

Status of Applications Quarterly Report

Quarter 1
(April 1, 2012 to June 30, 2012)

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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 licence (PL), site licence (SL) and clinical trial applications (CTA) received and processed by 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

Format and content of report

NHPD's Quarterly Report reflects the coming into force of the *Natural Health Products (Unprocessed Product Licence Applications) Regulations* (NHP-UPLAR) on August 4, 2010 and the publication of performance targets related to Product Licence Applications (PLAs) in the NHPD Application Management Policy on August 9, 2010.

NHPD reports on two types of PLAs:

1. applications received before NHP-UPLAR came into force (pre-UPLAR PLAs), and
2. applications received after NHP-UPLAR came into force (post-UPLAR PLAs).

Overall PLA Statistics Summary

NHPD has received 69 934 PLAs from January 1, 2004 to June 30, 2012. Of this total, **63 493 (91%) PLAs have been completed, including the issuance of 36 160 Product Licences representing 51 992 products.** The remaining completed applications were either refused by NHPD or withdrawn by the applicant. In total, 1 817 companies have received a product licence to date.

Pre-UPLAR PLA Statistics Summary

Of the 10 885 PLAs and amendments received before August 5th, 2010 (pre-UPLAR PLAs) and which had not been completed prior to that date, 7 219 (66%) have now been completed. NHPD is committed to completing the remaining 3 666 applications before NHP-UPLAR is repealed in February 2013.

Post-UPLAR PLA Statistics Summary

Of the 18 732 applications and amendments received on and after August 5th, 2010 (post-UPLAR PLAs), 46% fully meet NHPD's pre-cleared information (60-day review target) and the remaining 54% require full assessment (180-day review target).

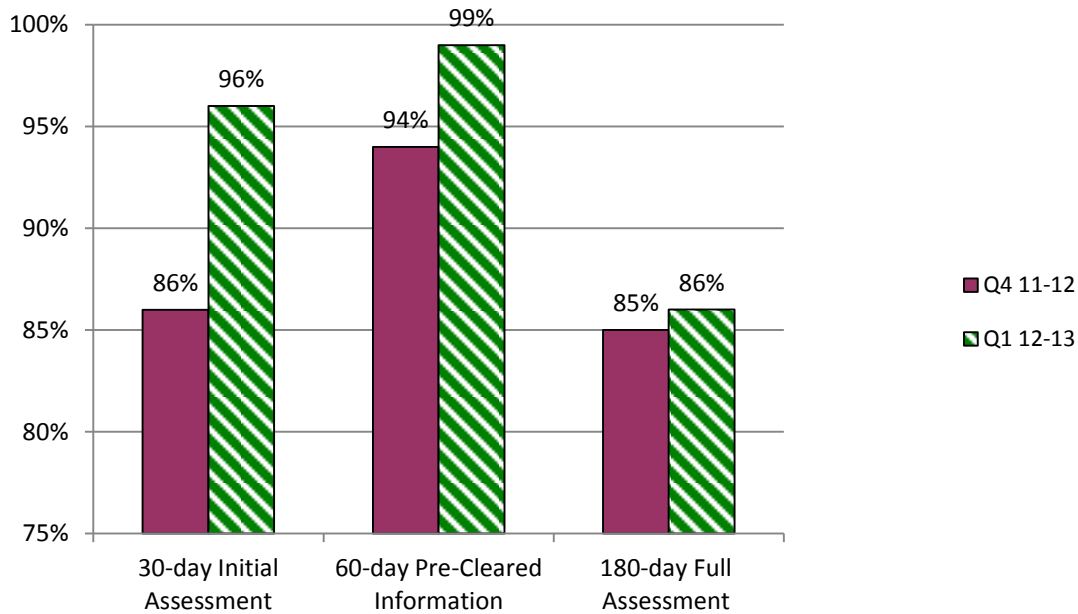
During Quarter 1, NHPD met performance targets as follows:

30-day initial assessment: 96%

60-day pre-cleared information: 99%

180-day full assessment: 86%

Chart 1 – Performance Targets Met by NHPD: Quarter 1 compared to Quarter 4



Overall Site Licence Application (SLA) Statistics Summary

NHPD has received 1 985 Site Licence Applications from January 1, 2004 to June 30, 2012. Of this total, 1 939 (98%) SLAs have been completed, including the issuance of 1 333 Site Licences. The remaining completed applications were either refused by NHPD or withdrawn by the applicant. A total of 2 526 Site Licence Renewals have been received for issued Site Licences. 98% of all Site Licence Renewals have been completed.

During Quarter 1, NHPD received 37 SLAs and 60 Site Licence Renewals and completed 48 SLAs and 89 Site Licence Renewals.

Overall Clinical Trial Application (CTA) Statistics Summary

From January 1, 2004 to June 30, 2012, NHPD has received 390 CTAs. Of this total, 378 (97%) CTAs have been completed, including the issuance of 322 Notices of Authorization. The remaining completed applications were either refused by NHPD or withdrawn by the applicant. A total of 336 CTA Amendments and Notifications have been received for issued Notices of Authorization. 99% of all CTA Amendments and Notifications have been completed.

During Quarter 1, NHPD received 13 CTAs and 6 CTA Amendments and completed 10 CTAs and 5 CTA Amendments.

Quarter 1 (April 1, 2012 to June 30, 2012)

During this quarter, a total of 2 748 PLAs were completed, 77% (2 114) of these completions resulted in product licences, 11% (301) were refusals and the remaining 12% (333) of completions were as a result of the applicant withdrawing the application.

Of the 301 applications refused this quarter, the reasons were as follows:

- 41% failed to meet basic application requirements.
- 37% were refused when applicants did not respond to a request for further information.
- 15% were refused when the applicant's response to a request for further information did not meet the requirements.
- 5% did not meet the definition of a NHP.
- 2% were refused for containing an ingredient not listed in the Natural Health Products Ingredient Database (NHPID).

Highlights

2 114

NHPs licensed
during Quarter 1

301

PLAs refused
during Quarter 1

333

PLAs withdrawn
during Quarter 1

Unacceptable Applications

Since June 2009, certain applications are returned to applicants via regular mail if they are deemed to be unacceptable for processing, as referenced in section 7.2 of NHPD's Application Management Policy. These applications are accompanied by a Rejection Notice – Administrative Deficiency. NHPD reports on these applications by stating the total number of unacceptable application packages and the reasons for rejection.

During this quarter, a total of 4 PLAs were deemed unacceptable and were not included in total PLA statistics.

Of the 4 applications deemed unacceptable for processing this quarter, the reasons were as follows:

- 50% (2) missing attestation signature
- 50% (2) third party did not have authorization to sign on behalf of a company

Quarter 1 Statistics (April 1, 2012 to June 30, 2012)

Chart 2 – Total Number of PLAs Received and Completed during Quarter 1 compared to Quarter 4

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

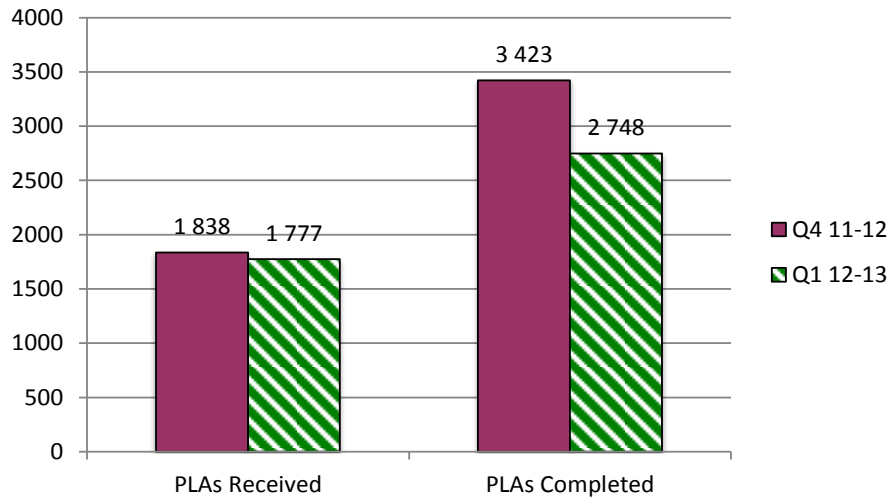


Chart 3 – Total Number of PLAs Completed during Quarter 1 compared to Quarter 4 (Licensed, Refused or Withdrawn)

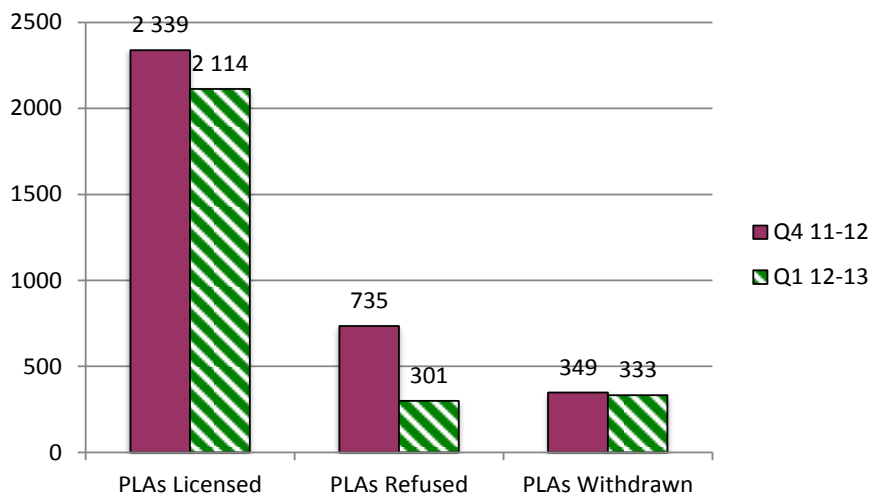


Chart 4 – Total Number of PLAs Completed during Quarter 1, Pre vs. Post UPLAR (n=2 748)

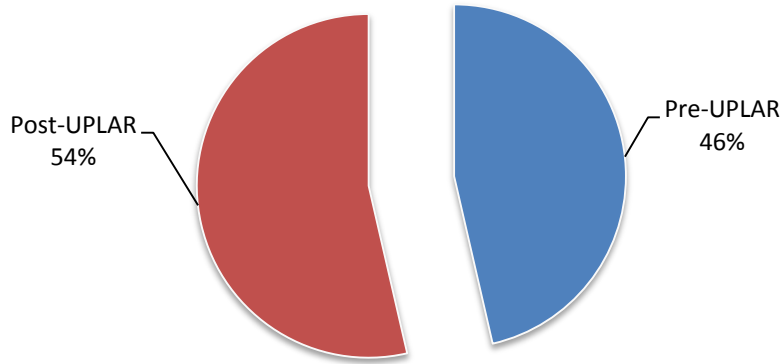
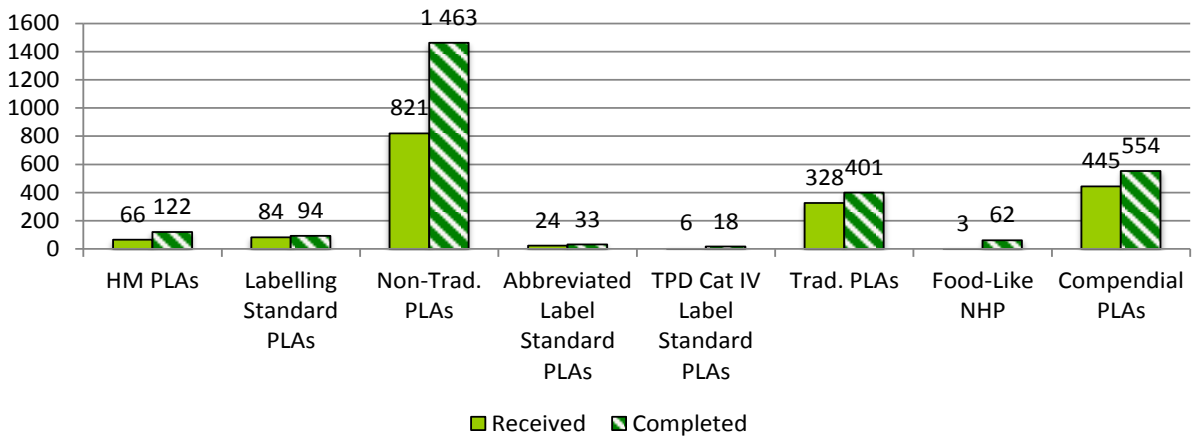


Chart 5 – Total Number of PLAs - by application type - Received and Completed during Quarter 1

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



* See Appendix A for definitions of acronyms found in Chart 5.

Chart 6 – Total Number of PL Amendments Received and Completed during Quarter 1 compared to Quarter 4

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

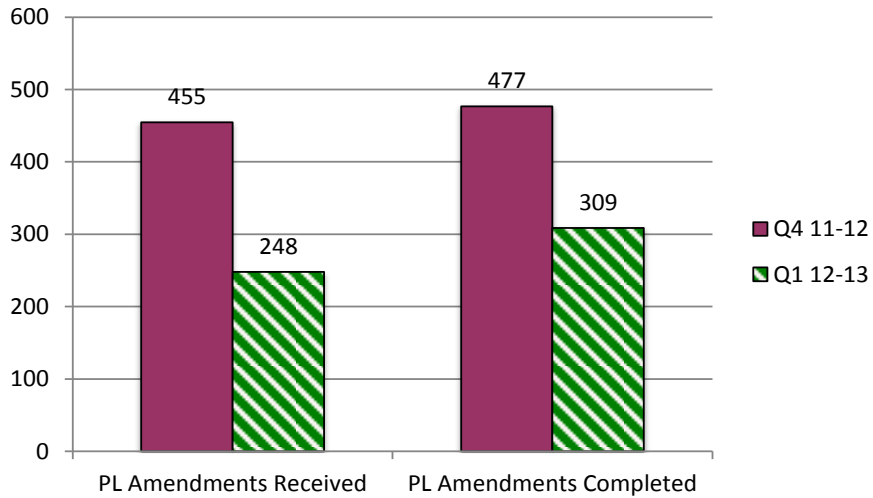


Chart 7– Total Number of PL Notifications Received and Completed during Quarter 1 compared to Quarter 4

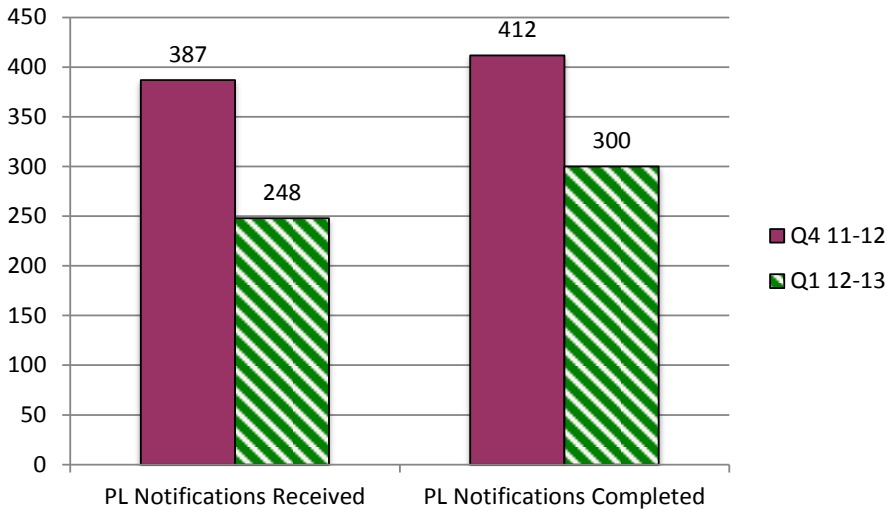


Chart 8 – Total Number of SLAs Received and Completed during Quarter 1 compared to Quarter 4

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

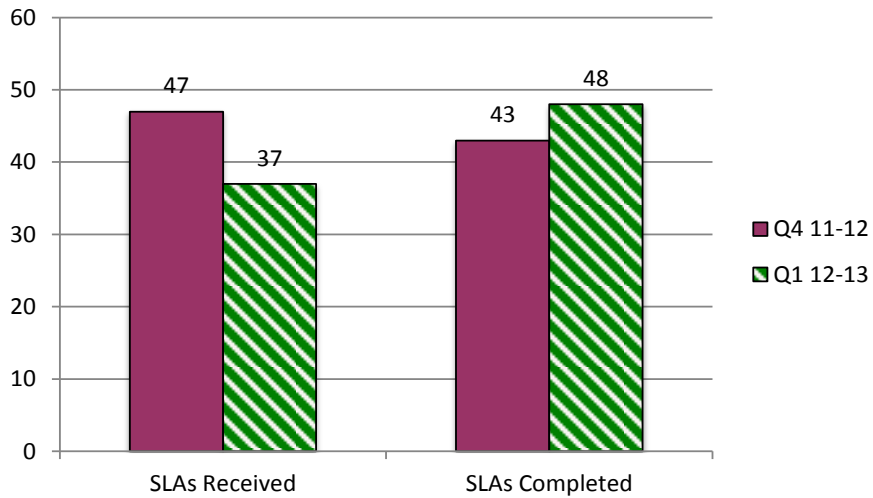
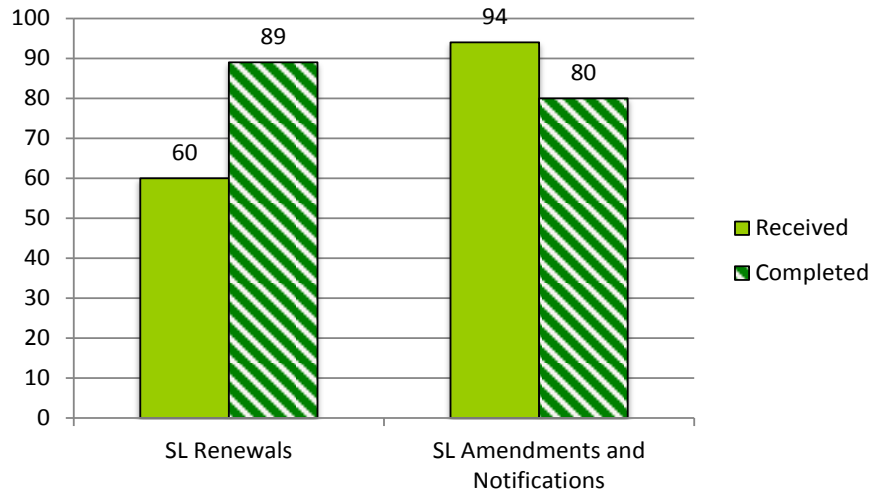


Chart 9 – Total Number of SL Amendments, Notifications and Renewals Received and Completed during Quarter 1

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



Update on PLAs received before August 5, 2010 (pre-UPLAR)

This section provides figures on the current status of PLAs which were received before August 5, 2010 and not complete as of that date. All applications received after this date will be measured against NHPD's performance targets (see Tables 2-5). These performance targets were communicated to applicants via the NHPD Application Management Policy. Please note these numbers also include product licence amendments.

As shown in Table 1 below, the number of applications remaining at NHPD as of August 5, 2010 was 10 885. The number remaining as of June 30, 2012 is 3 666. The objective is to complete the remaining 3 666 before NHP-UPLAR is repealed in February 2013. At the same time, NHPD will be focused on completing all applications received on or after August 5, 2010 in accordance with the performance targets communicated in the Application Management Policy.

Table 1: Total PLAs and Amendments received before August 5, 2010 which were not complete as of that date

| Status – PLAs Completed or In Progress | Number | % of Total (10 885) |
|---|--------------|---------------------|
| Licensed | 4 047 | |
| Refused | 1 795 | |
| Withdrawn by applicant | 1 377 | |
| Total Completed | 7 219 | 66% |
| In Licensing – administrative processing required | 36 | |
| To Be Refused – administrative processing required | 0 | |
| Full Assessment in progress | 1 146 | |
| With Applicant pending response to IRN | 646 | |
| Total Undergoing Assessment | 1 828 | 17% |
| In queue for Full Assessment | 1 195 | |
| Total In Queue for Full Assessment | 1 195 | 11% |
| Halted ¹ pending internal decision related to safety or efficacy | 641 | |
| Miscellaneous Administrative Issues | 2 | |
| Total Other | 643 | 6% |

¹ Halted applications during this quarter included those containing energy drinks, nhps in food format, aromatherapy products and weight loss / weight management products. Recently unhalted issues with review underway include enzymes and probiotics.

Chart 10 – Pre-UPLAR Applications Not Complete by Application Type (n = 3 666)

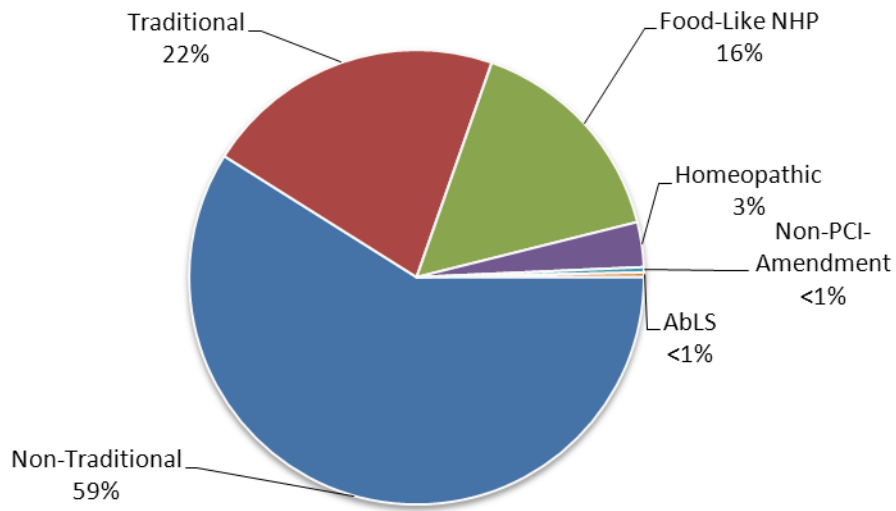
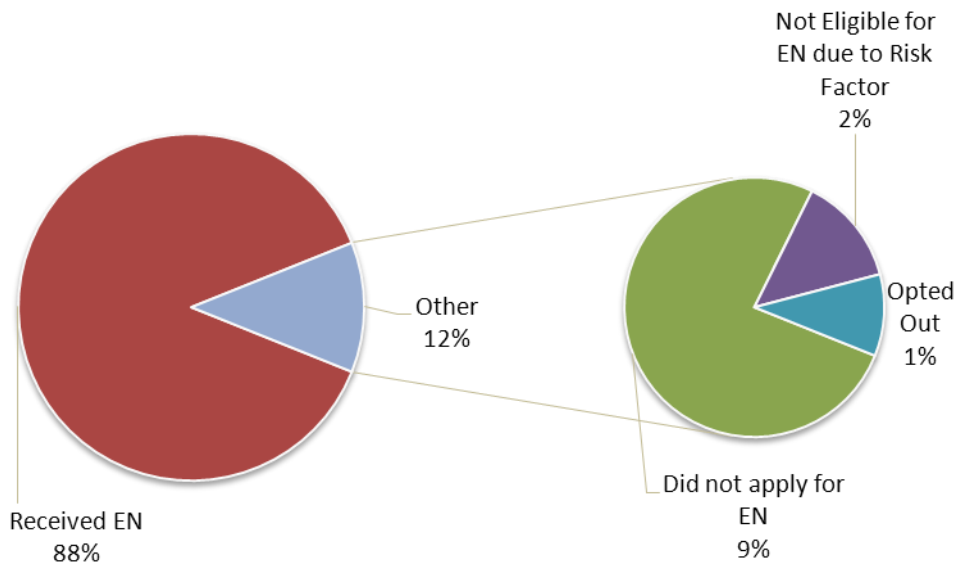


Chart 11 – Pre-UPLAR PLAs Not Complete: Ability to Sell (n = 3 652)



Update on PLAs received on or after August 5, 2010 (post-UPLAR)

This section provides figures on the current status of PLAs which were received on or after August 5, 2010. All applications received after this date will be measured against NHPD's performance targets. These performance targets were communicated to applicants via the NHPD Application Management Policy. Please note these numbers also include product licence amendments.

For the purposes of the performance targets, these applications are separated into two categories: those which fully meet pre-cleared information and those which require full assessment of safety, efficacy and/or quality information. Pre-cleared information includes NHPD Monographs, Labelling Standards and Abbreviated Labelling Standards. Products falling within the parameters described in these documents are subject to shorter review times. See Appendix A for the definition of pre-cleared information.

Applications fully meeting pre-cleared information (60-day review target)

The performance on these applications is outlined in Table 2 below. For these types of applications, NHPD has consistently met the 60-day performance target. Please note that this table only includes amendments supported by pre-cleared information.

Table 2: PLAs and Amendments completed in Quarter 1 that fully meet Pre-Cleared Information

| Application Type | Completed | % Completed within 60 days |
|---------------------------------|------------|----------------------------|
| Compendial | 553 | 99% |
| Labelling Standards | 94 | 100% |
| Abbreviated Labelling Standards | 26 | 81% |
| Amendments | 200 | 99% |
| Total | 873 | 99% |

Of the 101 applications still in progress, 100% were received less than 60 days ago.

Applications requiring full assessment of safety, efficacy and/or quality information (30-day review target for Administrative Processing and Initial Assessment)

For these types of applications, NHPD’s objective is to perform the administrative processing and initial assessment within a 30-day timeframe as described in the Application Management Policy. This 30-day target applies only to applications and amendments received on or after August 5, 2010. At the end of the 30-day timeframe, applicants receive an Application Acceptance Letter or a Notice of Refusal – Initial Assessment. In some cases, the application may be withdrawn by the applicant during the 30-day period. The performance on these applications is outlined in Table 3 below.

This quarter, 1 117 applications, which require full assessment of safety, efficacy and/or quality information, received an Application Acceptance Letter or decision. In 96% of cases, this was completed within the 30-day target.

Table 3: Breakdown of PLAs and Amendments for which an Application Acceptance Letter or decision was issued during Quarter 1

| Action | Count | % Completed within 30 days | % of Total n=1 117 |
|---|-------|----------------------------|--------------------|
| Application Acceptance Letter issued | 1 029 | 97% | 92% |
| Notice of Refusal – Initial Assessment issued | 88 | 91% | 8% |
| Withdrawn by the Company | 14 | 93% | N/A |

Of the 322 applications which have not yet received an Application Acceptance Letter or decision, 100% were received less than 30 days ago.

Applications which require full assessment of safety, efficacy and/or quality information (180-day review target for Full Assessment)

For these types of applications, NHPD’s objective is to meet the 180-day review target as described in the Application Management Policy. This 180-day target applies only to applications and amendments received on or after August 5, 2010 that have been issued an Application Acceptance Letter. This quarterly report provides more detail in regards to the 180-day timeline and the percentage of applications completed within that timeline.

This quarter, NHPD completed 756 applications requiring full assessment of safety, efficacy and/or quality. In 86% of cases, this was completed within the 180-day target.

Table 4: Breakdown of PLAs and Amendments which require full assessment that were completed during Quarter 1

| Action | Count | % Completed within 180 days | % of Total n=756 |
|-------------------------------------|-------|-----------------------------|------------------|
| Product Licence Issued | 690 | 89% | 91% |
| Notice of Refusal – Full Assessment | 66 | 61% | 9% |
| Withdrawn by the Company | 36 | 64% | N/A |

Currently, there are 2 535 applications which require full assessment that have been accepted and are currently in progress. 976 have exceeded 180 days. In 86% of cases (843 applications), this was as a result of a halted¹ issue.

¹ Halted applications during this quarter included those containing energy drinks, nhps in food format, aromatherapy products and weight loss / weight management products. Recently unhalted issues with review underway include enzymes and probiotics.

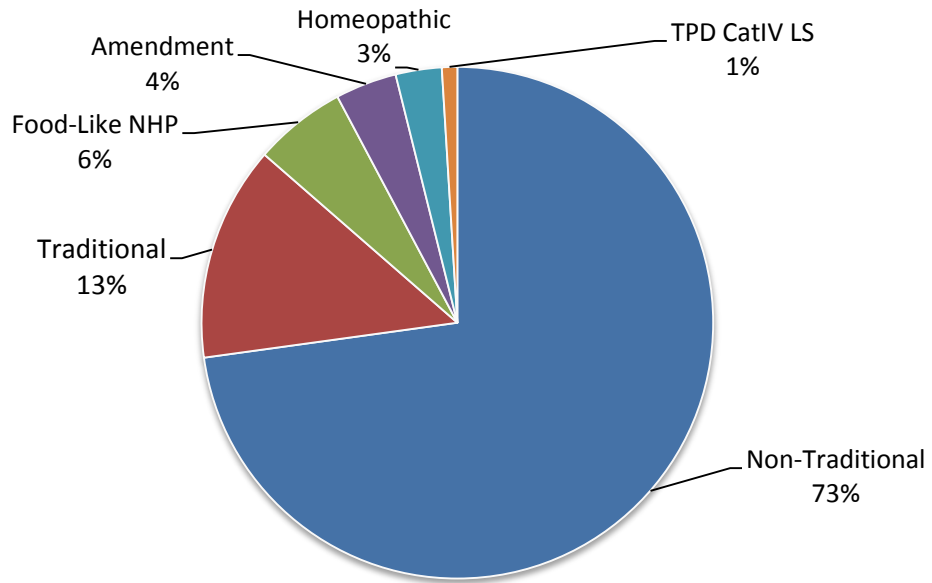
Table 5 outlines the status of the 7 158 PLAs received after August 5, 2010 that were issued an Application Acceptance Letter and are therefore subject to NHPD's 180-day performance target for full assessment as outlined in the Application Management Policy.

Table 5: Status of all PLAs and Amendments received after August 5, 2010 which have received an Application Acceptance Letter

| Status | Number | % of Total (7 158) |
|---|---------------|-------------------------------|
| Licensed | 3 522 | |
| Refused | 868 | |
| Withdrawn by applicant | 233 | |
| Total Completed | 4 623 | 65% |
| In Licensing – administrative processing required | 49 | |
| To Be Refused – administrative processing required | 0 | |
| Has received at least one request for further information | 714 | |
| Full Assessment in progress | 1 490 | |
| Total Undergoing Assessment | 2 253 | 31% |
| Halted ¹ pending internal decision related to safety or efficacy | 282 | |
| Total Halted | 282 | 4% |

¹ Halted applications during this quarter included those containing energy drinks, nhps in food format, aromatherapy products and weight loss / weight management products. Recently unhalted issues with review underway include enzymes and probiotics.

Chart 12 – Post-UPLAR PLAs not yet complete which have received an Application Acceptance Letter by Application Type (n = 2 535)



Appendix A – Acronyms and Definitions

| | |
|--|---|
| PL: | Product Licence |
| SL: | Site Licence |
| PLA: | Product Licence Application |
| SLA: | Site Licence Application |
| NHPD: | Natural Health Products Directorate |
| Abbreviated Labelling Standard (AbLS): | Document created by NHPD outlining information about the established safety and / or efficacy of a product or ingredient. AbLS is one type of pre-cleared information. |
| Amendment: | Product Licence Application proposing revisions to an existing product licence |
| HM PLA: | Homeopathic Medicines Product Licence Application |
| Labelling Standard (LS): | Document created by NHPD outlining information about the established safety and efficacy of a type of product. LS is one type of pre-cleared information. |
| Non-Trad. PLA: | Non-Traditional Product Licence Application |
| Trad. PLA: | Traditional Product Licence Application |
| TPD Cat IV / Label Standard PLA: | Product Licence Application citing a Category IV Monograph or Labelling Standard from the Therapeutic Products Directorate |
| Compendial PLA: | Product Licence Application citing a monograph found in the NHPD's Compendium of Monographs |
| Application Management Policy: | The Application Management Policy outlines the way in which PLAs for natural health products are submitted in accordance with the <i>Natural Health Products Regulations</i> . The policy also outlines the responsibilities and expectations for natural health product applicants before and throughout the application review process. In addition, the policy outlines the proposed performance targets for the management of all types of PLAs. This policy is available on NHPD's website and applies to all PLAs submitted after August 5, 2010. |

| | |
|---|---|
| Completed: | When NHPD issues a Product Licence, Notice of Refusal or when the applicant withdraws their application, the application is considered to be "completed". |
| Halted: | An application which cannot be further processed due to the need for an internal decision related to safety and/or efficacy |
| Initial Assessment: | <p>An assessment of the evidence in support of safety, efficacy and quality to ensure that the requisite information for the type of application in question, as defined in the <i>Natural Health Product Regulations</i> and as described in various guidance documents has been submitted.</p> <p>An Application Acceptance Letter is issued when the information and material submitted are deemed complete and are acceptable for full assessment.</p> <p>Alternatively, if deficiencies are identified during the initial assessment, a Refusal Letter - Initial Assessment will be issued.</p> <p>For applications received on or after August 5, 2010, this assessment is performed within 30 days of receipt of the application. This assessment is performed only for applications which require full assessment of safety, efficacy and / or quality information.</p> |
| Information Request Notice (IRN): | A notice sent from NHPD to an applicant requesting additional information to support the safety, efficacy or quality of a product. As outlined in the Application Management Policy, this notice is sent during the Full Assessment stage and the applicant has 30 days to respond. Applicants can contact the Submission Coordinator indicated on the notice with questions or clarifications. |
| Natural Health Products (Unprocessed Product Licence Applications) Regulations: | Also referred to as UPLAR or NHP-UPLAR. These Regulations allow for certain products to be issued exemption numbers by Health Canada. In order to qualify, products must: have had a complete product licence application (PLA) submitted; not have been withdrawn; still be with Health Canada for a final licensing decision; and not fall within certain risk criteria. Products for which an exemption number is issued by Health Canada will be exempted from the current prohibition against sale without a product licence (as set out in s.4 of the <i>Natural Health Products Regulations</i>). In other words, these products can now be sold legally. These Regulations were registered on August 4, 2010 and will be repealed 30 months following that date on February 4, 2013. |

| | |
|--------------------------|--|
| Pre-Cleared Information: | Information which has been pre-cleared by the NHPD includes NHPD Monographs, Labelling Standards and Abbreviated Labelling Standards. These documents outline the parameters under which a product can be sold including allowable claims, dose limits and risk information required on the product label. If a company wishes to receive a licence and their product falls within the parameters of any of these documents, the licence can be issued in 60 days. Pre-cleared information can also be used to help support other applications types; for example, one ingredient within a multi-ingredient product may be supported by a monograph for that ingredient. |
| UPLAR: | See definition of <i>Natural Health Products (Unprocessed Product Licence Applications) Regulations</i> above. |
| Pre-UPLAR PLAs: | PLAs received prior to the publication of the <i>Natural Health Products (Unprocessed Product Licence Applications) Regulations</i> on August 5th, 2010 which were not yet complete as of that date |
| Post-UPLAR PLAs: | PLAs received on or after August 5th, 2010. These applications are subject to the performance targets set out in Application Management Policy. |