

Status of Applications Quarterly Report

Quarter 1

(April 1, 2010 to June 30, 2010)

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**Natural Health Products Directorate
Health Canada**

The *Status of Applications Quarterly 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. The purpose of this report is to provide the Canadian public with statistical data on the product and site licence applications received and processed by the NHPD.

Reporting Schedule*:

- 1st Quarter: April 1 to June 30
- 2nd Quarter: July 1 to September 30
- 3rd Quarter: October 1 to December 31
- 4th Quarter: January 1 to March 31

*Based on fiscal year, not calendar year.

Questions, comments or feedback regarding the content of the *Status of Applications Quarterly Report* may be addressed to **PLA.info.DLMM@hc-sc.gc.ca**.

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Performance Summary and Highlights

Since the implementation of the *Natural Health Products Regulations* in January 2004 until the end of June 2010, Health Canada has received 52,363 Product Licence Applications (PLAs). Of this total, **41,412 (79%) PLAs have been completed, including the issuance of 22,820 Product Licences representing 29,758 products.** The remaining completed applications were either refused by NHPD or withdrawn by the applicant. In total, 1206 companies have received a product licence to date.

Highlights

22,820

NHPs licensed
since 2004

41,412

PLAs completed
since 2004

To date, 84% of applications in “backlog” and 70% of “regular workload” applications have been completed or are in the process of being completed. In addition, 99% of “backlog” applications and 79% of “regular workload” applications have been addressed (see Appendix A for definitions).

Quarter 1 (April 1, 2010 to June 30, 2010)

During this quarter, a total of 3,661 PLAs were completed, 73.0% (2,671) of these completions resulted in product licences, 21.8% (760) were refusals and the remaining 6.3% (230) of completions were as a result of the applicant withdrawing the application.

Of the 760 applications refused this quarter, the reasons were as follows:

- 55% failed to meet basic application requirements.
- 28% were refused when applicants did not respond to a request for further information.
- 12% were refused when the applicant's response to a request for further information did not meet the requirements.
- 4% were refused when quality, safety and/or efficacy issues were identified.
- 1% did not meet the definition of a NHP.
- <1% were refused as a result of significant changes having been made to the product itself in response to a request for further information (i.e. an "unsolicited change").

Highlights

2,671

NHPs licensed
during Quarter 1

760

PLAs refused
during Quarter 1

230

PLAs withdrawn
during Quarter 1

Quarter 1 Statistics (April 1, 2010 to June 30, 2010)

Chart 1 – Total Number of Product Licence Applications (PLAs) Received and Completed during Quarter 1

Note – “Completed” includes all applications that were licensed, refused or withdrawn by the applicant.

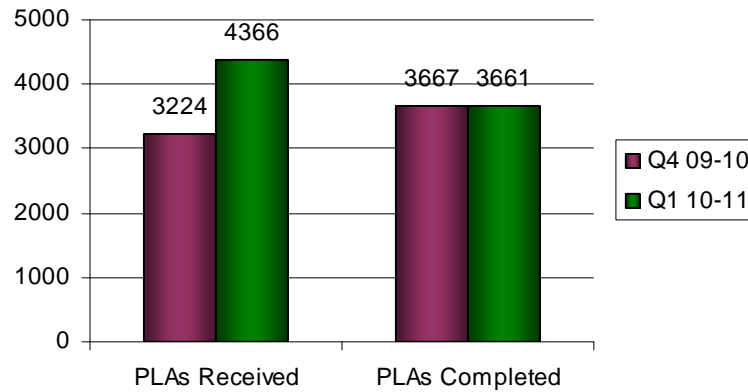


Chart 2 – Total Number of Product Licence Applications (PLAs) Completed during Quarter 1 (Licensed, Refused or Withdrawn)

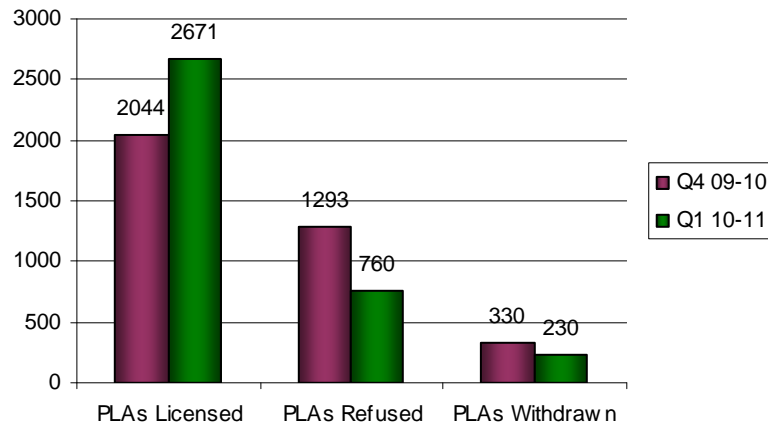


Chart 3 – Total Number of Product Licence Applications (PLAs) Completed during Quarter 1 (by Year of Application)

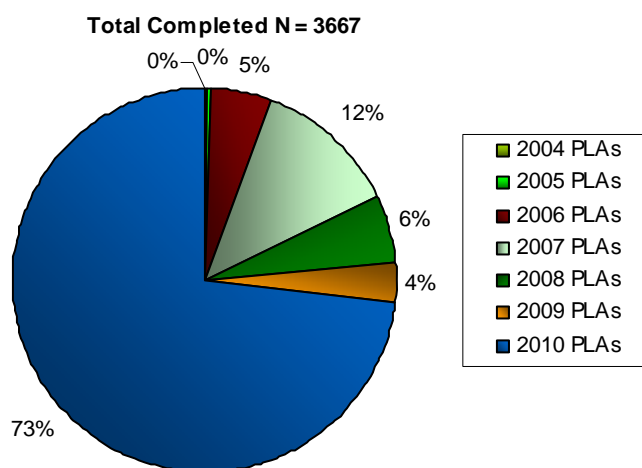
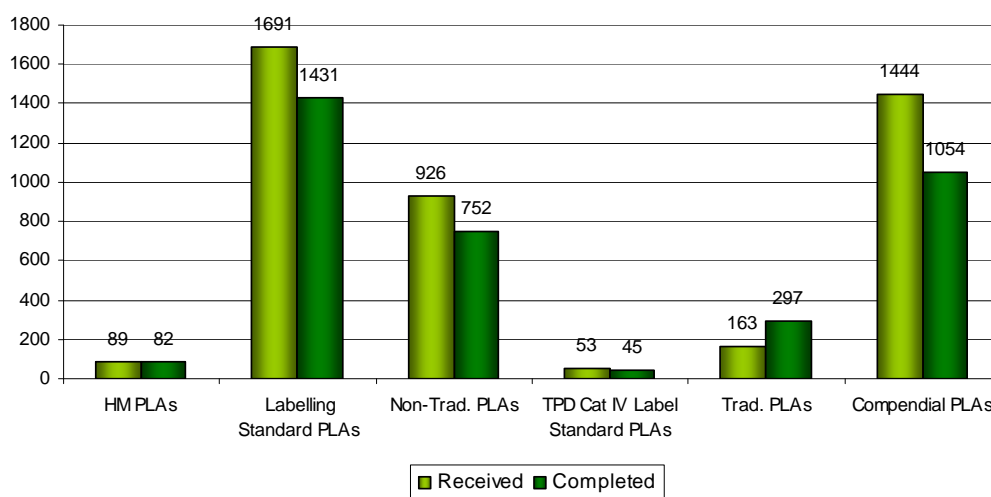


Chart 4 – Total Number of Product Licence Applications (PLAs) - by application type - Received and Completed during Quarter 1

Note – “Completed” includes all applications that were licensed, refused or withdrawn by the applicant.



* See Appendix A for definitions of acronyms found in Chart 4.

Chart 5 – Total Number of Product Licence (PL) Amendments Received and Completed during Quarter 1

Note – “Completed” includes all applications that were licensed, refused or withdrawn by the applicant.

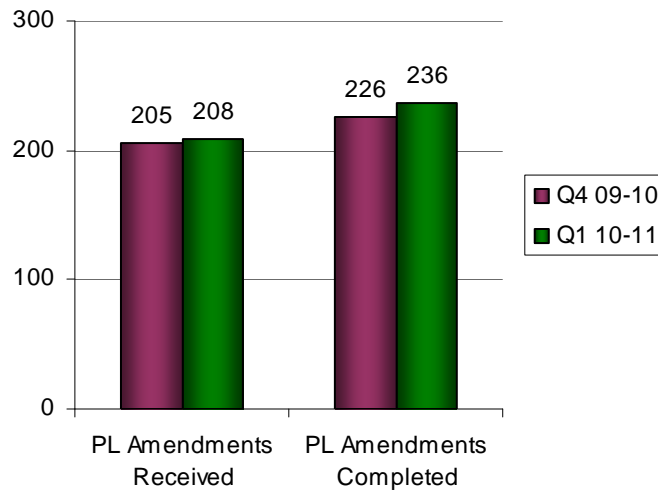


Chart 6 – Total Number of Product Licence (PL) Notifications Received and Completed during Quarter 1

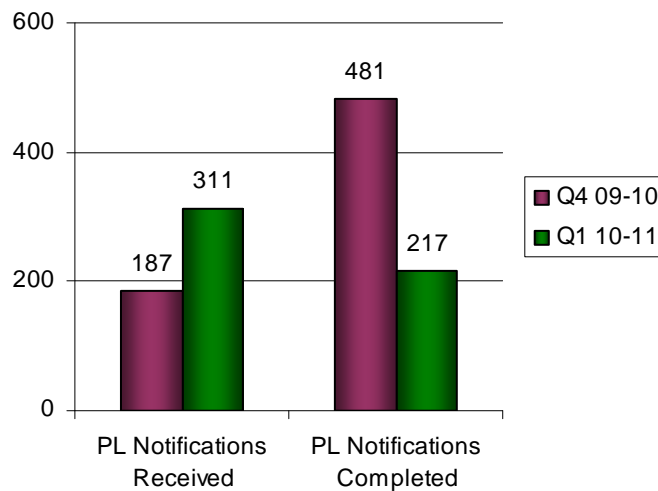


Chart 7 – Total Number of Site Licence Applications (SLAs) Received and Completed during Quarter 1

Note – “Completed” includes all applications that were licensed, refused or withdrawn by the applicant.

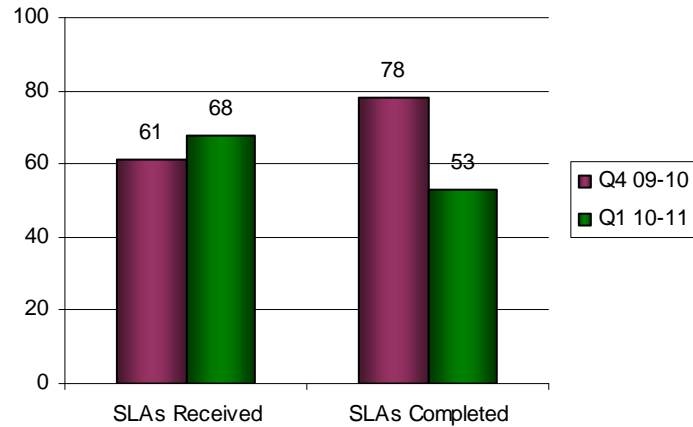
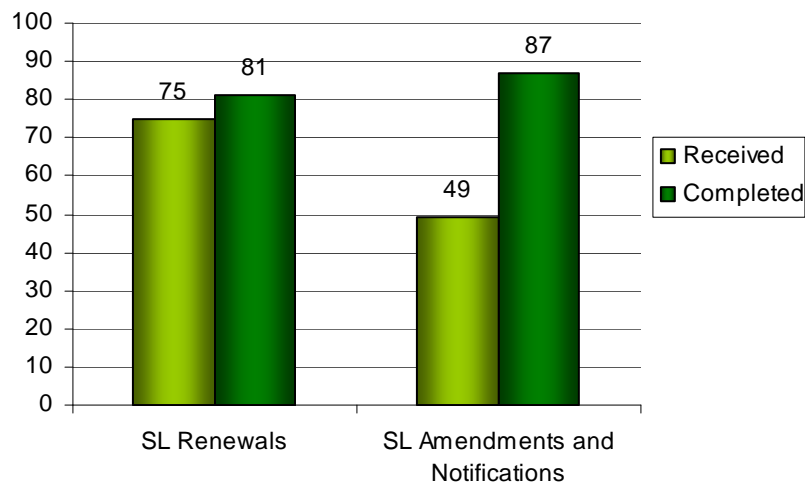


Chart 8 – Total Number of Site Licence (SL) Amendments, Notifications and Renewals Received and Completed during Quarter 1

Note – “Completed” includes all applications that were licensed, refused or withdrawn by the applicant.



Update on the Product Licence Application Backlog and Regular Workload

As defined by the NHPD, the “backlog” consists of the 12,976 PLAs received before April 1, 2008 which were incomplete as of that date (i.e. the PLA was not licensed, withdrawn or refused). All other PLAs received on or after April 1, 2008 are considered regular workload and are not part of the PLA backlog the NHPD had committed itself to addressing by March 31, 2010. For the purposes of reporting, these are called “regular workload” PLAs. At this point, 99% of all backlog applications have been addressed – most of the remaining 1% are halted pending resolution of issues surrounding safety and efficacy.

As a result of the implementation of the Non-Traditional & Traditional Process Improvement Projects and other improvement initiatives, the number of incomplete “backlog” PLAs now equals 2,185 PLAs, signalling a reduction of 84% from the original 12,976 PLAs.

Highlights

84%

reduction of the backlog

99%

of backlog PLAs have been addressed

Table 1: Total “Backlog” PLAs as of June 30, 2010

Table 1 provides figures on the current status of the PLA “backlog”. Please note these numbers do not include amendments or notifications; however all backlog notifications and amendments are complete.

Status	Number	% of Total (12,976)
Licensed	3560	
In Licensing – administrative processing required	91	
Refused	4161	
To Be Refused – administrative processing required	61	
Withdrawn by applicant	2978	
Addressed PLAs - Completed	10851	83.6%
Has received one or more Information Request Notice (IRN) or E-IRN	1110	
Halted pending internal decision related to safety or efficacy	852	
Addressed PLAs – Received one or more IRN or E-IRN	1962	15.1%
Require Initial Assessment to determine if file requires E-IRN	0	
To receive E-IRN	0	
Awaiting or undergoing full review	3	
Halted pending internal decision related to safety or efficacy	154	
Miscellaneous Administrative Issues	6	
Non-Addressed PLAs	163	1.3%

Table 2: Total “Regular Workload” PLAs as of June 30, 2010

Table 2 provides figures on the current status of all PLAs which were received on or after April 1, 2008 and are therefore not considered “backlog”. Please note these numbers do not include amendments or notifications.

Status	Number	% of Total (26,106)
Licensed	13068	
In Licensing – administrative processing required	823	
Refused	3711	
To Be Refused – administrative processing required	129	
Withdrawn by applicant	649	
Addressed PLAs – Completed	18380	70.4%
Has received one or more Information Request Notice (IRN) or E-IRN	2087	
Halted pending internal decision related to safety or efficacy	262	
Addressed PLAs – Received one or more IRN or E-IRN	2349	18.1%
Applications (all types) recently received at NHPD	776	
Require Initial Assessment to determine if file requires E-IRN	1292	
To receive E-IRN	69	
Awaiting or undergoing full review	1892	
Halted pending internal decision related to safety or efficacy	1305	
Miscellaneous Administrative Issues	43	
Non-Addressed PLAs	5377	20.6%

Update on Amendments and Notifications

Since January 2004, NHPD has received 1,852 notifications and 1,889 amendments. NHPD has completed 90% of notifications and 82% of amendments to date.

Of the amendments that have been completed, 91.2% resulted in a revised product licence, 3.1% resulted in a refusal and 5.7% were withdrawn by the licensee.

All backlog amendments have been completed. Table 3 provides figures on the current status of amendments which were received on or after April 1, 2008 and are therefore not considered "backlog".

Table 3: Total "Regular Workload" Amendments as of June 30, 2010

Status	Number	% of Total (1533)
Licensed	1095	
In Licensing – administrative processing required	41	
Refused	35	
To Be Refused – administrative processing required	3	
Withdrawn by applicant	59	
Addressed Amendments – Completed	1233	80%
Has received one or more Information Request Notice (IRN) or E-IRN	40	
Addressed Amendments – Received one or more E-IRN or IRN	40	3%
Applications recently received at NHPD (in processing)	144	
Awaiting or undergoing full review	81	
Miscellaneous Administrative Issues	35	
Non-Addressed Amendments	260	17%

Appendix A – Acronyms and Definitions

Abbreviated Labelling Standard (AbLS):	Document created by NHPD outlining information about the established safety and/or efficacy of a product or ingredient
Addressed:	When NHPD issues a Product Licence, Notice of Refusal, Information Request Notice or when the applicant withdraws their application, the application is considered to be "addressed".
Backlog:	All PLAs received before April 1, 2008 which were not complete as of that date
Compendial PLA:	Product Licence Application citing a monograph found in the NHPD's <i>Compendium of Monographs</i>
Completed:	When NHPD issues a Product Licence, Notice of Refusal or when the applicant withdraws their application, the application is considered to be "completed".
DIN:	Drug Identification Number
E-IRN:	Information Request Notice focusing on critical evidence deficiencies
Halted:	An application which cannot be further processed due to the need for an internal decision related to safety and/or efficacy
HM PLA:	Homeopathic Medicines Product Licence Application
IRN:	Information Request Notice
NHPD:	Natural Health Products Directorate
Non-Trad. PLA:	Non-Traditional Product Licence Application
Non-Traditional Process Improvement Project:	Project initiated by NHPD, in 2008, which involves screening Non-Traditional applications for critical evidence deficiencies through an initial assessment process
PL:	Product Licence
PLA:	Product Licence Application
Regular workload:	All PLAs received on or after April 1, 2008
SL:	Site Licence
SLA:	Site Licence Application

TPD Cat IV / Label Standard PLA:	Product Licence Application citing a Category IV Monograph or Labelling Standard from the Therapeutic Products Directorate
Traditional Process Improvement Project:	Project initiated by NHPD, in 2009, which involves screening Traditional applications for critical evidence deficiencies through an initial assessment process
Trad. PLA:	Traditional Product Licence Application
Trans-DIN PLA:	Transitional DIN Product Licence Application