 2006 8
•	Chart 5.0 - Non-Traditional Product Licence Applications Received and
	Completed since September 2006

	•	Chart 6.0 - TPD Category IV / Labelling Standard Product Licence
		Applications Received and Completed since September 2006 10
	•	Chart 7.0 - Traditional Product Licence Applications Received and
		Completed since September 2006
	•	Chart 8.0 - Transitional DIN Product Licence Applications Received and
		Completed since September 2006
SITE I	LIC	ENSING STATISTICS13
	•	Chart 9.0 - Site Licence Applications Received and Completed since
		September 2006
	•	Chart 10.0 - Site Licence Applications Completed (i.e. Licensed and
		Withdrawn/Refused) since September 200613
	•	Chart 11.0 - Distribution by Level of Site Licence Applications
		Currently Being Worked On14
AMME	ENI	DMENTS, NOTIFICATIONS, and RENEWALS STATISTICS 14
	•	Chart 12.0 - Flow of Product Licence Amendments and Notifications
		Received and Completed since September 200615
	•	Chart 13.0 - Distribution by Level of Product Licence Amendments and
		Notifications Currently Being Worked On15
	•	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 On16

# **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 July 6, 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.

Comp. Applications Received Non-Comp. **Applications** Received Comp. Applications Completed Non-Comp. Applications Completed Sep-06 Nov-06 Jan-07 Mar-07 May-07 Jul-07

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

Chart 2.0 - Product Licence Applications Completed (i.e. Licensed and Withdrawn/Refused) since September 2006.

Chart 2.0 – Product Licence Applications Completed (i.e. Licensed and Withdrawn/Refused) since September 2006

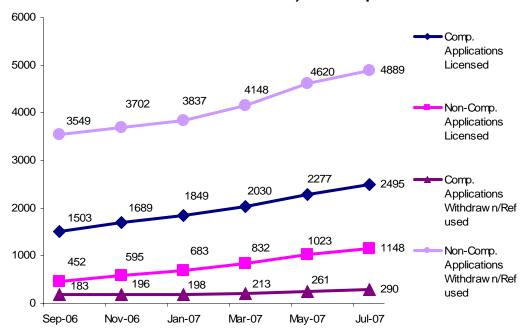


Chart 3.0 - Distribution by Level of Compendial Product Licence Applications Currently Being Worked On.

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

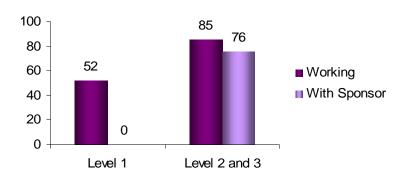


Table 3.1 - Breakdown Within Each Level of
Compendial Product Licence Applications Currently
Being Worked On

Level 1 Levels 2 and 3
In Queue 0 80

	LCAC! !	Levels 2 and 3
In Queue	0	80
Working	52	85
With Sponsor	0	76
Halted	35	0
PC Pending	1	0

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

Chart 4.0 - Homeopathic Medicine (HM) Product Licence Applications Received and Completed since September

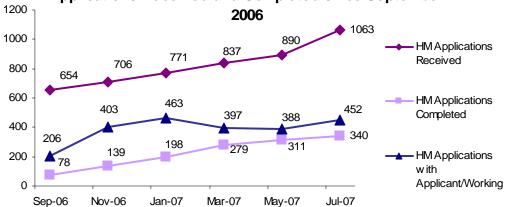


Table 4.1 - Breakdown Within Each Level of Homeopathic Medicine (HM) Product Licence Applications Currently Being Worked On

	Level 1	Level 2	Level 3
In Queue	0	12	259
Working	3	94	319
With Sponsor	0	0	36
Halted	0	0	0
PC Pending	0	0	0

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

**Chart 5.0 - Non-Traditional Product Licence Applications Received and Completed since** September 2006 11001 11787 Non-Trad. Applications Received Non-Trad. Applications Completed Non-Trad. Applications with Applicant/Working Sep-06 Nov-06 Jan-07 Mar-07 May-07

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	95	5325	
Working	79	433	1494	
With Sponsor	1	33	666	
Halted	0	0	0	
PC Pending 25 0 0				

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

Chart 6.0 - TPD Category IV/Labelling Standard **Product Licence Applications Received and** 900 Completed since September 2006 800 704 733 685 663 670 700 Cat. IV/LS Applications 600 Received 500 Cat. IV/LS Applications 400 347 348 374 320 322 Completed 292 300 239 Cat. IV/LS Applications with 200 263 127 107 Applicant/Working 97 100 88 0 Sep-06 Nov-06 Jan-07 Mar-07 May-07 Jul-07

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	323		
Working	6	2	67		
With Sponsor	0	1	12		
Halted	0	0	0		
PC Pending 0 0					

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

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

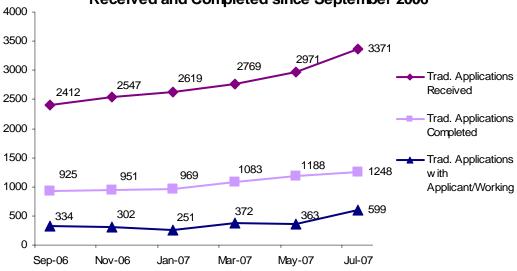


Table 7.1 - Breakdown Within Each Level of Traditional Product Licence Applications Currently Being Worked On					
Level 1 Level 2 Level 3					
In Queue	0	9	1511		
Working	20	256	235		
With Sponsor	0	6	82		
Halted	0	0	0		
PC Pending	3	0	0		

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

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

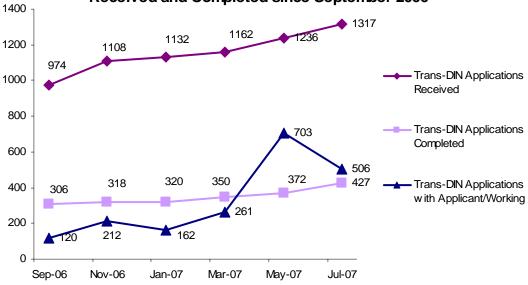


Table 8.1 - Breakdown Within Each Level of Transitional DIN Product Licence Applications Currently Being Worked On

	Level 1	Level 2	Level 3
In Queue	0	1	381
Working	15	270	70
With Sponsor	0	141	10
Halted	0	0	0
PC Pending	2	0	0

### SITE LICENSING STATISTICS

Note - Statistics for this report were generated on July 6, 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 9.0 - Site Licence Applications Received and Completed Since September 2006

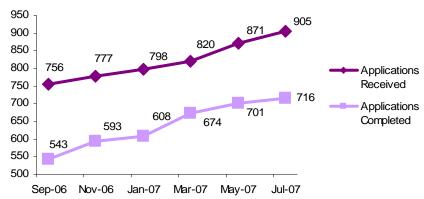


Chart 10.0 - Site Licence Applications Completed (i.e. Licensed and Withdrawn/Refused) since September 2006.

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.

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

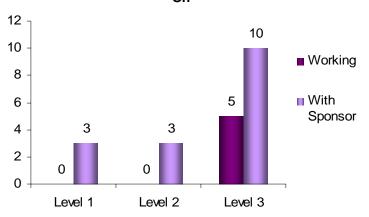


Table 11.1 - Breakdown Within Each Level of Site Licence Applications Currently Being Worked On					
Level 1 Level 2 Level 3					
In Queue	0	3	3		
Working	0	3	1		
With Sponsor	5	10	3		

## AMMENDMENTS, NOTIFICATIONS, and RENEWALS STATISTICS

Note - Statistics for this report were generated on July 6, 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 From, 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 12.0 - Flow of Product Licence Amendments and Notifications Received and Completed since September 2006

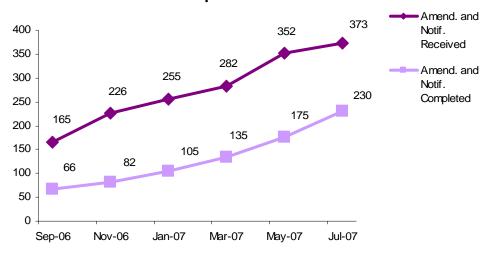


Chart 13.0 - Distribution by Level of Product Licence Amendments and Notifications Currently Being Worked On.

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

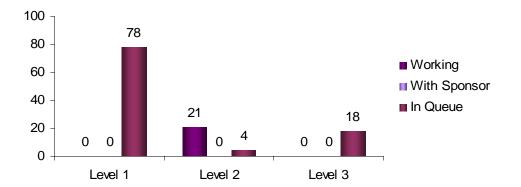


Chart 14.0 - Flow of Site Licence Amendments, Notifications and Renewals Received and Completed since September 2006.

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

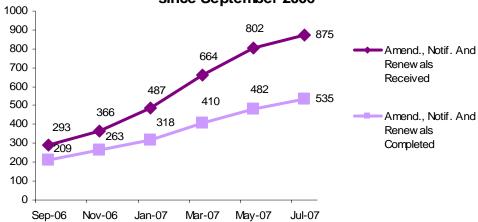


Chart 15.0 - Distribution by Level of Site Licence Amendments, Notifications and Renewals Currently Being Worked On.

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

