

# Quarterly Drug Submission Performance Report

April - June **2003** *avril - juin*

## ***Rapport trimestriel de la performance sur les présentations de drogue***

Therapeutic Products Directorate – Part 1 of 2

*Direction des produits thérapeutiques – Partie 1 de 2*

## OVERVIEW

In keeping with the current organization of the Health Products and Food Branch, the quarterly drug submission performance report consists of 2 parts:

- Part 1 - Therapeutic Products Directorate (TPD),
- Part 2 - Biologics & Radiopharmaceuticals Evaluation Centre (BREC) [of the Biologics and Genetic Therapies Directorate].

The reporting period extends over 5 quarters permitting comparisons of statistics from June 2002 through June 2003.

## WHAT'S NEW IN THIS REPORT?

This report incorporates several new tables allowing more detailed reporting for various aspects of the drug submission handling process. In addition, due to changes in the regulations and associated policies and guidances, several previously reported statistics have become obsolete and are therefore removed from the report.

Details of these changes are as follows:

### GENERAL

- During 2002, the former Bureau of Pharmaceutical Assessment of the Therapeutic Products Directorate was reorganized into 5 different review Bureaux: 1) the Bureau of Metabolism, Oncology and Reproductive Sciences; 2) the Bureau of Gastroenterology, Infection and Viral Diseases; 3) the Bureau of Cardiology, Allergy and Neurological Sciences; 4) the Bureau of Pharmaceutical Sciences and 5) the Senior Medical Advisory Bureau. Where possible, statistics are reported using a stacked bar format to provide insight into the distribution among Bureaux. These Bureau breakdowns are only available from Q4-2002 to Q2-2003.

### SECTION 1- SUBMISSIONS RECEIVED AND FINAL OUTCOMES

- Tables have been added to reflect the number of requests received and requests granted or denied for Priority Review.

### SECTION 2- APPEALS, SECTION 3- WORKLOAD AND BACKLOG AND SECTION 4- PERFORMANCE

- No changes.

Any questions or comments on this report should be forwarded to:

***Marilyn Schwartz, B.Sc. (Pharm)***

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## APERÇU

Conformément à l'organisation actuelle de la Direction générale des produits de santé et des aliments, le rapport sur le Performance des présentations de drogues trimestrielle comporte deux parties:

- Partie 1 - Direction des produits thérapeutiques (DPT),
- Partie 2 - Centre d'évaluation des produits biologiques et radiopharmaceutiques (CEPBR) [Direction des produits biologiques et des thérapies génétiques].

La période visée par ce rapport s'échelonne sur 5 trimestres, ce qui permet la comparaison de statistiques de juin 2002 à juin 2003.

## NOUVEAUTÉS DU RAPPORT

Ce rapport comprend plusieurs nouveaux tableaux permettant de rendre compte de façon plus détaillée de divers aspects du processus de traitement des présentations de drogue. De plus, en raison des changements apportés à la réglementation et aux politiques et lignes directrices connexes, plusieurs statistiques recueillies précédemment sont maintenant périmées et ont par conséquent été enlevées du rapport.

Voici les détails de ces modifications :

## GÉNÉRAL

- Au cours de l'année 2002, l'ancien Bureau de l'évaluation des produits pharmaceutiques a été réorganisé en 5 bureaux d'examen différents : 1) le Bureau du métabolisme, de l'oncologie et des sciences de la reproduction, 2) le Bureau de la gastroentérologie et des maladies infectieuses et virales, 3) le Bureau de la cardiologie, des allergies et des sciences neurologiques, 4) le Bureau des sciences pharmaceutiques et 5) le Bureau du conseiller médical principal. Autant que possible, les statistiques sont présentées sous forme de graphes à barres empilées à fin d'offrir un aperçu sur la répartition parmi les Bureaux. Ces détails sont disponibles seulement de Q2 - 2002 à Q2 - 2003.

## SECTION 1- PRÉSENTATIONS REÇUES ET RÉSULTATS FINAUX

- Des tableaux ont été ajoutés pour montrer le nombre de demandes de statut d'évaluation prioritaire reçues et le nombres de demandes de statut d'évaluation prioritaire accordées ou refusées.

## SECTION 2- APPELS, SECTION 3- CHARGE DE TRAVAIL ET ARRIÉRÉ ET SECTION 4-PERFORMANCE

- Aucune modification.

Toute question ou observation concernant le rapport doit être transmise à:

**Marilyn Schwartz, B.Sc. (Pharm)**

Gestionnaire

Division des politiques sur les présentations et renseignements

Bureau des services opérationnels

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### SECTION 4 - Performance

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## ACRONYMS / ACRONYMES

### DIRECTORATE, BUREAU or (DIVISION) / DIRECTION, BUREAU ou (DIVISION)

|                 |  |
|-----------------|--|
| BGTD / DPBTG    | - Biologics and Genetic Therapies Directorate / <i>Direction des produits biologiques et des thérapies génétiques</i>                        |
| TPD / DPT       | - Therapeutic Products Directorate / <i>Direction des produits thérapeutiques</i>  |
| BCANS / BCASN   | - Bureau of Cardiology, Allergy and Neurological Sciences / <i>Bureau de cardiologie, allergologie et des sciences neurologiques</i>         |
| BGIVD / BGIMV   | - Bureau of Gastroenterology, Infection and Viral Diseases / <i>Bureau de gastroentérologie, maladies infectieuses et virales</i>            |
| BMORS / BMOSR   | - Bureau of Metabolism, Oncology and Reproductive Sciences / <i>Bureau de métabolisme, de l'oncologie et des sciences de la reproduction</i> |
| BPS / BSP       | - Bureau of Pharmaceutical Sciences / <i>Bureau des sciences pharmaceutiques</i>   |
| BREC / CEPBR    | - Biologics and Radiopharmaceuticals Evaluation Centre / <i>Centre d'évaluation des produits biologiques et radiopharmaceutiques</i>         |
| SMAB / BCMP     | - Senior Medical Advisor Bureau / <i>Bureau du conseiller médical principale</i>   |
| (SIPD) / (DPPR) | - Submission and Information Policy Division / <i>Division des politiques sur les présentations et renseignements</i>                        |

### SUBMISSION TYPES / GENRES DE PRÉSENTATION

|               |  |
|---------------|--|
| ANDS / PADN   | - Abbreviated New Drug Submission / <i>Présentation abrégée de drogue nouvelle</i>                               |
| CTA / DEC     | - Clinical Trial Application / <i>Demandes d'essais cliniques</i>  |
| CTA-A / MDEC  | - Clinical Trial Application-Amendment / <i>Modification aux demandes d'essais cliniques</i>                     |
| DINA          | - Drug Identification Number Application (TPD) / <i>Demande de numéro d'identification de drogue (DPT)</i>       |
| DINB          | - Drug Identification Number Application (BREC) / <i>Demande de numéro d'identification de drogue (CEPBR)</i>    |
| DIND          | - Drug Identification Number Disinfectants / <i>Numéro d'identification de drogue (désinfectants)</i>            |
| DINF          | - Drug Identification Number (Category IV) / <i>Numéro d'identification de drogue (Catégorie IV)</i>             |
| DINH          | - Drug Identification Number Homeopathics / <i>Numéro d'identification de drogue (homéopathiques)</i>            |
| INDS / PDNR   | - Investigation New Drug Submission / <i>Présentation de drogue nouvelle de recherche</i>                        |
| NDS / PDN     | - New Drug Submission / <i>Présentation de drogue nouvelle</i>   |
| NC / MP       | - Notifiable Change - New Drug / <i>Modification nécessitant un préavis-drogue nouvelle</i>                      |
| PCP / PA      | - Pest Control Product / <i>Produits antiparasitaires</i>  |
| SANDS / SPADN | - Supplemental Abbreviated New Drug Submission / <i>Supplément à une présentation abrégée de drogue nouvelle</i> |
| SNDS / SPDN   | - Supplemental New Drug Submission / <i>Supplément à une présentation de drogue nouvelle</i>                     |

### CLASS / CATÉGORIE

|  |   |
|--|---|
| Admin  | - Administrative / <i>Présentation administrative</i>   |
| Comp/C&M / Comp/C&F  | - Comparative Bio., Clinical, or Pharmacodynamic/ Chemistry & Manufacturing / <i>Bio.. comparative, clinique ou pharmacodynamique/ Chimie et fabrication</i>                |
| C&M/ Labelling / C&F/Étiquetage                                | - Chemistry & Manufacturing/ Labelling / <i>Chimie et fabrication/Étiquetage</i>  |
| Clin/C&M / Clin/C&F  | - Clinical/Chemistry & Manufacturing / <i>Clinique/Chimie et fabrication</i>  |
| Clin Only / Clin seulement                                     | - Clinical Only / <i>Clinique seulement</i>   |
| Labelling Only / Étiquetage seulement                          | - Labelling Only / <i>Étiquetage seulement</i>  |
| NAS / NSA  | - New Active Substance / <i>Nouvelle substance active</i>   |
| NOC/c-NAS / AC/c-NSA   | - Notice of Compliance with Conditions/New Active Substance / <i>Avis de conformité conditionnels/ nouvelle substance active</i>  |
| Priority - NAS / <i>Priorité-NSA</i>                           | - Priority (New Active Substance) / <i>Priorité (Nouvelle substance active)</i>   |
| Priority - Clin/C&M / <i>Priorité - Clin/C&amp;F</i>           | - Priority-Clinical/Chemistry & Manufacturing / <i>Priorité - Clinique/Chimie et fabrication</i>  |
| Priority - Clin Only / <i>Priorité-Clin seulement</i>          | - Priority-Clinical Only / <i>Priorité-Clinique seulement</i>   |
| Priority - C&M/ Labelling / <i>Priorité-C&amp;F/Étiquetage</i> | - Priority-Chemistry & Manufacturing/ Labelling / <i>Priorité-Chimie et Fabrication/Étiquetage</i>  |
| Priority - Comp/C&M / <i>Priorité-Comp/C&amp;F</i>             | - Priority-Comparative Bio., Clinical, or Pharmacodynamic/ Chemistry & Manufacturing / <i>Priorité-Biocomparative, clinique ou pharmacodynamique/ Chimie et fabrication</i> |
| Priority-Rx to OTC-No New / <i>Priorité Rx à VL pni</i>        | - Priority Rx to Over the Counter - No New Indication / <i>Priorité Rx à vente libre - pas de nouvelle indication</i>   |
| Rx to OTC-New / <i>Rx à VL ni</i>                              | - Rx to Over the Counter - New Indication / <i>Rx à vente libre - nouvelle indication</i>   |
| Rx to OTC-No New / <i>Rx à VL pni</i>                          | - Rx to Over the Counter - No New Indication / <i>Rx à vente libre - pas de nouvelle indication</i>   |

### DOCUMENTS

|   |  |
|---|--|
| NOC / AC  | - Notice of Compliance / <i>Avis de conformité</i>   |
| NOC - Conditional / <i>AC conditionnels</i>           | - Notice of Compliance with Conditions / <i>Avis de conformité conditionnels</i>                             |
| Issuable NOC (Patent) / <i>AC délivrable (Brevet)</i> | - NOC on Hold due to Patent Regulations / <i>AC retenu du fait du Règlement sur les médicaments brevetés</i> |
| Issuable NOC (Rx-OTC) / <i>AC délivr. (Rx à VL)</i>   | - NOC on Hold due to De-Scheduling / <i>AC retenu du fait du retrait du médicament d'une annexe</i>          |
| NON / ANC   | - Notice of Non-Compliance / <i>Avis de non-conformité</i>   |
| NOD / ADI   | - Notice of Deficiency / <i>Avis d'insuffisance</i>  |
| NON Withdrawal / <i>ANC retrait</i>                   | - Notice of Non-Compliance Withdrawal Letter / <i>Avis de non-conformité -Lettre de retrait</i>              |
| NOD Withdrawal / <i>ADI retrait</i>                   | - Notice of Deficiency Withdrawal Letter / <i>Avis d'insuffisance - Lettre de retrait</i>                    |

For further clarification refer to the Management of Drug Submission Guidance posted at:

Pour de plus amples informations veuillez referer à la directive sur la gestion des présentations de drogue:

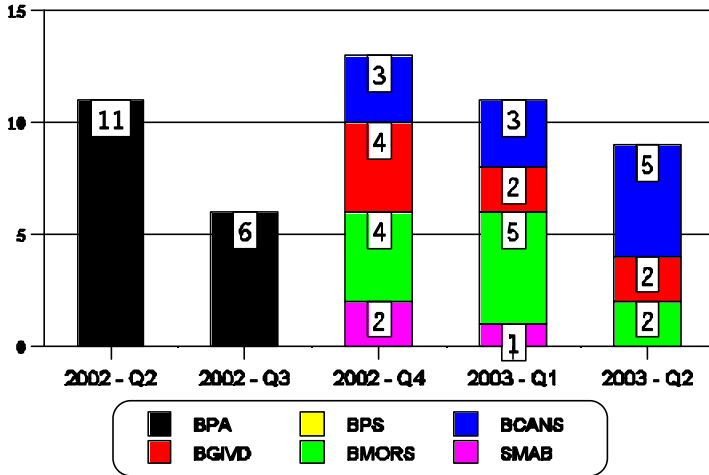
<http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/policy.html>

## **SECTION 1 - Submissions Received & Final Outcomes /**

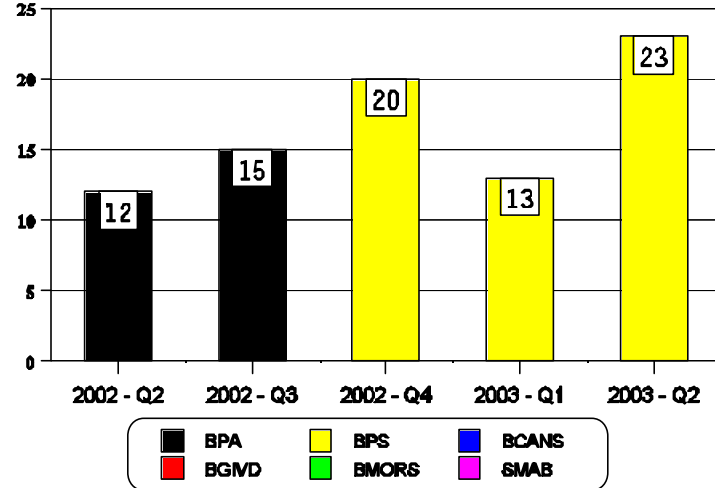
## ***SECTION 1 - Présentations reçues et résultats définitifs***

## NDS & ANDS Received / PDN et PADN reçues

**NDS / PDN**



**ANDS / PADN**

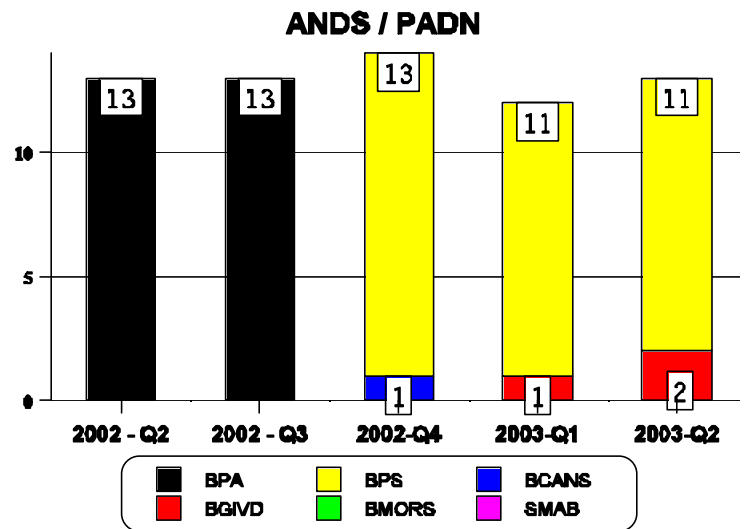
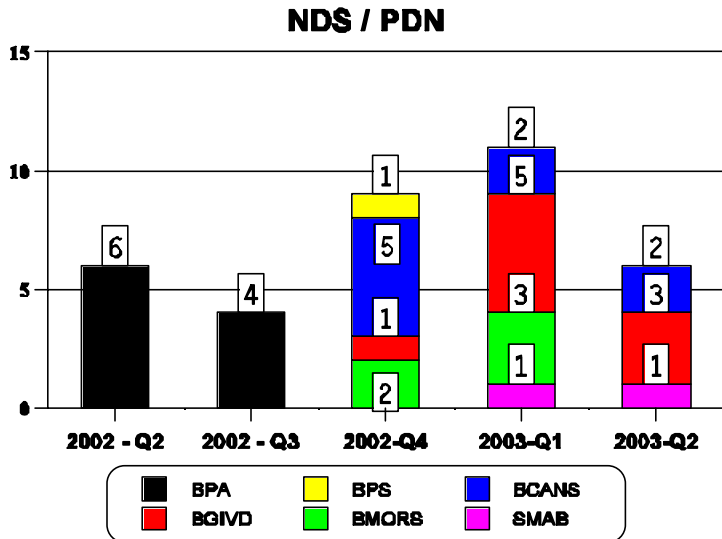


| NDS / PDN   |         |         |         |         | ANDS / PADN |         |         |         |         |
|---|---------|---------|---------|---------|-------------|---------|---------|---------|---------|
| 2002 Q2   | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 | 2002 Q2     | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
| 11  | 6       | 13      | 11      | 9       | 12          | 15      | 20      | 13      | 23      |
| <b>TOTAL</b>  |         |         |         |         |             |         |         |         |         |
| <b>CLASS / CATÉGORIE</b>  |         |         |         |         |             |         |         |         |         |
|   | 1       | 1       | 1       |         |             |         |         |         |         |
|   |         |         |         |         |             |         |         |         |         |
| 1   | 1       |         | 1       |         |             |         |         |         |         |
| 5   | 1       | 4       | 4       | 4       |             |         |         |         |         |
|   |         |         |         | 1       |             |         |         |         |         |
| 4   | 2       | 6       | 3       | 4       |             |         |         |         |         |
|   | 1       |         | 1       |         |             |         |         |         |         |
| 1   |         | 1       | 1       |         | 8           | 11      | 17      | 10      | 19      |
|   |         |         |         |         | 4           | 4       | 3       | 3       | 4       |
|   |         | 1       |         |         |             |         |         |         |         |
| 83  | 29      | 33      | 62      | 17      | 19          | 21      | 16      | 14      | 9       |
| *Admin (SIPD) - Manufacturer/Product Name Changes<br>*Admin (DPPR) - Modif. apportées au nom du produit/fabricant |         |         |         |         |             |         |         |         |         |

\* Admin (SIPD) totals include submissions from TPD and BGTD.

\* Les totaux d'Admin (SIPD) incluent des présentations de DPT et de DPBTG.

## NOC Issued/Issuable\* for NDS & ANDS / AC émis/pouvant être émis\* pour PDN et PADN



| NDS / PDN         |         |         |         |         | ANDS / PADN  |    |    |    |    |
|-------------------|---------|---------|---------|---------|--|----|----|----|----|
| 2002 Q2           | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 | TOTAL  |    |    |    |    |
| 6                 | 4       | 9       | 11      | 6       | 13   | 13 | 14 | 12 | 13 |
| CLASS / CATÉGORIE |         |         |         |         |  |    |    |    |    |
| 1                 |         | 1       | 1       |         | Priority-NAS / Priorité-NSA  |    |    |    |    |
|                   | 1       |         |         |         | Priority-Clin Only / Priorité-Clin seulement   |    |    |    |    |
|                   |         |         |         |         | Priority-Clin/C&M / Priorité-Clin/C&F  |    |    |    |    |
| 5                 | 2       | 3       | 3       | 3       | NAS / NSA  |    |    |    |    |
|                   |         | 3       | 4       | 3       | Clin/C&M / Clin/C&F  |    |    |    |    |
|                   |         | 1       |         |         | Clin Only / Clin seulement   |    |    |    |    |
|                   | 1       |         | 1       |         | Comp/C&M / Comp/C&F  |    |    |    |    |
|                   |         | 1       |         |         | C&M/Labeling / C&F/Étiquetage  |    |    |    |    |
|                   |         |         | 2       |         | Admin (Non-SIPD) / Admin (non-DPPR)  |    |    |    |    |
| 76                | 27      | 43      | 34      | 39      | **Admin (SIPD) - Manufacturer/Product Name Changes<br>**Admin (DPPR) - Modif. apportées au produit/fabricant |    |    |    |    |
|                   |         |         |         |         | 22   | 20 | 15 | 18 | 8  |

\*Issued/Issuable includes NOCs issued, NOCs issued with Conditions and NOCs held due to Patent regulations.

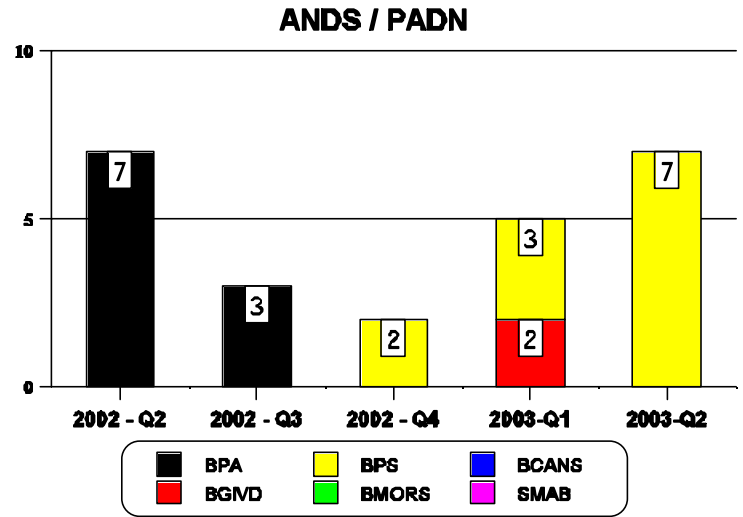
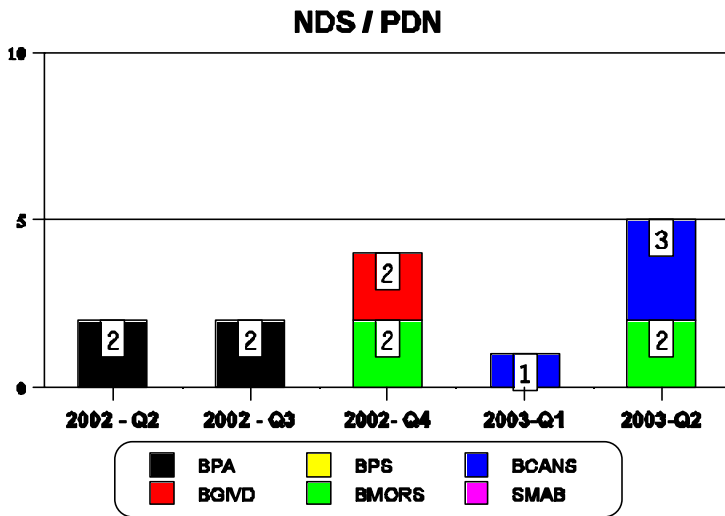
\*Émis/pouvant être émis y compris les AC émis, les AC Conditionnels et les AC retenus du fait du Règlement sur les médicaments brevetés.

\*\*Admin (SIPD) totals include submissions from TPD and BGTD.

\*\* Les totaux d'Admin (SIPD) incluent des présentations de DPT et de DPBTG.



## NON Issued for NDS & ANDS ANC émis pour PDN et PADN



| NDS / PDN                |         |         |         |         | ANDS / PADN |         |         |         |         |
|--------------------------|---------|---------|---------|---------|-------------|---------|---------|---------|---------|
| 2002 Q2                  | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 | 2002 Q2     | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
| 2                        | 2       | 4       | 1       | 5       | 7           | 3       | 2       | 5       | 7       |
| <b>TOTAL</b>             |         |         |         |         |             |         |         |         |         |
| <b>CLASS / CATÉGORIE</b> |         |         |         |         |             |         |         |         |         |
|                          |         |         |         |         |             |         |         |         |         |
|                          |         |         |         |         |             |         |         |         |         |
|                          |         |         |         |         |             |         |         |         |         |
| 2                        |         | 2       |         | 1       |             |         |         |         |         |
|                          | 2       | 2       | 1       | 4       |             |         |         |         |         |
|                          |         |         |         |         |             |         |         |         |         |
|                          |         |         |         |         |             |         |         |         |         |
|                          |         |         |         |         | 7           | 1       | 2       | 4       | 3       |
|                          |         |         |         |         |             | 2       |         | 1       | 4       |

## Documents Issued for NDS /ANDS Documents émis pour PDN/PADN

| NDS / PDN |         |         |         |         | ANDS / PADN   |         |         |         |         |    |
|-----------|---------|---------|---------|---------|---|---------|---------|---------|---------|----|
| 2002 Q2   | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 | DOCUMENT  |         |         |         |         |    |
| 2002 Q2   | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 | 2002 Q2   | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |    |
|           |         |         |         |         | Total NOC / AC total  |         |         |         |         |    |
| 6         | 4       | 9       | 11      | 6       |   | 13      | 13      | 14      | 12      | 13 |
|           |         |         | 2       |         | NOC with Conditions* / AC-conditionnels*  |         |         |         |         |    |
|           |         |         |         | 1       | Issuable NOC (Patent)** / AC pouvant être émis (Brevet)**                       | 3       | 2       | 6       | 3       | 7  |
| 5         | 3       | 4       | 6       | 5       | NOC 1 <sup>st</sup> Review *** / AC 1 <sup>er</sup> examen***                   | 9       | 6       | 10      | 6       | 10 |
| 2         | 2       | 4       | 1       | 5       | NON / ANC   | 7       | 3       | 2       | 5       | 7  |
|           | 3       | 2       |         | 4       | NOD / ADI   |         |         |         | 1       | 1  |
| 1         |         | 1       | 2       |         | NON Withdrawal / ANC retrait  | 1       |         | 1       |         | 1  |
| 2         |         |         |         | 1       | NOD Withdrawal / ADI retrait  |         | 1       |         |         |    |
|           |         |         |         |         | Rejection Letter - Screening /<br>Lettre de rejet lors de l'examen préliminaire |         |         | 1       |         |    |
| 1         | 4       | 2       | 4       | 3       | Screening Deficiency Notice /<br>Avis d'insuff. lors de l'examen préliminaire   | 4       | 3       | 6       | 14      | 8  |
| 3         |         | 1       |         | 2       | Cancelled (Withdrawn) by Company<br>Annulé(Retrait) par la compagnie            | 3       |         | 1       | 1       | 1  |

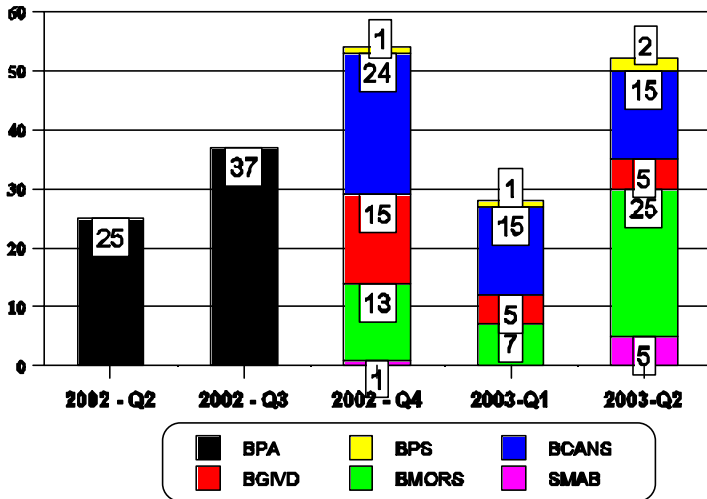
\* NOC with Conditions is a subset of the total NOC, and indicates the number NOCs issued under the "Notice of Compliance with Conditions (NOC/c)" policy dated November 6, 2002.  
AC-conditionnels sont un sous-ensemble du total des AC délivrés et émises en vertu de la politique sur les avis de conformité conditionnels, le 6 novembre 2002.

\*\* Issuable NOC (Patent), is a subset of the total NOC, and indicates the number of NOCs held due to Patent regulations.  
Les AC pouvant être émis (Brevet) sont un sous-ensemble du total des AC et indiquent le nombre d'AC retenus du fait du Règlement sur les médicaments brevetés.

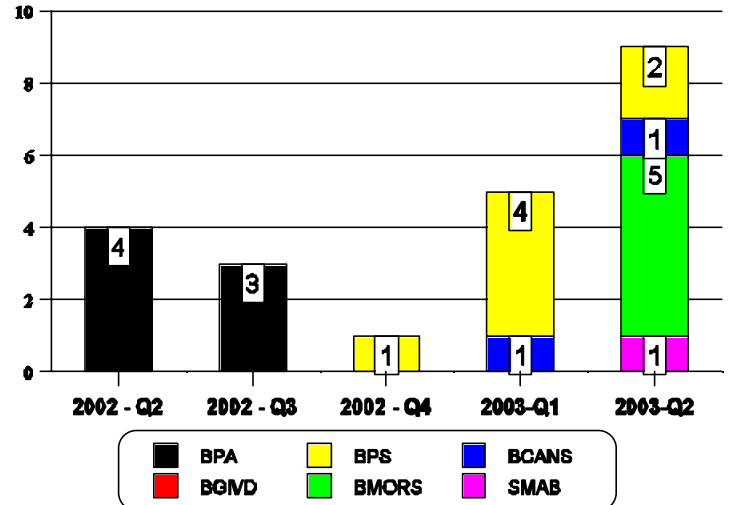
\*\*\* NOC 1st review is a subset of total NOC issued for submissions that have not been issued an NON or NOD and excludes refiled and administrative submissions.  
Les AC 1<sup>er</sup> examen sont un sous-ensemble du total des AC émis pour les présentations qui n'ont pas reçu de AND ou de ADI et excluent les présentations ayant fait l'objet d'un nouveau dépôt et les présentations administratives.

## SNDS & SANDS Received SPDN et SPADN reçues

SNDS / SPDN



SANDS / SPADN



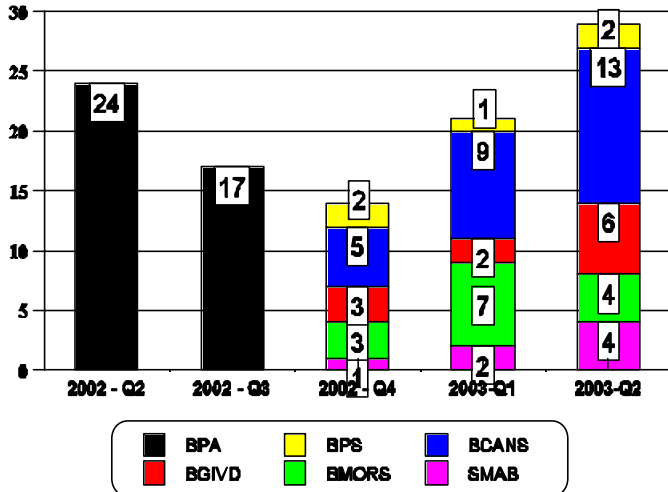
| SNDS / SPDN  |         |         |         |         | SANDS / SPADN |         |         |         |         |
|--|---------|---------|---------|---------|---------------|---------|---------|---------|---------|
| 2002 Q2  | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 | 2002 Q2       | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
| 25   | 37      | 53      | 28      | 52      | 4             | 3       | 1       | 5       | 9       |
| <b>TOTAL</b>   |         |         |         |         |               |         |         |         |         |
| <b>CLASS / CATÉGORIE</b>   |         |         |         |         |               |         |         |         |         |
| 1  |         | 1       |         |         |               |         |         |         |         |
| Priority-Clin Only / <i>Priorité-Clin seulement</i>  |         |         |         |         |               |         |         |         |         |
|  |         |         |         |         |               |         |         |         |         |
| Priority-Clin/C&M / <i>Priorité-Clin/C&amp;F</i>   |         |         |         |         |               |         |         |         |         |
| 5  | 6       | 7       | 3       | 10      |               |         |         |         |         |
| Clin/C&M / <i>Clin/C&amp;F</i>   |         |         |         |         |               |         |         |         |         |
| 16   | 23      | 36      | 17      | 23      |               |         |         |         | 5       |
| Clin Only / <i>Clin seulement</i>  |         |         |         |         |               |         |         |         |         |
| 2  | 2       | 1       | 2       | 3       | 4             | 2       | 1       |         | 1       |
| Comp/C&M / <i>Comp/C&amp;F</i>   |         |         |         |         |               |         |         |         |         |
|  | 3       | 4       | 2       | 3       |               |         |         | 1       | 1       |
| C&M/Labeling / <i>C&amp;F/Étiquetage</i>   |         |         |         |         |               |         |         |         |         |
| 1  | 2       | 4       | 4       | 13      |               | 1       |         | 4       | 2       |
| Labelling Only / <i>Étiquetage seulement</i>   |         |         |         |         |               |         |         |         |         |
|  | 1       |         |         |         |               |         |         |         |         |
| Rx to OTC - No New Ind. / <i>Rx à VL pni</i>   |         |         |         |         |               |         |         |         |         |
|  |         |         |         |         |               |         |         |         |         |
| Admin (Non-SIPD) / <i>Admin (non-DPPR)</i>   |         |         |         |         |               |         |         |         |         |
| 6  | 2       | 5       | 9       | 2       | 3             | 1       | 3       |         | 1       |
| *Admin (SIPD) - Manufacturer/Product Name Changes<br>*Admin (DPPR) - Modif. apportées au produit/fabricant |         |         |         |         |               |         |         |         |         |

\* Admin (SIPD) totals include submissions from TPD and BGTD.

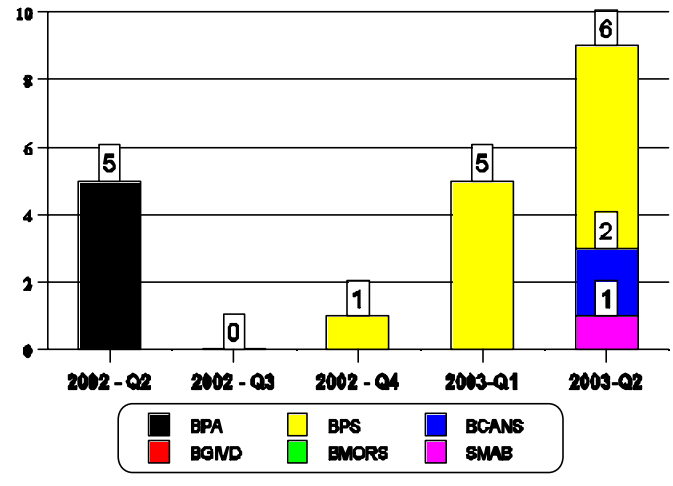
\* Les totaux d'Admin (SIPD) incluent des présentations de DPT et de DPBTG.

## NOC Issued/Issuable\* for SNDS & SANDS AC émis/pouvant être émis\* pour SPDN et SPADN

**SNDS / SPDN**



**SANDS / SPADN**



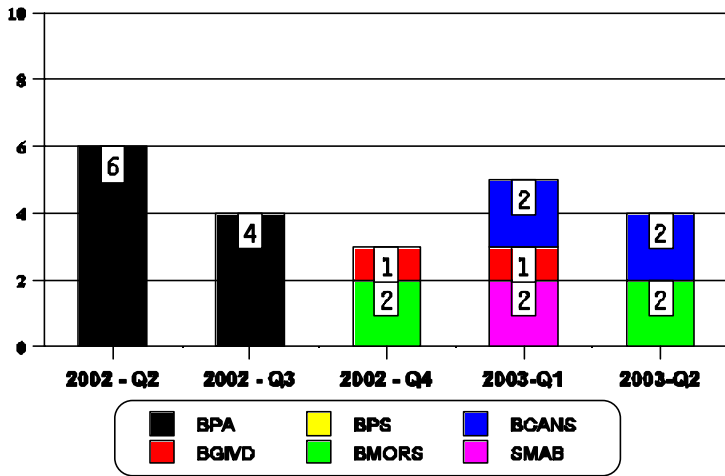
| SNDS / SPDN              |         |         |         |         | SANDS / SPADN  |         |         |         |         |         |
|--------------------------|---------|---------|---------|---------|--|---------|---------|---------|---------|---------|
| 2002 Q2                  | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 | TOTAL  | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
| 24                       | 17      | 14      | 21      | 29      |  | 5       | 0       | 1       | 5       | 9       |
| <b>CLASS / CATÉGORIE</b> |         |         |         |         |  |         |         |         |         |         |
|                          |         |         |         |         |  |         |         |         |         |         |
|                          |         |         |         |         |  |         |         |         |         |         |
| 2                        | 2       |         |         |         |  |         |         |         |         |         |
|                          |         |         |         |         |  |         |         |         |         |         |
|                          |         |         |         | 1       |  |         |         |         |         |         |
| 1                        | 3       | 4       | 4       | 3       |  |         |         |         |         |         |
| 16                       | 10      | 6       | 13      | 13      |  |         |         |         |         |         |
| 3                        | 1       | 2       |         | 4       |  | 2       |         | 1       | 4       | 2       |
| 2                        | 1       | 2       | 1       | 1       |  |         |         |         | 1       |         |
|                          |         |         | 3       | 7       |  | 3       |         |         |         | 7       |
|                          |         |         |         |         |  |         |         |         |         |         |
| 6                        | 2       | 1       | 12      | 4       | **Admin (SIPD) - Manufacturer/Product Name Changes<br>**Admin (DPPR) - Modif. apportées au produit/fabricant | 3       | 1       | 3       |         | 1       |

\* Issued/Issuable includes NOCs issued, NOCs held due to Patent regulations or due to De-scheduling (Rx-OTC).  
Émis/pouvant être émis y compris les AC émis, les AC retenus de fait du Règlement sur les médicaments brevetés ou du retrait du médicament (Rx à VL) d'une annexe.

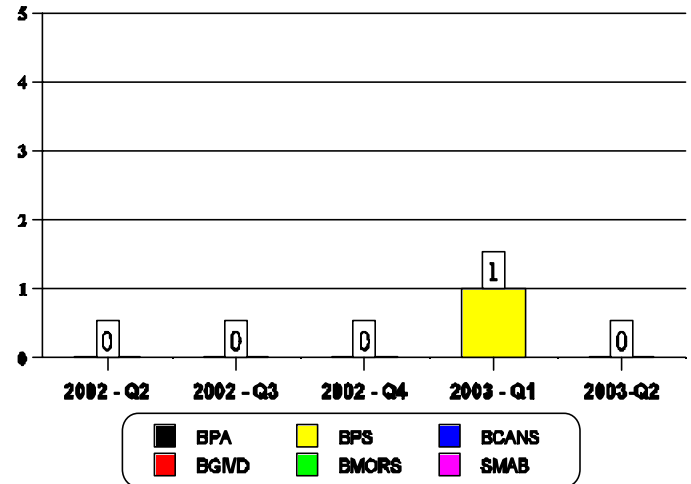
\*\* Admin (SIPD) totals include submissions from TPD and BGTD.  
Les totaux d'Admin (SIPD) incluent des présentations de DPT et de DPBTG.

## NON Issued for SNDS & SANDS ANC émis pour SPDN et SPADN

**SNDS / SPDN**



**SANDS / SPADN**



| SNDS / SPDN                           |         |         |         |         | SANDS / SPADN |         |         |         |         |
|---------------------------------------|---------|---------|---------|---------|---------------|---------|---------|---------|---------|
| 2002 Q2                               | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 | 2002 Q2       | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
| 6                                     | 4       | 3       | 5       | 4       | 0             | 0       | 0       | 1       | 0       |
| <b>TOTAL</b>                          |         |         |         |         |               |         |         |         |         |
| <b>CLASS / CATÉGORIE</b>              |         |         |         |         |               |         |         |         |         |
| 1                                     |         |         | 1       | 1       |               |         |         |         |         |
| Clin/C&M / Clin/C&F                   |         |         |         |         |               |         |         |         |         |
| 4                                     | 2       | 3       | 2       | 2       |               |         |         |         |         |
| Clin Only / Clin seulement            |         |         |         |         |               |         |         |         |         |
| 1                                     | 1       |         | 1       | 1       |               |         |         | 1       |         |
| Comp/C&M / Comp/C&F                   |         |         |         |         |               |         |         |         |         |
|                                       |         |         |         |         |               |         |         |         |         |
| C&M/Labeling / C&M/Étiquetage         |         |         |         |         |               |         |         |         |         |
|                                       | 1       |         | 1       |         |               |         |         |         |         |
| Rx to OTC - No New Ind. / Rx à VL pni |         |         |         |         |               |         |         |         |         |

## Documents Issued for SNDS/SANDS Documents émis pour SPDN/SPADN

| SNDS / SPDN |         |         |         |         | SANDS / SPADN  |   |   |   |   |   |
|-------------|---------|---------|---------|---------|--|---|---|---|---|---|
| 2002 Q2     | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 | DOCUMENT   |   |   |   |   |   |
| 2002 Q2     | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |  |   |   |   |   |   |
|             |         |         |         |         | Total NOC / AC total   | 5 | 0 | 2 | 5 | 9 |
|             |         |         |         |         | NOC with Conditions* / AC-conditionnels*                               |   |   |   |   |   |
|             |         |         | 1       |         | NOCc Qualifying Notice / Avis d'admissibilité à un AC C                |   |   |   |   |   |
|             |         |         |         | 2       | Issuable NOC (Patent)** / AC pouvant être émis (Brevet)**              |   |   |   | 2 | 1 |
|             |         |         |         |         | Issuable NOC (Rx-OTC)** / AC pouvant être émis (Rx à VL)**             |   |   |   |   |   |
| 18          | 13      | 13      | 15      | 24      | NOC 1 <sup>st</sup> Review*** / AC 1 <sup>er</sup> examen***           | 0 | 0 | 2 | 3 | 9 |
| 6           | 4       | 3       | 5       | 4       | NON / ANC  |   |   |   | 1 |   |
| 2           | 4       |         |         | 3       | NOD / ADI  |   |   |   | 1 |   |
| 3           |         |         | 1       | 1       | NON Withdrawal / ANC retrait   |   |   |   |   |   |
|             |         |         |         |         | NOD Withdrawal / ADI retrait   |   |   |   |   |   |
|             |         |         |         |         | Rejection Letter - Screening / Lettre de rejet lors de l'exam. prélim. |   |   |   |   |   |
| 1           | 2       | 6       | 3       | 2       | Screening Deficiency Notice / Avis d'insuff. lors de l'exam. prélim.   |   | 1 | 1 | 1 | 2 |
| 3           | 2       | 3       |         | 3       | Cancelled (Withdrawn) by Company / Annulé(Retrait) par la compagnie    |   |   |   |   |   |

\* NOC with Conditions is a subset of the total NOC, and indicates the number NOCs issued under the "Notice of Compliance with Conditions (NOC/c)" policy dated November 6, 2002.

AC-conditionnels sont un sous-ensemble du total des AC délivrés et émises en vertu de la politique sur les avis de conformité conditionnels, le 6 novembre 2002.

\*\* Issuable NOC (Patent) and Issuable NOC (Rx-OTC), are subsets of the total NOC, and indicate the number of NOC held due to Patent regulations or De-scheduling (Rx-OTC)

Les AC pouvant être émis (Brevet) et les AC pouvant être émis brevetés ou du retrait du médicament (Rx à VL) d'une annexe sont un sous-ensemble du total des AC et indiquent le nombre d'AC retenus du fait du Règlement sur les médicaments brevetés ou du retrait du médicament (Rx à VL) d'une annexe.

\*\*\* NOC 1st review is a subset of total NOC issued for submissions that have not been issued an NON or NOD and excludes refiled and administrative submissions.

Les 1<sup>er</sup> AC examen sont un sous-ensemble du total des AC émis pour les présentations qui n'ont pas reçu de AND ou de ADI et excluent les présentations ayant fait l'objet d'un nouveau dépôt et les présentations administratives.

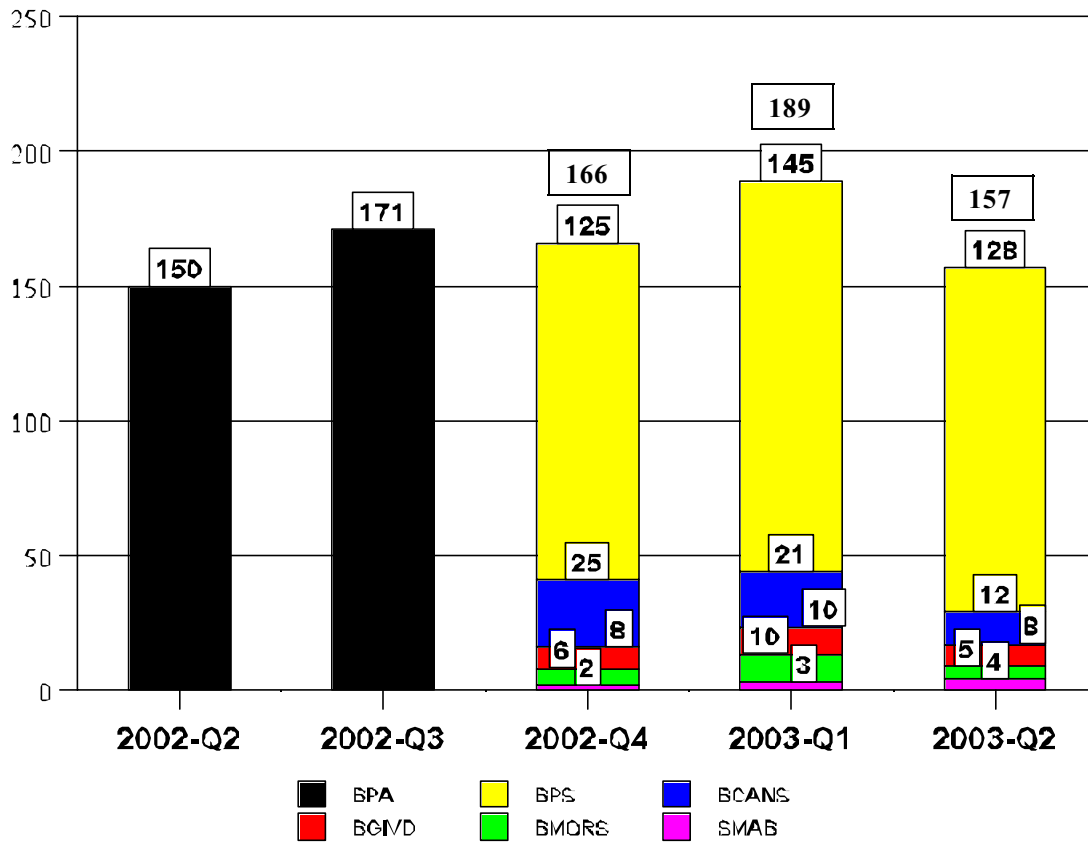
## Priority Request NDS and SNDS Received / Demandes de statut d'évaluation prioritaire PDN et SPDN reçus

| Type / Genre                        | Class / Catégorie                     | 2002 Q2  | 2002 Q3  | 2002 Q4  | 2003 Q1  | 2003 Q2  |
|-------------------------------------|---------------------------------------|----------|----------|----------|----------|----------|
| <b>Priority- NDS /Priorité-PDN</b>  |                                       |          |          |          |          |          |
|                                     | NAS / NSA                             | 2        | 2        | 1        | 2        | 1        |
|                                     | Clin Only / Clin seulement            | 1        |          |          |          |          |
|                                     | Clin/C&M / Clin/C&F                   | 1        |          | 1        |          | 1        |
| <b>Priority-SNDS /Priorité-SPDN</b> |                                       |          |          |          |          |          |
|                                     | Rx to OTC - No New Ind. / Rx à VL pri |          |          |          |          |          |
|                                     | Clin Only / Clin seulement            | 1        | 2        | 1        | 1        |          |
| <b>TOTAL</b>                        |                                       | <b>5</b> | <b>4</b> | <b>3</b> | <b>3</b> | <b>2</b> |

## Priority Request NDS and SNDS Rendered / Décisions rendues sur les demandes de statut d'évaluation prioritaire PDN et SPDN

| Type / Genre                         | Class / Catégorie                   | 2002 - Q2       |               | 2002 - Q3       |               | 2002 - Q4       |               | 2003 - Q1       |               | 2003 - Q2       |               |
|--------------------------------------|-------------------------------------|-----------------|---------------|-----------------|---------------|-----------------|---------------|-----------------|---------------|-----------------|---------------|
|                                      |                                     | Granted Accordé | Denied Refusé | Granted Accordé | Denied Refusé | Granted Accordé | Denied Refusé | Granted Accordé | Denied Refusé | Granted Accordé | Denied Refusé |
| <b>Priority-NDS / Priorité-PDN</b>   |                                     |                 |               |                 |               |                 |               |                 |               |                 |               |
|                                      | NAS / NSA                           |                 | 1             | 1               |               |                 |               | 1               |               |                 | 1             |
|                                      | Clin/C&M / Clin/C&F                 | 1               |               |                 |               |                 |               |                 |               | 1               |               |
|                                      | Clin Only / Clin seulement          |                 |               |                 | 1             |                 |               |                 |               |                 |               |
| <b>Priority-SNDS / Priorité-SPDN</b> |                                     |                 |               |                 |               |                 |               |                 |               |                 |               |
|                                      | Clin Only / Clin seulement          | 1               | 1             |                 | 2             |                 | 1             |                 | 2             |                 |               |
|                                      | Rx to OTC-No New Ind. / Rx à VL pri | 1               |               |                 |               |                 |               |                 |               |                 |               |
| <b>TOTAL</b>                         |                                     | <b>3</b>        | <b>2</b>      | <b>1</b>        | <b>3</b>      | <b>0</b>        | <b>1</b>      | <b>1</b>        | <b>2</b>      | <b>1</b>        | <b>1</b>      |

### NC Received MP reçues

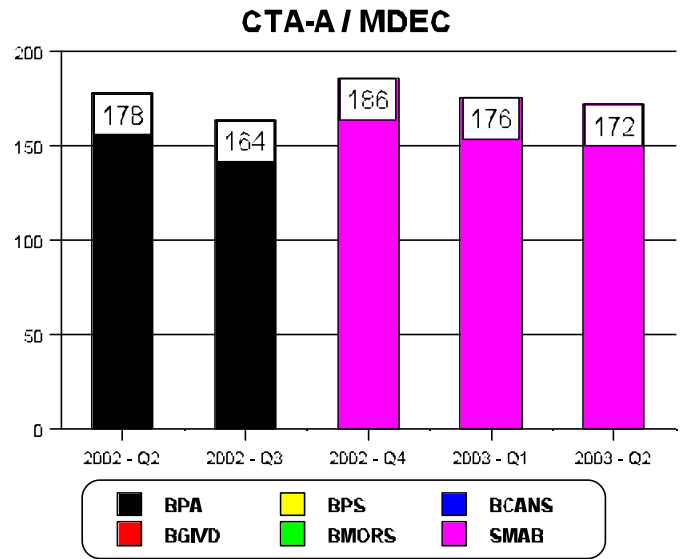
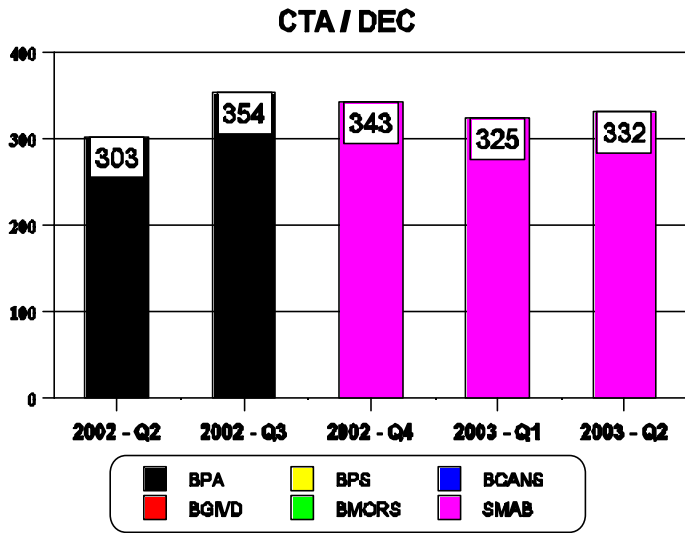


### Documents Issued for NC Documents délivrés pour MP

|   | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|---------|---------|---------|---------|---------|
| No objection Letter / Lettre de non-objection                           | 127     | 122     | 154     | 106     | 186     |
| Not Satisfactory Notice / Avis de non-satisfaction                      | 21      | 12      | 1       | 15      | 2       |
| Rejection Letter (Screening) / Lettre de rejet (examen préliminaire)    | 0       | 6       | 10      | 2       | 1       |
| Screening Deficiency Notice / Avis d'insuffisance (examen préliminaire) | 25      | 6       | 15      | 13      | 7       |
| Cancelled (Withdrawn) by Company / Annulé (Retrait) par la compagnie    | 8       | 2       | 8       | 7       | 6       |



## CTA & CTA-A Received / DEC & MDEC reçues



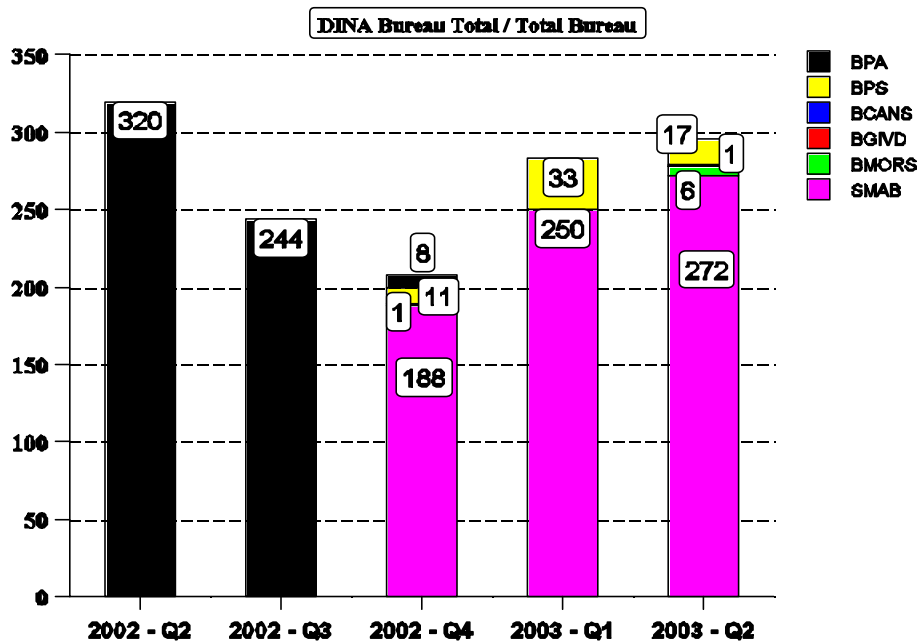
| CTA / DEC         |         |         |         |         | CTA-A / MDEC                                       |     |     |     |     |     |     |     |    |     |
|-------------------|---------|---------|---------|---------|--|-----|-----|-----|-----|-----|-----|-----|----|-----|
| 2002 Q2           | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 | TOTAL  |     |     |     |     |     |     |     |    |     |
| 302               | 354     | 343     | 325     | 332     | 178  | 164 | 186 | 176 | 172 |     |     |     |    |     |
| CLASS / CATÉGORIE |         |         |         |         |  |     |     |     |     |     |     |     |    |     |
| 136               | 171     | 175     | 161     | 159     | PH1 Bioequivalence-7 / PH1 de bioéquivalence-7     |     |     |     |     | 16  | 8   | 4   | 10 | 6   |
| 13                | 9       | 12      | 8       | 16      | PH1Healthy Human-7 / PH1 des humains en santé-7    |     |     |     |     | 1   |     | 1   | 1  | 1   |
| 4                 | 1       |         |         | 1       | PH1 Healthy Human-30 / PH1 des humains en santé-30 |     |     |     |     | 2   | 1   |     |    | 1   |
| 5                 | 10      | 12      | 16      | 9       | PH 1 Other-30 / PH1 autre-30                       |     |     |     |     | 6   | 5   | 9   | 8  | 10  |
| 43                | 63      | 55      | 49      | 67      | PH2-30 / PH2 -30                                   |     |     |     |     | 43  | 37  | 38  | 54 | 44  |
| 93                | 88      | 79      | 79      | 71      | PH3-30 / PH3-30                                    |     |     |     |     | 104 | 103 | 124 | 91 | 100 |
|                   | 1       | 3       | 2       |         | Phase 1 /2-30 / Phase 1/2-30                       |     |     |     |     | 2   | 1   | 3   | 1  | 1   |
| 4                 | 5       | 4       |         | 1       | Phase 2 /3-30 / Phase 2/3-30                       |     |     |     |     | 1   | 1   | 1   | 3  | 1   |
| 4                 | 6       | 3       | 10      | 8       | Phase Unassign-30 / Indéterminé phase-30           |     |     |     |     | 3   | 8   | 6   | 8  | 8   |

| CTA - DEC |         |         |         |         | Documents Issued for CTA & CTA-A<br>Documents émis pour les DEC & MDEC |  |  |  |  | CTA-A / MDEC |         |         |         |         |
|-----------|---------|---------|---------|---------|--|--|--|--|--|--------------|---------|---------|---------|---------|
| 2002 Q2   | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 | DOCUMENT   |  |  |  |  | 2002 Q2      | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
| 270       | 335     | 340     | 290     | 299     | No objection Letter / Lettre de non-objection                          |  |  |  |  | 173          | 161     | 172     | 172     | 160     |
|           | 1       | 2       |         |         | Not Satisfactory Notice / Avis de non-satisfaction                     |  |  |  |  |              |         |         |         |         |
| 10        | 2       |         | 5       | 4       | Cancelled (Withdrawn) by Company / Annulé(Retrait) par la compagnie    |  |  |  |  |              |         |         |         | 4       |

## DIN Applications Received Demandes de DIN reçues

| DINA  | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|---------|---------|---------|---------|---------|
| TOTAL   | 320     | 244     | 208     | 284     | 296     |
| <b>CLASS / CATÉGORIE</b>                        |         |         |         |         |         |
| Admin (Non SIPD) / Admin (non-DPPR)             | 34      | 41      | 24      | 29      | 30      |
| Form / Formule                                  | 72      | 87      | 82      | 69      | 103     |
| Form & Supp.Data/Formule+données justificatives | 24      | 10      | 11      | 14      | 21      |
| Labelling Standard / Norme d'étiquetage         | 190     | 106     | 91      | 172     | 142     |
| Admin (SIPD) / Admin (DPPR)                     | 79      | 48      | 52      | 71      | 67      |

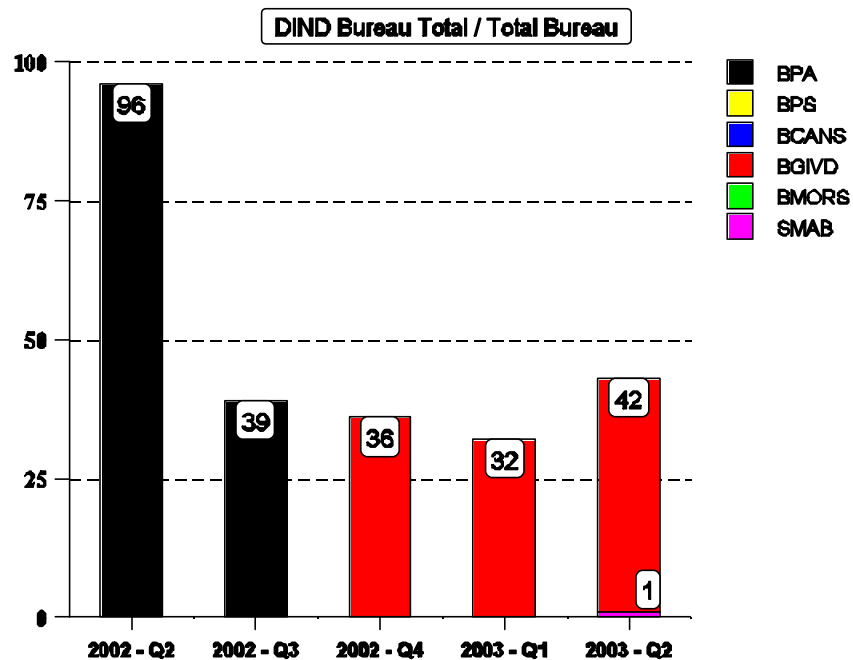
| DINA (see graph below)<br>BUREAU TOTAL / TOTAL BUREAU | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|---------|---------|---------|---------|---------|
| BPA / BEPP  | 320     | 244     | 8       |         |         |
| BPS / BSP   |         |         | 11      | 33      | 17      |
| BCANS / BCASN   |         |         | 1       |         |         |
| BGIVD / BGIMV   |         |         |         |         | 1       |
| BMORS / BMOSR   |         |         |         |         | 6       |
| SMAB / BCMP   |         |         | 188     | 250     | 272     |



## DIN Applications Received / Demandes de DIN reçues

| DIND*   | *2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|----------|---------|---------|---------|---------|
| TOTAL   | 96       | 39      | 36      | 32      | 43      |
| <b>CLASS / CATÉGORIE</b>                        |          |         |         |         |         |
| Admin (Non SIPD) / Admin (non-DPPR)             | 85       | 25      | 25      | 23      | 22      |
| Form / Formule                                  | 5        | 10      | 6       | 5       | 15      |
| Form & Supp.Data/Formule+données justificatives | 5        | 4       | 4       | 3       | 4       |
| Labelling Standard / Norme d'étiquetage         | 1        |         | 1       | 1       | 2       |
| Admin (SIPD) / Admin (DPPR)                     | 14       | 4       | 1       | 6       | 3       |

| DIND (see graph below)<br>BUREAU TOTAL / TOTAL BUREAU | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|---------|---------|---------|---------|---------|
| BPA / BEPP  | 96      | 39      |         |         |         |
| BPS / BSP   |         |         |         |         |         |
| BCANS / BCASN   |         |         |         |         |         |
| BGIVD / BGIMV   |         |         | 36      | 32      | 42      |
| BMORS / BMOSR   |         |         |         |         |         |
| SMAB / BCMP   |         |         |         |         | 1       |



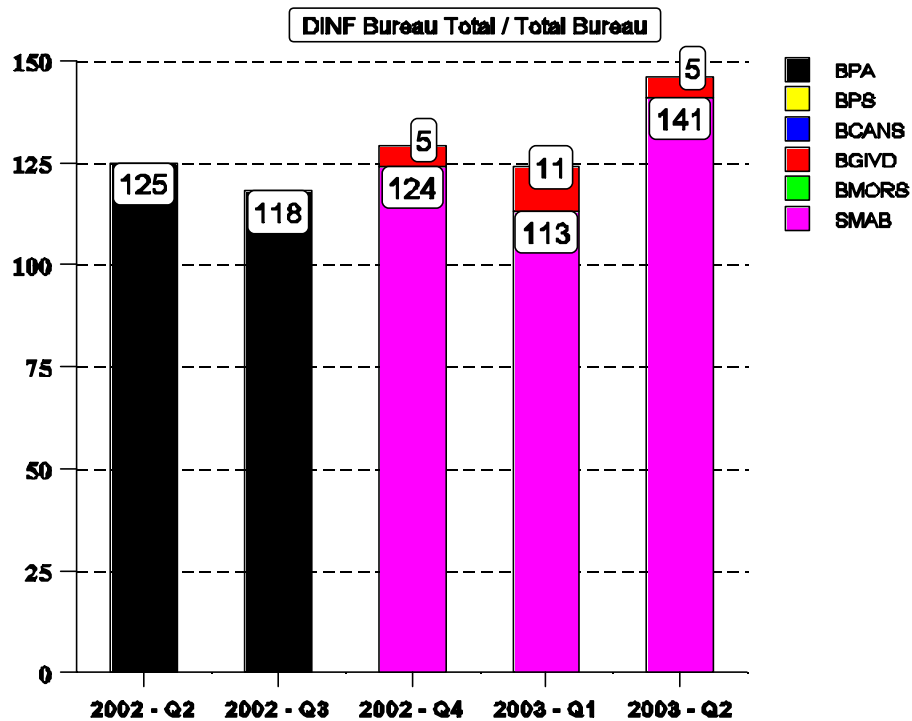
\*Note: The total received for DIND increased significantly due to the conversion of PCP to DIND.

\* Note: Les demandes de DIND reçues ont augmenté de manière significative dû à l'intégration des produits autiparasitaires (PCP) au DIND.

## DIN Applications Received Demandes de DIN reçues

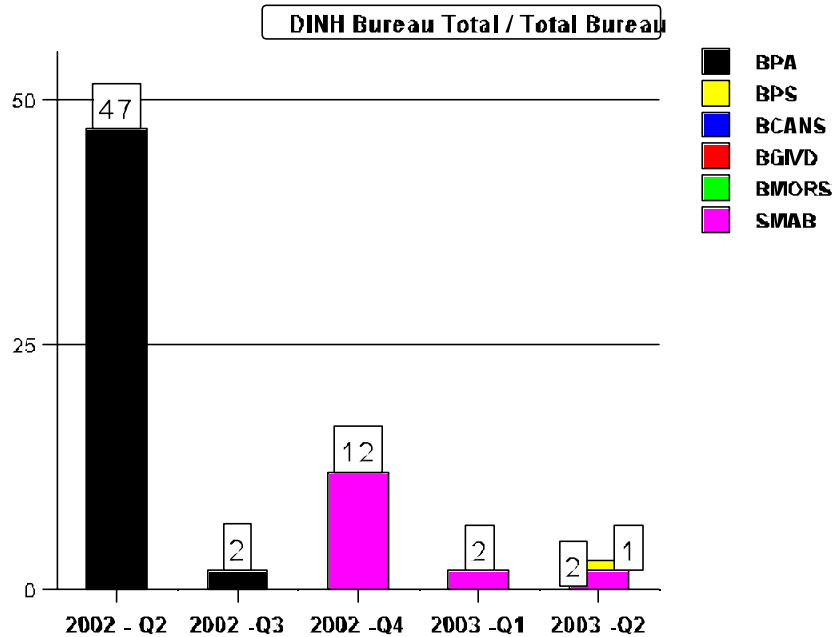
| DINF                                    | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|---------|---------|---------|---------|---------|
| TOTAL                                   | 125     | 118     | 129     | 124     | 146     |
| <b>CLASS / CATÉGORIE</b>                |         |         |         |         |         |
| Labelling Standard / Norme d'étiquetage | 125     | 118     | 129     | 124     | 146     |

| DINF (see graph below)<br>BUREAU TOTAL / TOTAL BUREAU | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|---------|---------|---------|---------|---------|
| BPA / BEPP  | 125     | 118     |         |         |         |
| BPS / BSP   |         |         |         |         |         |
| BCANS / BCASN   |         |         |         |         |         |
| BGIVD / BGIMV   |         |         | 5       | 11      | 5       |
| BMORS / BMOSR   |         |         |         |         |         |
| SMAB / BCMP   |         |         | 124     | 113     | 141     |



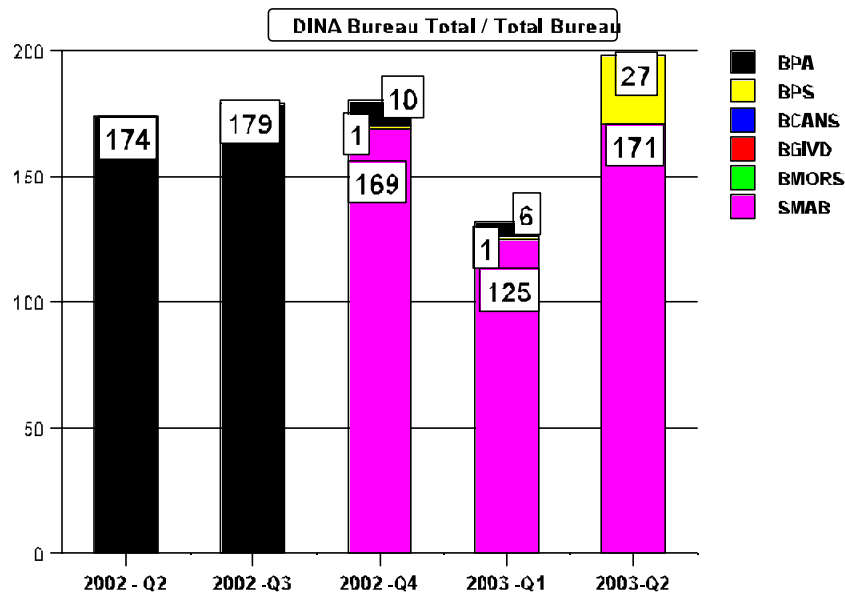
## DIN Applications Received Demandes de DIN reçues

| DINH  | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|---------|---------|---------|---------|---------|
| TOTAL   | 47      | 2       | 12      | 2       | 3       |
| <b>CLASS / CATÉGORIE</b>                                      |         |         |         |         |         |
| Admin (Non SIPD) / Admin (non-DPPR)                           |         |         | 2       |         |         |
| Form / Formule  | 37      |         | 4       |         |         |
| Form & Supp.Data/Formule+données justificatives               |         | 1       | 4       | 1       | 1       |
| Labelling Standard / Norme d'étiquetage                       | 10      | 1       | 2       | 1       | 2       |
| <b>DINH (see graph below)<br/>BUREAU TOTAL / TOTAL BUREAU</b> |         |         |         |         |         |
| BPA / BEPP  | 47      | 2       |         |         |         |
| BPS / BSP   |         |         |         |         | 1       |
| BCANS / BCASN   |         |         |         |         |         |
| BGIVD / BGIMV   |         |         |         |         |         |
| BMORS / BMOSR   |         |         |         |         |         |
| SMAB / BCMP   |         |         | 12      | 2       | 2       |



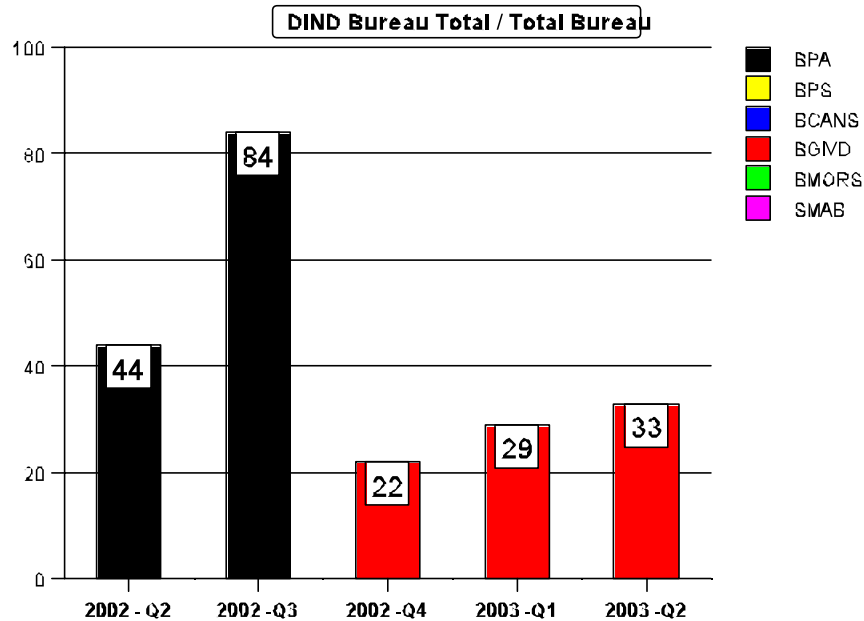
### DINs Issued / DINs émis

| DINA   | 2002 Q2        | 2002 Q3        | 2002 Q4        | 2003 Q1        | 2003 Q2        |
|--|----------------|----------------|----------------|----------------|----------------|
|  | TOTAL          | 174            | 179            | 180            | 132            |
| <b>CLASS / CATÉGORIE</b>                             |                |                |                |                |                |
| Admin (Non SIPD) / Admin (non-DPPR)                  | 26             | 20             | 39             | 24             | 16             |
| Form / Formule                                       | 43             | 25             | 47             | 30             | 42             |
| Form & Supp.Data/Formule+données justificatives      | 7              | 4              | 7              | 10             | 15             |
| Labelling Standard / Norme d'étiquetage              | 98             | 130            | 87             | 68             | 125            |
| Admin (SIPD) / Admin (DPPR)                          | 77             | 55             | 53             | 53             | 88             |
| Cancelled (Withdrawn) by co./Annulé (Retrait) par la | 13             | 8              | 11             | 24             | 22             |
| <b>DINA (see graph below)</b>                        |                |                |                |                |                |
| <b>BUREAU TOTAL / TOTAL BUREAU</b>                   | <b>2002 Q2</b> | <b>2002 Q3</b> | <b>2002 Q4</b> | <b>2003 Q1</b> | <b>2003 Q2</b> |
| BPA / BEPP   | 174            | 179            | 10             | 6              |                |
| BPS / BSP  |                |                | 1              | 1              | 27             |
| BCANS / BCASN  |                |                |                |                |                |
| BGIVD / BGIMV  |                |                |                |                |                |
| BMORS / BMOSR  |                |                |                |                |                |
| SMAB / BCMP  |                |                | 169            | 125            | 171            |



### DINs Issued / DINs émis

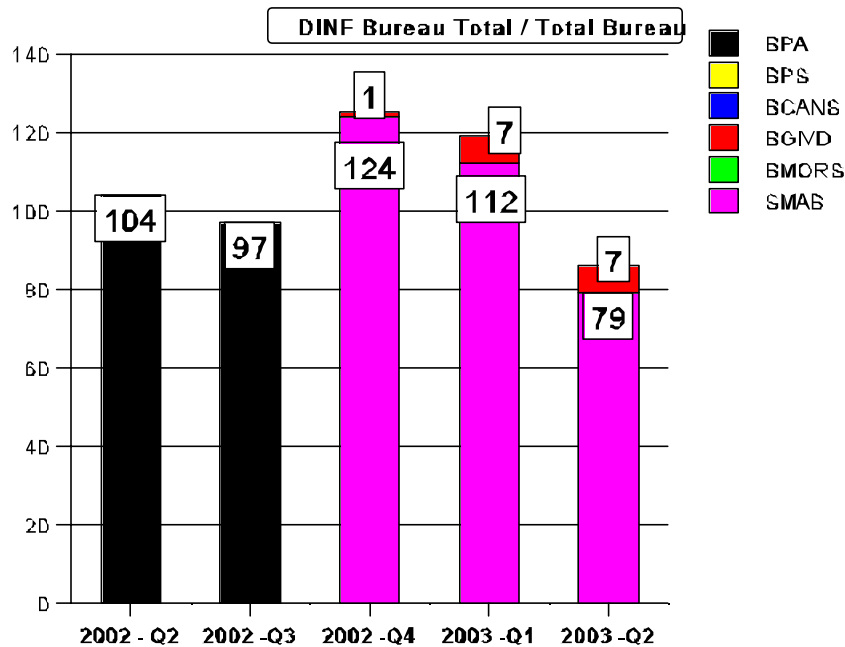
| DIND  | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|---------|---------|---------|---------|---------|
| TOTAL   | 44      | 84      | 22      | 29      | 33      |
| <b>CLASS / CATÉGORIE</b>                                  |         |         |         |         |         |
| Admin (Non SIPD) / Admin (non-DPPR)                       | 27      | 77      | 8       | 23      | 28      |
| Form / Formule  | 6       | 3       | 9       | 4       | 4       |
| Form & Supp.Data/Formule+données justificatives           | 9       | 3       | 4       | 2       | 1       |
| Labelling Standard / Norme d'étiquetage                   | 2       | 1       | 1       |         |         |
| Admin (SIPD) / Admin (DPPR)                               | 13      | 6       | 1       | 4       | 5       |
| <b>DIND (see graph below) BUREAU TOTAL / TOTAL BUREAU</b> |         |         |         |         |         |
| BPA / BEPP  | 44      | 84      |         |         |         |
| BPS / BSP   |         |         |         |         |         |
| BCANS / BCASN   |         |         |         |         |         |
| BGIVD / BGIMV   |         |         | 22      | 29      | 33      |
| BMORS / BMOSR   |         |         |         |         |         |
| SMAB / BCMP   |         |         |         |         |         |



## DINs Issued / DINs émis

| DINF  | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|---------|---------|---------|---------|---------|
| TOTAL   | 104     | 97      | 125     | 119     | 86      |
| <b>CLASS / CATÉGORIE</b>  |         |         |         |         |         |
| Labelling Standard / Norme d'étiquetage                         | 104     | 97      | 125     | 119     | 86      |
| Cancelled (Withdrawn) by co / Annulé (Retrait) par la compagnie | 6       | 1       | 1       |         | 5       |

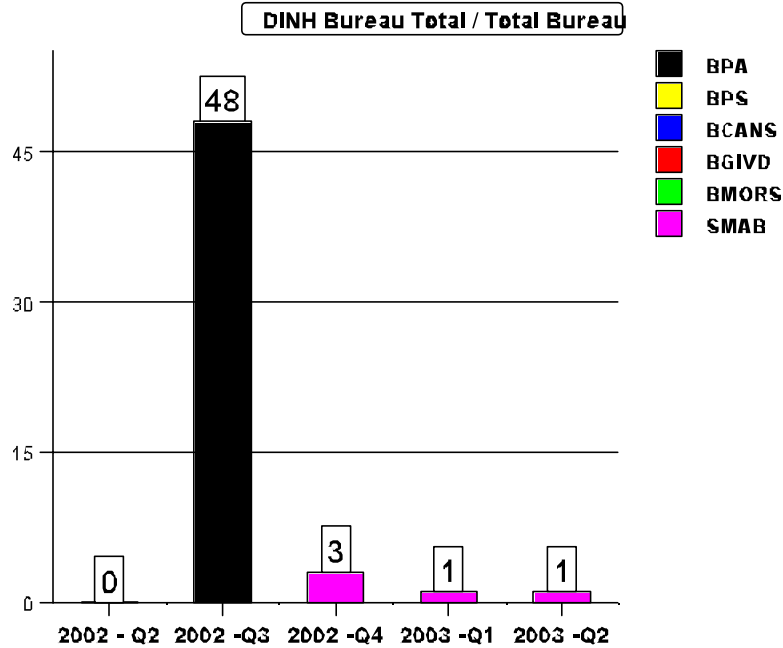
| DINF (see graph below)<br>BUREAU TOTAL / TOTAL BUREAU | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|---------|---------|---------|---------|---------|
| BPA / BEPP  | 104     | 97      |         |         |         |
| BPS / BSP   |         |         |         |         |         |
| BCANS / BCASN   |         |         |         |         |         |
| BGIVD / BGIMV   |         |         | 1       | 7       | 7       |
| BMORS / BMOSR   |         |         |         |         |         |
| SMAB / BCMP   |         |         | 124     | 112     | 79      |





### DINs Issued / DINs émis

| DINH  | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|---------|---------|---------|---------|---------|
| TOTAL   | 0       | 48      | 3       | 1       | 1       |
| <b>CLASS / CATÉGORIE</b>                                  |         |         |         |         |         |
| Admin (Non SIPD) / Admin (non-DPPR)                       |         |         |         | 1       | 1       |
| Form / Formule  |         |         |         |         |         |
| Form & Supp.Data / Formule+données justificatives         |         | 1       | 3       |         |         |
| Labelling Standard / Norme d'étiquetage                   |         | 47      |         |         |         |
| <b>DINH (see graph below) BUREAU TOTAL / TOTAL BUREAU</b> |         |         |         |         |         |
| BPA / BEPP  | 0       | 48      | 3       |         |         |
| BPS / BSP   |         |         |         |         |         |
| BCANS / BCASN   |         |         |         |         |         |
| BGIVD / BGIMV   |         |         |         |         |         |
| BMORS / BMOSR   |         |         |         |         |         |
| SMAB / BCMP   |         |         |         | 1       | 1       |



## Documents Issued by class for DINA (p 1 of 2) Documents émis par catégories pour Demande DINA (p 1 de 2)

| CLASS/CATÉGORIE                           | DOCUMENT   | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|--|---------|---------|---------|---------|---------|
|   | Total DIN<br><i>DIN total</i>  | 174     | 179     | 180     | 132     | 198     |
|   | *DIN 1 <sup>st</sup> Review<br><i>*DIN 1<sup>er</sup> examen</i>                           | (141)   | (156)   | (136)   | (99)    | (179)   |
| <b>Admin (Non-SIPD) / Admin(non-DPPR)</b> |  |         |         |         |         |         |
|   | Rejection Letter Screening<br><i>Lettre de rejet lors de l'exam.prelim.</i>                |         |         | 2       |         | 3       |
|   | Screening Deficiency Notice<br><i>Avis d'insuff. lors de l'exam. prelim.</i>               | 3       |         | 3       | 4       |         |
| <b>Form / Formule</b>                     |  |         |         |         |         |         |
|   | NON<br>ANC   | 18      | 4       | 8       | 10      | 2       |
|   | NOD<br>ADI   | 2       | 4       |         | 1       |         |
|   | NON Withdrawal<br><i>ANC retrait</i>   |         | 1       | 1       |         | 1       |
|   | New Drug Letter<br><i>Lettre drogue nouvelle</i>   | 5       | 4       | 3       | 3       | 4       |
|   | Screening Deficiency Notice<br><i>Avis d'insuff. lors de l'exam. prelim.</i>               | 8       | 10      | 9       | 19      | 7       |
|   | Rejection Letter Screening<br><i>Lettre de rejet lors de l'exam. prelim.</i>               | 5       | 6       | 3       | 4       | 7       |
|   | Labelling Standard Letter<br><i>Lettre de norme d'étiquetage</i>                           | 3       | 6       | 2       | 4       | 3       |
|   | Withdrawal Unaccep. Response to NON Screening<br><i>Retrait réponse à ANC inacceptable</i> | 1       | 1       |         | 1       | 1       |
|   | Withdrawal no response to NON<br><i>Retrait aucune réponse au ANC</i>                      | 7       | 9       |         | 4       | 4       |
|   | Withdrawal no response to NOD<br><i>Retrait aucune réponse au ADI</i>                      |         | 3       | 2       |         | 1       |

\* DIN 1st review is a subset of total DINs issued for submissions that have not been issued an NON or NOD and excludes administrative submissions.  
Les DIN 1<sup>er</sup> examen sont un sous-ensemble du total des DIN émis pour les présentations qui n'ont pas reçu de ANC ou de ADI & excluent les présentations administratives.

## Documents Issued by class for DINA (p 2 of 2) Documents émis par catégories pour Demande DINA (p 2 de 2)

| CLASS/CATÉGORIE  | DOCUMENT  | 2002<br>Q2 | 2002<br>Q3 | 2002<br>Q4 | 2003<br>Q1 | 2003<br>Q2 |
|--|---|------------|------------|------------|------------|------------|
| <b>Form &amp; Supporting Data / Formule + données justificatives</b> |   |            |            |            |            |            |
|  | NON<br>ANC  | 6          | 2          | 6          | 1          |            |
|  | NOD<br>ADI  | 1          |            |            |            |            |
|  | NON Withdrawal<br>ANC retrait   |            | 1          |            |            |            |
|  | New Drug Letter<br>Lettre drogue nouvelle                             | 1          |            | 3          | 1          | 1          |
|  | Extension Letter<br>Lettre de prolongation                            |            |            |            |            |            |
|  | Screening Deficiency Notice<br>Avis d'insuff. lors de l'exam. prélim. | 7          | 1          | 5          | 8          | 6          |
|  | Rejection Letter Screening<br>Lettre de rejet lors de l'exam. prélim. | 4          | 4          | 4          | 3          |            |
|  | Withdrawal no response to NOD<br>Retrait aucune réponse au ADI        |            |            |            |            |            |
|  | Withdrawal no response to NON<br>Retrait aucune réponse au ANC        | 1          | 4          | 2          | 1          | 2          |
| <b>Labelling Standard / Norme d'étiquetage</b>                       |   |            |            |            |            |            |
|  | Extension Letter<br>Lettre de prolongation                            |            | 1          |            |            |            |
|  | Screening Deficiency Notice<br>Avis d'insuff. lors de l'exam. prélim. | 18         | 25         | 28         | 38         | 30         |
|  | Rejection Letter Screening<br>Lettre de rejet lors de l'exam. prélim. | 7          | 8          | 10         | 21         | 18         |
|  | Labelling Standard Letter<br>Lettre de norme étiquetage               | 4          | 1          | 2          | 4          |            |
|  | New Drug Letter<br>Lettre drogue nouvelle                             |            | 1          |            |            | 3          |

\* DIN 1st review is a subset of total DINs issued for submissions that have not been issued an NON or NOD and excludes administrative submissions.  
Les DIN 1<sup>er</sup> examen sont un sous-ensemble du total des DIN émis pour les présentations qui n'ont pas reçu de ANC ou de ADI & excluent les présentations administratives.

**Documents Issued by class: DIND**  
**Documents émis par catégories: DIND**

| CLASS/CATÉGORIE   | DOCUMENT   | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|--|---------|---------|---------|---------|---------|
|   | Total DIN<br>DIN total   | 44      | 84      | 22      | 29      | 33      |
|   | *DIN 1 <sup>st</sup> Review<br>*DIN 1 <sup>er</sup> examen           | (13)    | (5)     | (4)     | (6)     | (31)    |
| <b>Admin (Non-SIPD) / Admin (non-DPPR)</b>                      |  |         |         |         |         |         |
|   | Rejection Letter Screening / Lettre de rejet lors de l'exam.prélim   |         | 1       |         | 3       | 1       |
| <b>Form / Formule</b>   |  |         |         |         |         |         |
|   | NON/ANC  |         | 3       | 8       |         |         |
|   | Screening Deficiency Notice / Avis d'insuff. lors de l'exam.prélim.  | 1       | 1       |         | 1       |         |
|   | Rejection Letter Screening / Lettre de rejet lors de l'exam. prélim. |         | 1       |         |         |         |
| <b>Form &amp; Supporting / Formule + données justificatives</b> |  |         |         |         |         |         |
|   | NOD<br>ADI   | 1       |         |         |         |         |
|   | NON<br>ANC   | 3       | 3       | 3       |         | 1       |
|   | NON Withdrawal / ANC retrait   |         |         | 1       |         |         |
|   | Screening Deficiency Notice / Avis d'insuff. lors de l'exam.prélim.  |         |         |         |         | 1       |
|   | Withdrawal no response to NON / Retrait aucune réponse au ANC        |         |         |         | 1       |         |

**Documents Issued: DINF / Documents émis: DINF**

| CLASS/CATÉGORIE                                | DOCUMENT   | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|--|--|---------|---------|---------|---------|---------|
|  | Total DIN / DIN total  | 104     | 97      | 125     | 119     | 86      |
| <b>Labelling Standard / Norme d'étiquetage</b> |  |         |         |         |         |         |
|  | Screening Deficiency Notice/ Avis d'insuff. lors de l'exam.prélim. | 4       | 5       | 4       | 5       | 1       |
|  | Rejection Letter Screening /Lettre de rejet lors de l'exam.prélim. | 14      | 1       | 2       | 5       |         |
|  | Labelling Standard Letter / Lettre de norme d'étiquetage           | 2       | 4       | 6       | 2       | 1       |

**Documents Issued: DINH / Documents émis: DINH**

| CLASS/CATÉGORIE   | DOCUMENT   | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|--|---------|---------|---------|---------|---------|
|   | Total DIN<br>DIN total                                     | 0       | 48      | 3       | 1       | 1       |
|   | *DIN 1 <sup>st</sup> Review<br>*DIN 1 <sup>er</sup> examen | (0)     | (48)    | (3)     | (0)     | (1)     |
| <b>Form &amp; Supporting / Formule + données justificatives</b> |  |         |         |         |         |         |
|   | NON<br>ANC   |         | 1       |         |         |         |

\* DIN 1st review is a subset of total DINs issued for submissions that have not been issued an NON or NOD and excludes submissions processed administratively by TPD.  
Les DIN 1<sup>er</sup> examen sont un sous-ensemble du total des DIN délivrés pour les présentations qui n'ont pas eu d'émissions de ANC & de ADI & excluent les présentations traitées par les services admin. du Bureau de l'évaluation des produits pharmaceutiques.

**SECTION 2 - Appeals /**  
***SECTION 2 - Appels***

## Level 1 Appeals Received / Appels du premier palier reçus

| Type / Genre         | Class / Catégorie   | 2000      | 2001      | 2002      | 2003     |
|----------------------|---|-----------|-----------|-----------|----------|
| <b>DINA</b>          |   |           |           |           |          |
|                      | Administrative / Administrative                           |           | 1         |           |          |
|                      | Form / Formule  | 1         | 1         | 1         |          |
|                      | Form + Supporting Data / Formule + données justificatives |           | 9         |           |          |
|                      | Labelling Standard / Norme d'étiquetage                   | 1         | 6         | 3         |          |
| <b>DINH</b>          |   |           |           |           |          |
|                      | Labelling Standard / Norme d'étiquetage                   |           | 1         |           |          |
| <b>DIND</b>          |   |           |           |           |          |
|                      | Form + Supporting Data / Formule + données justificatives |           |           | 1         |          |
| <b>NDS / PDN</b>     |   |           |           |           |          |
|                      | Administrative / Administrative                           |           | 1         |           |          |
|                      | Priority-NAS / Priorité-NSA                               |           |           |           |          |
|                      | NAS / NSA   |           | 1         | 2         |          |
|                      | Clin/C&M / Clin/C&F                                       |           | 3         | 2         | 2        |
| <b>ANDS / PADN</b>   |   |           |           |           |          |
|                      | C&M/Labelling / C&F/Étiquetage                            |           | 2         |           |          |
|                      | Comp/C&M / Comp/C&F                                       | 3         | 5         | 5         |          |
| <b>SNDS / SPDN</b>   |   |           |           |           |          |
|                      | Comp/C&M / Comp/C&F                                       |           | 1         | 1         |          |
|                      | Clin Only / Clin seulement                                | 2         | 1         | 1         |          |
|                      | Clin/C&M / Clin/C&F                                       | 1         |           |           |          |
| <b>SANDS / SPADN</b> |   |           |           |           |          |
|                      | Comp/C&M / Comp/C&F                                       | 1         |           |           |          |
| <b>INDS / PDNR</b>   |   |           |           |           |          |
|                      | Regular / régulier  | 1         |           |           |          |
| <b>NC / MP</b>       |   |           |           |           |          |
|                      | Regular / régulier  | 1         | 1         |           |          |
| <b>TOTAL</b>         |   | <b>11</b> | <b>35</b> | <b>16</b> | <b>2</b> |

## Level 1 Appeals Rendered Décisions d'appels du premier palier rendues

| Type / Genre         | Class / Catégorie                                | 2000               |                  | 2001               |                  | 2002               |                  | 2003               |                  |
|----------------------|--|--------------------|------------------|--------------------|------------------|--------------------|------------------|--------------------|------------------|
|                      |  | Granted<br>Accordé | Denied<br>Refusé | Granted<br>Accordé | Denied<br>Refusé | Granted<br>Accordé | Denied<br>Refusé | Granted<br>Accordé | Denied<br>Refusé |
| <b>DINA</b>          |  |                    |                  |                    |                  |                    |                  |                    |                  |
|                      | Administrative / Administrative                  |                    |                  | 1                  |                  |                    |                  |                    |                  |
|                      | Form / Formule                                   |                    | 1                |                    | 1                |                    |                  |                    |                  |
|                      | Form + Supporting Data / Formule + données just. |                    |                  |                    | 9                |                    |                  |                    |                  |
|                      | Labelling Standard / Norme d'étiquetage          |                    | 1                | 1                  | 4                | 1                  |                  |                    |                  |
| <b>DIND</b>          |  |                    |                  |                    |                  |                    |                  |                    |                  |
|                      | Form + Supporting Data / Formule + données just. |                    |                  |                    |                  |                    |                  |                    | 1                |
| <b>DINH</b>          |  |                    |                  |                    |                  |                    |                  |                    |                  |
|                      | Labelling Standard / Norme d'étiquetage          |                    |                  |                    | 1                |                    |                  |                    |                  |
| <b>NDS / PDN</b>     |  |                    |                  |                    |                  |                    |                  |                    |                  |
|                      | Priority NAS / Priorité-NSA                      | 1                  |                  |                    |                  |                    |                  |                    |                  |
|                      | NAS / NSA  |                    | 2                |                    |                  | 1                  | 1                |                    | 1                |
|                      | Clin/C&M / Clin/C&F                              |                    |                  | 1                  | 1                | 1                  | 1                | 1                  | 1                |
|                      | Administrative / Administrative                  |                    |                  |                    |                  |                    | 1                |                    |                  |
| <b>ANDS / PADN</b>   |  |                    |                  |                    |                  |                    |                  |                    |                  |
|                      | C&M/Labelling / C&F/Étiquetage                   |                    |                  | 1                  | 1                |                    |                  |                    |                  |
|                      | Comp/C&M / Comp/C&F                              | 1                  | 5                |                    | 6                |                    | 5                |                    |                  |
| <b>SANDS / SPADN</b> |  |                    |                  |                    |                  |                    |                  |                    |                  |
|                      | Comp/C&M / Comp/C&F                              |                    |                  |                    | 1                |                    |                  |                    |                  |
| <b>SNDS / SPDN</b>   |  |                    |                  |                    |                  |                    |                  |                    |                  |
|                      | Priority-Clin/C&M / Priorité-Clin/C&F            | 1                  |                  |                    |                  |                    |                  |                    |                  |
|                      | Clin Only / Clin seulement                       |                    | 1                |                    | 2                |                    | 1                |                    |                  |
|                      | Comp/C&M / Comp/C&F                              |                    |                  |                    | 1                |                    | 1                |                    |                  |
|                      | Clin/C&M / Clin/C&F                              |                    |                  | 1                  |                  |                    |                  |                    |                  |
| <b>NC / MP</b>       |  |                    |                  |                    |                  |                    |                  |                    |                  |
|                      | Regular / régulier                               |                    |                  |                    |                  |                    | 1                |                    |                  |
| <b>TOTAL</b>         |  | <b>3</b>           | <b>10</b>        | <b>6</b>           | <b>27</b>        | <b>3</b>           | <b>11</b>        | <b>1</b>           | <b>3</b>         |

## Level 2 Appeals Received / Appels du deuxième palier reçus

| Type / Genre  | Class / Catégorie          | 2000     | 2001     | 2002     | 2003     |
|---------------|----------------------------|----------|----------|----------|----------|
| NC / MP       |                            |          |          |          |          |
|               | Regular / régulier         |          | 1        |          |          |
| NDS / PDN     |                            |          |          |          |          |
|               | Clin/C&M / Clin/C&F        |          |          | 1        |          |
| ANDS / PADN   |                            |          |          |          |          |
|               | Comp/C&M / Comp/C&F        | 4        |          |          |          |
| SNDS / SPDN   |                            |          |          |          |          |
|               | Comp/C&M / Comp/C&F        |          | 1        |          |          |
|               | Clin Only / Clin seulement |          |          | 1        |          |
| SANDS / SPADN |                            |          |          |          |          |
|               | Comp/C&M / Comp/C&F        |          | 1        |          |          |
| <b>TOTAL</b>  |                            | <b>4</b> | <b>4</b> | <b>2</b> | <b>0</b> |

## Level 2 Appeals Rendered / Décisions d'appels du deuxième palier rendues

| Type / Genre | Class / Catégorie          | 2000               |                  | 2001               |                  | 2002               |                  | 2003               |                  |
|--------------|----------------------------|--------------------|------------------|--------------------|------------------|--------------------|------------------|--------------------|------------------|
|              |                            | Granted<br>Accordé | Denied<br>Refusé | Granted<br>Accordé | Denied<br>Refusé | Granted<br>Accordé | Denied<br>Refusé | Granted<br>Accordé | Denied<br>Refusé |
| NDS / PDN    |                            |                    |                  |                    |                  |                    |                  |                    |                  |
|              | NAS / NSA                  | 1                  | 1                |                    |                  |                    |                  |                    | 1                |
|              | Clin/C&M / Clin/C&F        |                    | 1                |                    |                  |                    |                  | 1                  |                  |
|              | Comp/C&M / Comp C&F        |                    |                  | 1                  | 1                |                    |                  |                    |                  |
| ANDS / PADN  |                            |                    |                  |                    |                  |                    |                  |                    |                  |
|              | Comp/C&M / Comp/C&F        | 1                  | 3                |                    | 1                |                    |                  |                    |                  |
| SNDS / SPDN  |                            |                    |                  |                    |                  |                    |                  |                    |                  |
|              | Comp/C&M / Comp C&F        |                    |                  |                    |                  | 1                  |                  |                    |                  |
|              | Rx to OTC-New / Rx à VL ni |                    | 1                |                    |                  |                    |                  |                    |                  |
| <b>TOTAL</b> |                            | <b>2</b>           | <b>5</b>         | <b>1</b>           | <b>2</b>         | <b>1</b>           | <b>0</b>         | <b>1</b>           | <b>1</b>         |

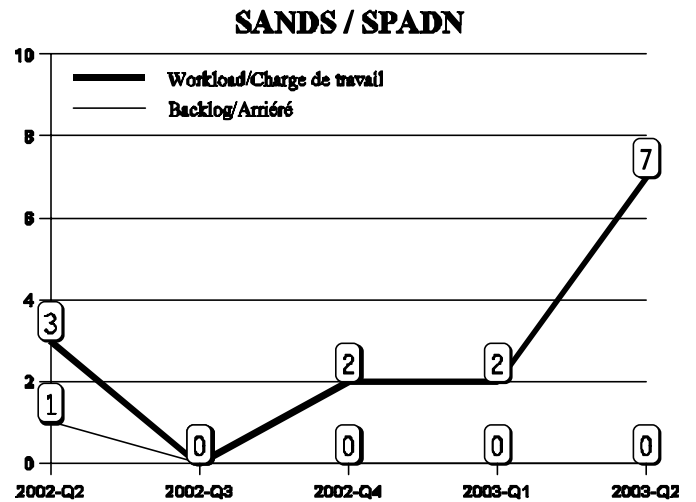
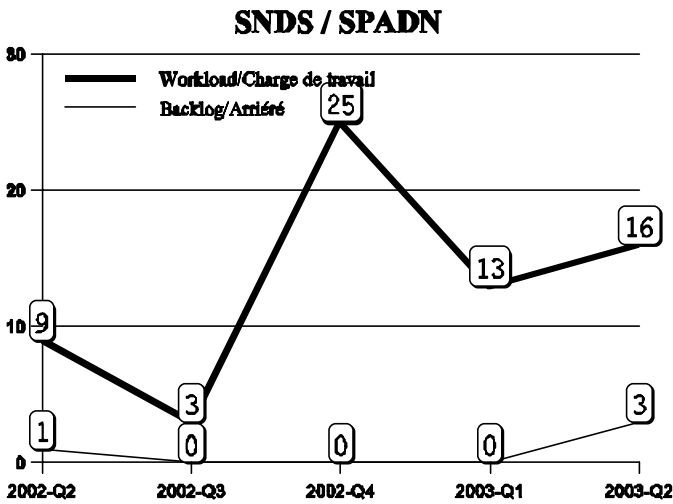
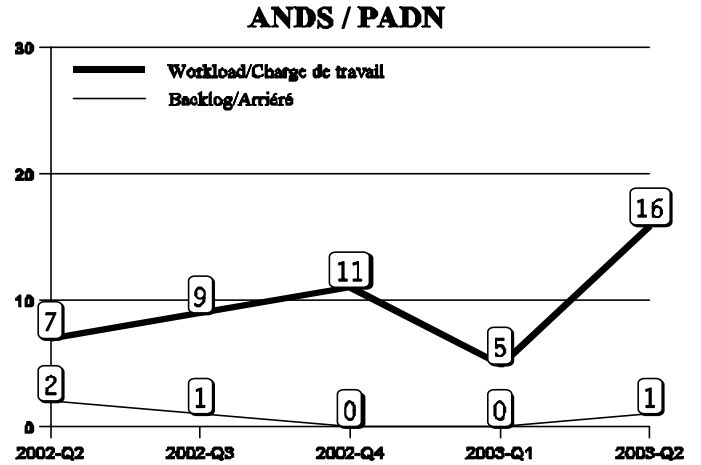
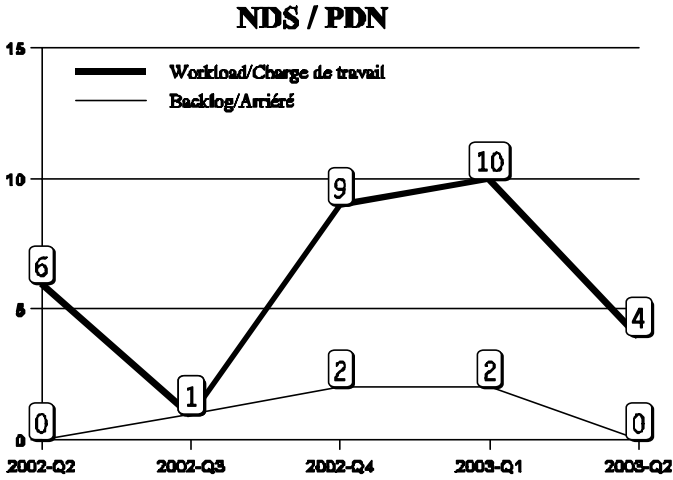


## **SECTION 3 - Workload & Backlog /**

### ***SECTION 3- Charge de travail et arriéré***

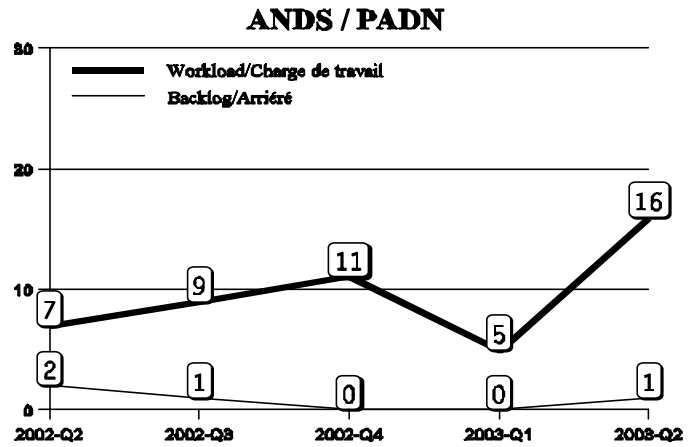
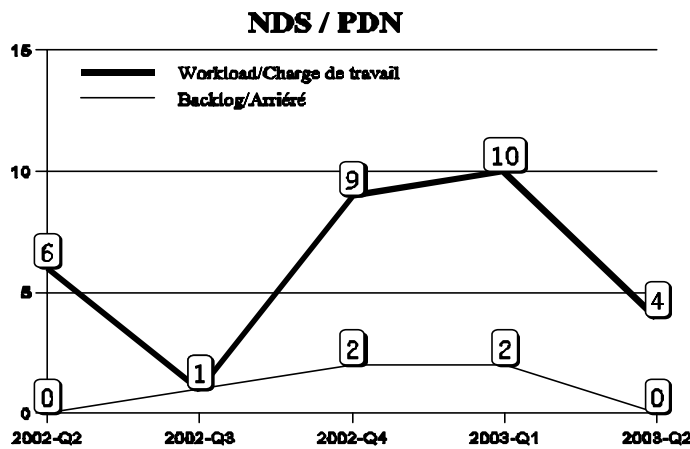
Bureau breakdown shown for ANDS, NDS, SNDS and SANDS for Q1 and Q2 of 2003.  
*Détail du bureau montré pour les PADN, PDN, SPDN et SPADN pour Q1 et Q2 à 2003.*

## SCREENING - Workload / Backlog by submission type and year L'EXAMEN PRÉLIMINAIRE - Charge de travail / Arriéré par type et année



**NOTE:** "Work load" is a count of all submission's in Screening 1 or Screening 2 on the final day of the quarter  
 "Backlog" is a subset of Workload and indicates the number of submission's that have exceeded their Performance Targets.  
 "Charge de travail" est le calcul de toutes les présentations dans Examen préliminaire 1 or Examen préliminaire 2 à de la dernière journée du trimestre  
 "Arriéré" est un sous-ensemble de la Charge de travail qui indique le nombre de présentations qui ont excédées leurs objectifs de performance.

## Screening - Workload/Backlog L'examen préliminaire - Charge de travail / Arriéré

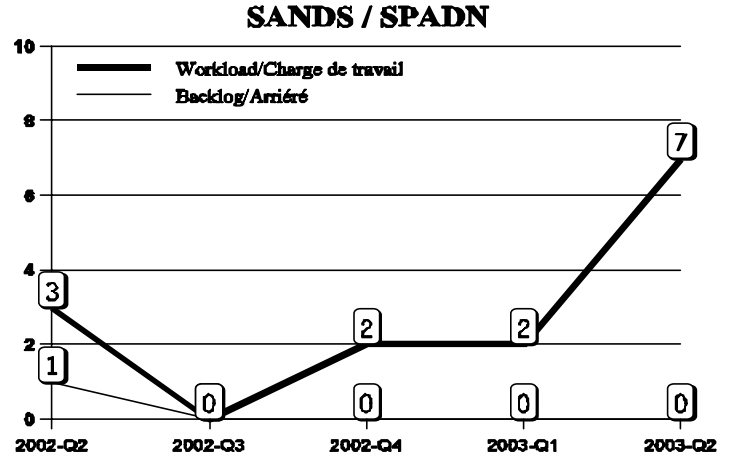
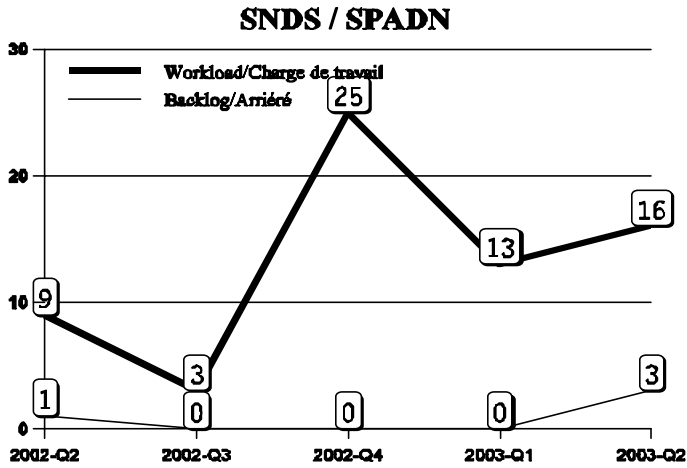


| NDS / PDN |         |         |         |         | ANDS / PADN                                  |       |                             |         |         |         |         |         |
|-----------|---------|---------|---------|---------|--|-------|-----------------------------|---------|---------|---------|---------|---------|
| 2002 Q2   | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 | Workload (Backlog)                           | TOTAL | Charge de travail (Arriéré) | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
| 6 (0)     | 1 (1)   | 9 (2)   | 10 (2)  | 4 (0)   |  |       |                             | 7 (2)   | 9 (1)   | 11 (0)  | 5 (0)   | 16 (1)  |
| 1(0)      | 1(1)    |         |         |         | Priority-Clin Only / Priorité-Clin seulement |       |                             |         |         |         |         |         |
|           |         |         |         |         | Priority-Clin/C&M / Priorité-Clin/C&F        |       |                             |         |         |         |         |         |
|           |         |         | 1(0)    |         | Priority-NAS / Priorité -NSA                 |       |                             |         |         |         |         |         |
| 3(0)      |         | 3(1)    | 3(0)    | 2(0)    | NAS / NSA                                    |       |                             |         |         |         |         |         |
|           |         |         | 1(0)    |         | NOC-c Clin/C&M / AC-c Clin/C&F               |       |                             |         |         |         |         |         |
| 2(0)      |         | 3(0)    | 3(0)    | 2(0)    | Clin/C&M / Clin/C&F                          |       |                             |         |         |         |         |         |
|           |         | 1(0)    | 1(1)    |         | Clin Only / Clin seulement                   |       |                             |         |         |         |         |         |
|           |         | 2(1)    | 1(1)    |         | Comp/C&M / Comp/C&F                          |       | 8(1)                        | 8(0)    | 3(0)    | 3(0)    | 13(1)   |         |
|           |         |         |         |         | C&M/ Labelling / C&F/Étiquetage              |       | 1(0)                        | 3(0)    | 2(0)    | 2(0)    | 3(0)    |         |

| NDS / PDN | 2003 Q1 | 2003 Q2 | BUREAU Workload (Backlog) | 2003 Q1 | 2003 Q2 | ANDS / PADN |
|-----------|---------|---------|---------------------------|---------|---------|-------------|
|           |         |         |                           |         |         |             |
|           |         |         | BPA / BEPP                |         |         |             |
|           |         |         | BPS / BSP                 | 5(0)    | 16(1)   |             |
|           | 2(0)    | 3(0)    | BCANS / BCASN             |         |         |             |
|           | 2(0)    | 1(0)    | BGIVD / BGIMV             |         |         |             |
|           | 4(1)    |         | BMORS / BMOSR             |         |         |             |
|           | 2(1)    |         | SMAB / BCMP               |         |         |             |

As of June 30, 2003, the average number of days in BACKLOG is: NDS - 0 days ; ANDS - 7 days  
 Au 30 juin, 2003 le nombre moyen de jours d'arriéré était : PDN - 0 jours ; PADN - 7 jours

## Screening - Workload/Backlog L'examen préliminaire - Charge de travail/Arriéré



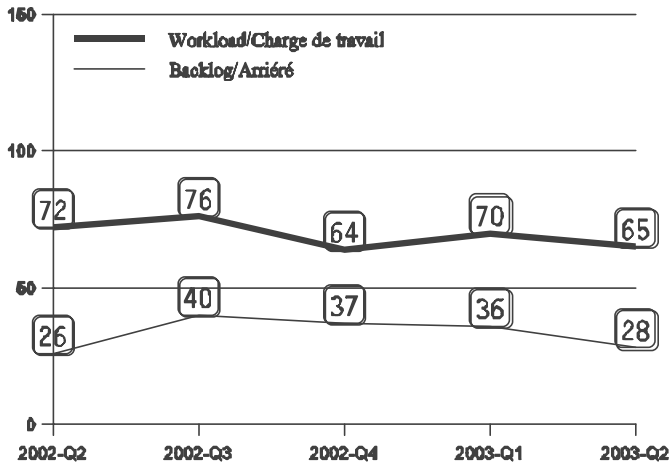
| SNDS / SPDN |          |           |           |           | SANDS / SPADN                        |       |                                |          |          |          |          |          |
|-------------|----------|-----------|-----------|-----------|--------------------------------------|-------|--------------------------------|----------|----------|----------|----------|----------|
| 2002 Q2     | 2002 Q3  | 2002 Q4   | 2003 Q1   | 2003 Q2   |                                      |       |                                |          |          |          |          |          |
| 9<br>(1)    | 3<br>(0) | 25<br>(0) | 13<br>(0) | 16<br>(3) | Workload<br>(Backlog)                | TOTAL | Charge de travail<br>(Arriéré) | 1<br>(1) | 0<br>(0) | 2<br>(0) | 2<br>(0) | 7<br>(0) |
|             |          |           |           |           |                                      |       |                                |          |          |          |          |          |
| 3(0)        | 2(0)     | 4(0)      | 3(0)      | 3(0)      | Clin/C&M / Clin/C&F                  |       |                                |          |          |          |          |          |
| 4(0)        | 1(0)     | 20(0)     | 7(0)      | 9(3)      | Clin Only / Clin seulement           |       |                                |          |          |          |          |          |
| 1(1)        |          | 1(0)      | 2(0)      | 3(0)      | Comp/C&M / Comp/C&F                  |       |                                |          |          |          |          |          |
|             |          |           | 1(0)      | 1(0)      | C&M/Labeling / C&F/Étiquetage        |       |                                |          |          |          |          |          |
| 1(0)        |          |           |           |           | Labeling Only / Étiquetage seulement |       |                                |          |          |          |          |          |
|             |          |           |           |           | Rx-OTC-No New Ind / Rx à VL ni       |       |                                |          |          |          |          |          |

| SNDS / SPDN | 2003 Q1 | 2003 Q2 | BUREAU Workload (Backlog) | 2003 Q1    | 2003 Q2 | SANDS / SPADN |
|-------------|---------|---------|---------------------------|------------|---------|---------------|
|             |         |         |                           | BPA / BEPP |         |               |
|             | 1(0)    | 2(0)    | BPS / BSP                 | 2(0)       | 3(0)    |               |
|             | 4(0)    | 5(0)    | BCANS / BCASN             |            |         |               |
|             | 3(0)    | 1(0)    | BGIVD / BGIMV             |            |         |               |
|             | 4(0)    | 4(0)    | BMORS/BMOSR               |            | 4(0)    |               |
|             | 1(0)    | 4(3)    | SMAB / BCMP               |            |         |               |

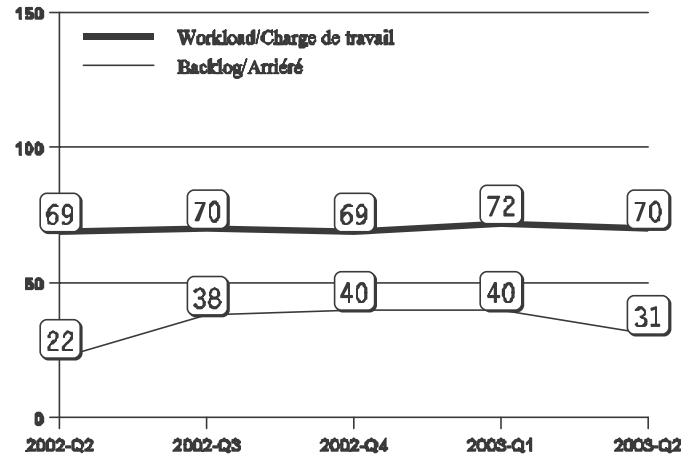
As of June 30, 2003 the average number of days in BACKLOG is: SNDS - 4 days; (Range 2 -7 days) SANDS - 0;  
 Au 30 juin 2003 le nombre moyen de jours d'arriéré était : SNDS - 4 jours; (écart:2 -7 jours); SPAND - 0;

## REVIEW - Workload / Backlog by submission type and year L'EXAMEN - Charge de travail / Arrière par type et année

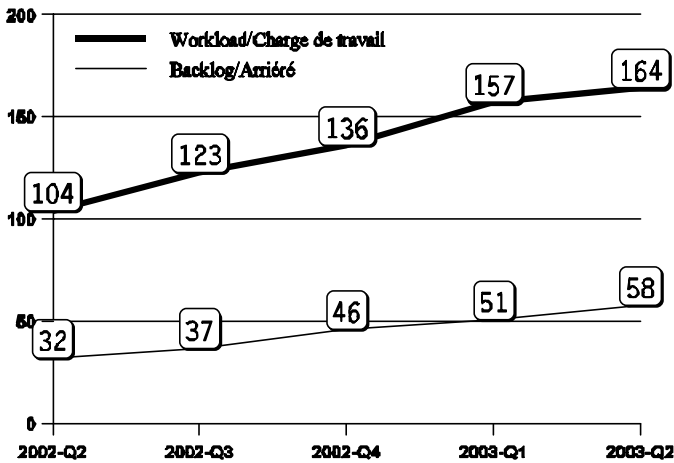
### NDS / PDN



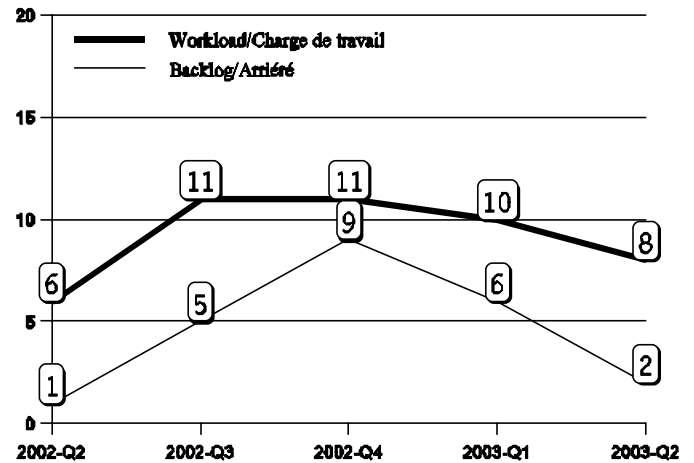
### ANDS / PADN



### SNDS / SPADN

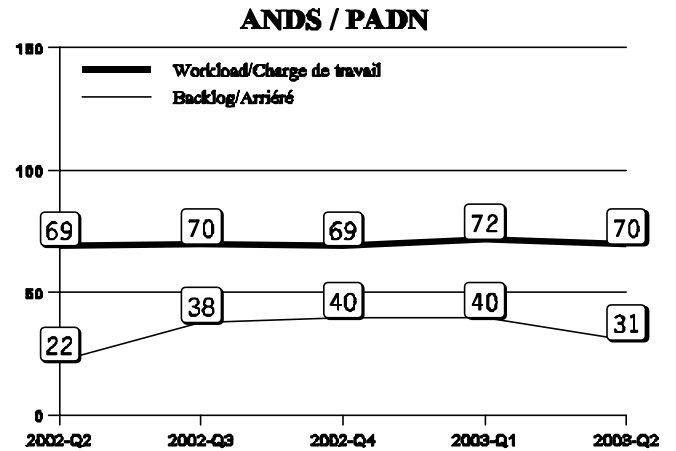
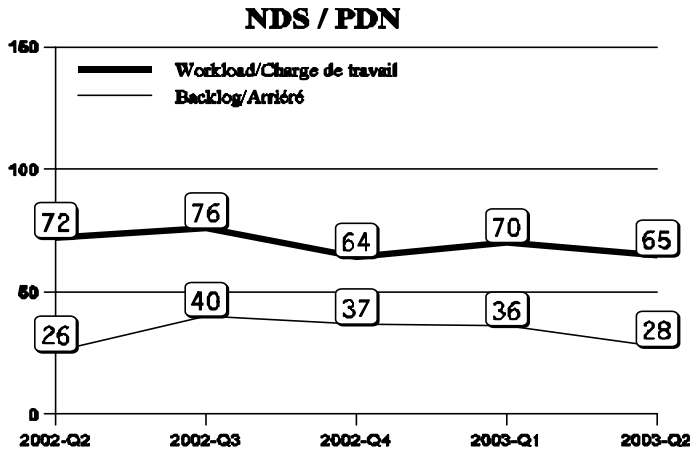


### SANDS / SPADN



**NOTE:** "Workload" is a count of all submissions in Review 1, Review 2 or Review-QN on the final day of the quarter.  
 "Backlog" is a subset of Workload and indicates the number of submissions that have exceeded their Performance Targets.  
 Q's in graph represent WORKLOAD totals.  
 "Charge de travail" est le calcul de toutes les présentations en Examen 1, Examen 2 ou Examen-QN au dernier jour du trimestre.  
 "Arrière" est un sous-ensemble de la Charge de travail qui indique le nombre de présentations qui ont excédées leurs objectifs de performance.  
 Les barres sous titrés 'Q' représentent la charge de travail trimestrielle.

## Review - Workload/Backlog L'examen - Charge de travail/Arrière

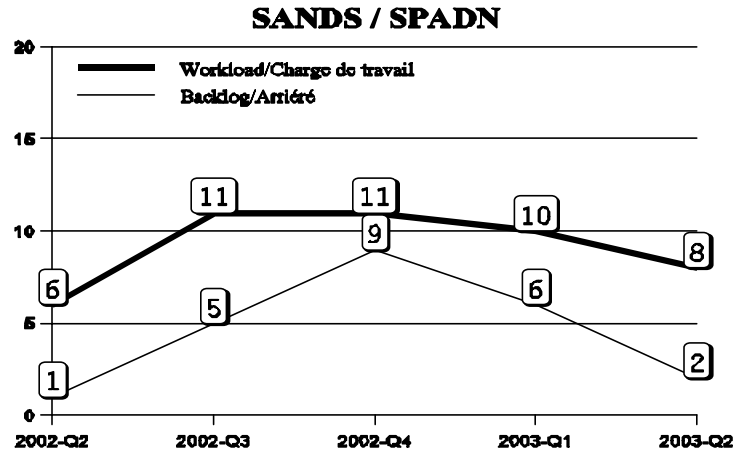
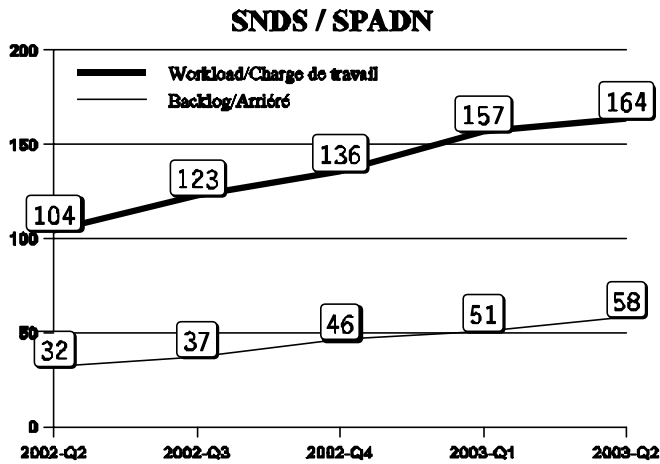


| NDS / PDN         |            |            |            |            | ANDS / PADN                                  |  |                             |  |            |            |            |            |            |        |
|-------------------|------------|------------|------------|------------|--|--|-----------------------------|--|------------|------------|------------|------------|------------|--------|
| 2002 Q2           | 2002 Q3    | 2002 Q4    | 2003 Q1    | 2003 Q2    | TOTAL  |  | Charge de travail (Arrière) |  | 2002 Q2    | 2002 Q3    | 2002 Q4    | 2003 Q1    | 2003 Q2    |        |
| 72<br>(26)        | 76<br>(40) | 64<br>(37) | 70<br>(36) | 65<br>(28) |  |  |                             |  | 69<br>(22) | 70<br>(38) | 69<br>(40) | 72<br>(40) | 70<br>(31) |        |
| CLASS / CATÉGORIE |            |            |            |            |  |  |                             |  |            |            |            |            |            |        |
| 2(0)              | 3(2)       | 3(1)       | 2(1)       | 3(2)       | Priority-NAS / Priorité-NSA                  |  |                             |  |            |            |            |            |            |        |
| 2(1)              | 1(1)       |            |            |            | Priority-Clin/C&M / Priorité-Clin/C&F        |  |                             |  |            |            |            |            |            |        |
| 1(1)              | 1(0)       | 1(0)       | 2(1)       |            | Priority-Clin Only / Priorité-Clin seulement |  |                             |  |            |            |            |            |            |        |
|                   |            |            |            | 1(0)       | NOCc-Clin/C&M - ACc/Clin/C&F                 |  |                             |  |            |            |            |            |            |        |
| 28(12)            | 31(16)     | 27(16)     | 29(17)     | 27(15)     | NAS / NSA                                    |  |                             |  |            |            |            |            |            |        |
| 32(10)            | 33(18)     | 31(19)     | 32(17)     | 29(11)     | Clin/C&M / Clin/C&F                          |  |                             |  |            |            |            |            |            |        |
| 4(1)              | 5(2)       | 1(0)       | 3(0)       | 4(0)       | Clin Only / Clin seulement                   |  |                             |  |            |            |            |            |            |        |
| 3(1)              | 2(1)       | 1(1)       | 2(0)       | 3(0)       | Comp/C&M / Comp/C&F                          |  |                             |  |            | 48(15)     | 51(29)     | 55(29)     | 58(29)     | 54(24) |
|                   |            |            |            |            | C&M/Labeling / C&F/Étiquetage                |  |                             |  |            | 21(7)      | 19(9)      | 14(11)     | 14(11)     | 16(7)  |

| NDS / PDN | 2003 Q1 | 2003 Q2 | BUREAU Workload (Backlog) | 2003 Q1 | 2003 Q2 | ANDS / PADN |
|-----------|---------|---------|---------------------------|---------|---------|-------------|
|           |         |         |                           |         |         |             |
|           |         |         | BPA / BEPP                | 1(0)    |         |             |
|           |         |         | BPS / BSP                 | 66(37)  | 68(30)  |             |
|           | 26(16)  | 20(11)  | BCANS / BCASN             | 1(0)    |         |             |
|           | 19(10)  | 18(10)  | BGIVD / BGIMV             | 3(3)    | 1(0)    |             |
|           | 18(7)   | 22(7)   | BMORS/BMOSR               | 1(0)    | 1(1)    |             |
|           | 6(3)    | 5(0)    | SMAB / BCMP               |         |         |             |

As of June 30, 2003, the average number of days in BACKLOG is: NDS - 183 days (Range: 28 - 372 days); ANDS - 158 days (Range: 8 - 342 days)  
 Au 30 juin 2003, le nombre moyen de jours d'arriéré était : PDN - 183 jours (écart: 28 - 372 jours); PADN - 158 jours (écart : 8 - 342 jours)

## Review - Workload/Backlog L'examen - Charge de travail/Arriéré



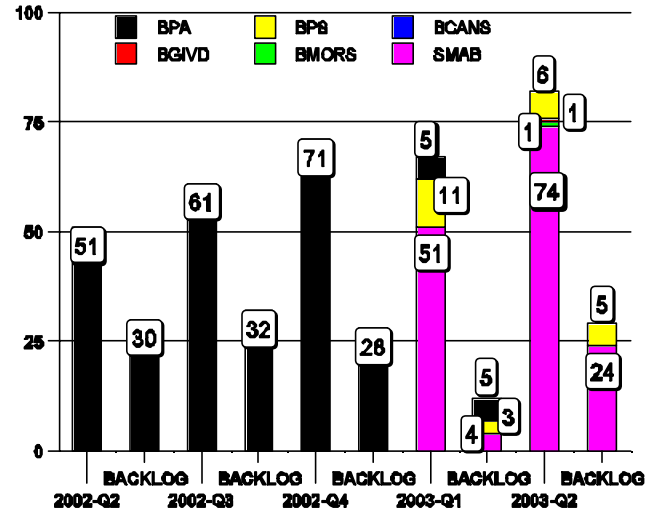
| SNDS / SPDN       |          |          |          |          | SANDS / SPADN                                |        |                             |        |         |         |         |         |         |
|-------------------|----------|----------|----------|----------|--|--------|-----------------------------|--------|---------|---------|---------|---------|---------|
| 2002 Q2           | 2002 Q3  | 2002 Q4  | 2003 Q1  | 2003 Q2  | TOTAL  |        | Charge de travail (Arriéré) |        | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
| 103 (32)          | 123 (37) | 136 (46) | 157 (51) | 164 (58) | 6 (1)  | 11 (5) | 11 (9)                      | 10 (6) | 8 (2)   |         |         |         |         |
| CLASS / CATÉGORIE |          |          |          |          |  |        |                             |        |         |         |         |         |         |
| 3(1)              |          | 1(0)     | 1(0)     | 1(1)     | Priority-Clin Only / Priorité-Clin seulement |        |                             |        |         |         |         |         |         |
| 1(1)              |          |          |          |          | Priority-Clin/C&M / Priorité-Clin/C&F        |        |                             |        |         |         |         |         |         |
|                   |          | 1(0)     | 1(1)     |          | Priority-RX-OTC-NNI / Priorité Rx à VL NI    |        |                             |        |         |         |         |         |         |
| 21(8)             | 27(13)   | 26(11)   | 29(10)   | 30(11)   | Clin/C&M / Clin/C&F                          |        |                             |        |         |         |         |         | 1(0)    |
| 57(16)            | 73(16)   | 82(22)   | 101(25)  | 102(25)  | Clin Only / Clin seulement                   |        |                             |        |         |         |         |         |         |
| 12(5)             | 11(5)    | 11(7)    | 12(8)    | 9(5)     | Comp/C&M / Comp/C&F                          |        | 5(1)                        | 9(4)   | 9(7)    | 5(4)    | 6(2)    |         |         |
| 6(0)              | 8(2)     | 6(2)     | 7(3)     | 8(4)     | C&M/Labeling / C&F/Étiquetage                |        | 1(0)                        | 1(1)   | 1(1)    |         |         |         | 1(0)    |
| 2(1)              | 3(1)     | 7(4)     | 5(4)     | 12(11)   | Labeling Only / Étiquetage seulement         |        |                             | 1(0)   | 1(1)    | 5(2)    |         |         |         |
| 1(0)              | 1(0)     | 2(0)     | 1(0)     | 2(1)     | Rx-OTC-No New Ind / Rx à VL ni               |        |                             |        |         |         |         |         |         |

| SNDS/SPDN | 2003 Q1 | 2003 Q2 | BUREAU Workload (Backlog) | 2003 Q1 | 2003 Q2 | SANDS/SPADN |
|-----------|---------|---------|---------------------------|---------|---------|-------------|
|           | 6 (3)   | 4(3)    | BPS / BSP                 | 8(4)    | 7(2)    |             |
|           | 70 (27) | 64(22)  | BCANS /BCASN              | 1(1)    |         |             |
|           | 45 (11) | 45(17)  | BGIVD / BGIMV             |         |         |             |
|           | 29 (5)  | 45(14)  | BMORS/BMOSR               |         | 1(0)    |             |
|           | 7 (5)   | 6(2)    | SMAB / BCMP               | 1(1)    |         |             |

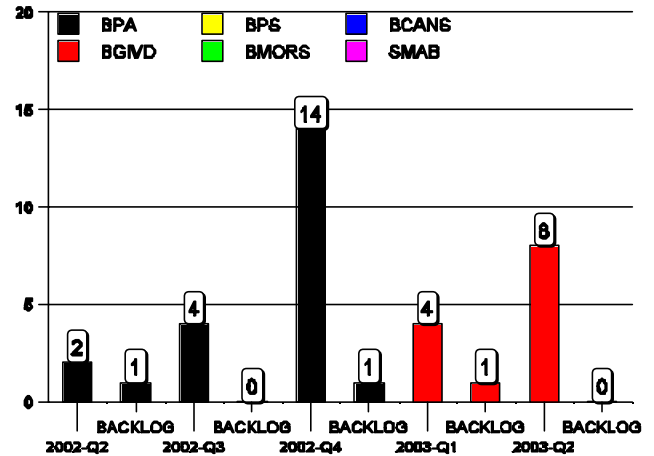
As of June 30, 2003 the average number of days in BACKLOG is: SNDS: 107 days (Range:5 -592 days) SANDS: 193 days (Range: 182 - 204 days)  
 Dès le 30 juin 2003, le nombre moyen de jours d'arriéré était : SPDN :107 jours (écart:5 -592 jours) SPADN:193 jours (écart: 182 - 204 jours)

## Screening - Workload/Backlog L'examen préliminaire - Charge de travail/Arrière

| DINA                     |  |       | 2002 Q2    | 2002 Q3    | 2002 Q4    | 2003 Q1     | 2003 Q2     |
|--------------------------|--|-------|------------|------------|------------|-------------|-------------|
| Workload (Backlog)       | Charge de travail (Arrière)                            | TOTAL | 51<br>(30) | 61<br>(32) | 71<br>(28) | 67<br>(12)  | 83<br>(28)  |
| <b>CLASS / CATÉGORIE</b> |  |       |            |            |            |             |             |
|                          | Form / Formule   |       | 25<br>(8)  | 45<br>(20) | 56<br>(17) | 59<br>(8)   | 66<br>(17)  |
|                          | Form & Supp. Data/<br>Formule + données justificatives |       | 26<br>(22) | 16<br>(12) | 15<br>(11) | 8<br>(4)    | 17<br>(11)  |
|                          | *Labelling Standard / Norme d'étiquetage               |       | 100<br>(6) | 81<br>(15) | 76<br>(30) | 125<br>(41) | 119<br>(70) |



| DIND                     |  |       | 2002 Q2  | 2002 Q3  | 2002 Q4   | 2003 Q1  | 2003 Q2  |
|--------------------------|--|-------|----------|----------|-----------|----------|----------|
| Workload (Backlog)       | Charge de travail (Arrière)                            | TOTAL | 2<br>(1) | 4<br>(0) | 14<br>(1) | 4<br>(1) | 8<br>(0) |
| <b>CLASS / CATÉGORIE</b> |  |       |          |          |           |          |          |
|                          | Form / Formule   |       | 1<br>(1) | 3<br>(0) | 10<br>(1) | 2<br>(1) | 8<br>(0) |
|                          | Form & Supp. Data/<br>Formule + données justificatives |       | 1<br>(0) | 1<br>(0) | 4<br>(0)  | 2<br>(0) |          |



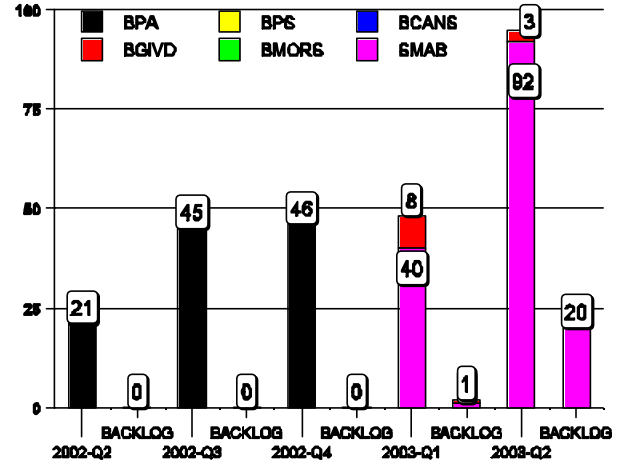
NOTE: "Workload" is a count of all submissions in Screening 1 or Screening 2 on the final day of the quarter.  
 "Backlog" is a subset of Workload and indicates the number of submissions that have exceeded their Performance Targets.  
 Q's in graph represent WORKLOAD totals.  
 \* Labelling Standard is not included in "Total".

"Charge de travail" est le calcul de toutes les présentations en Examen préliminaire 1 ou 2 au dernier jour du trimestre.  
 "Arrière" est un sous-ensemble de la Charge de travail qui indique le nombre de présentations qui ont excédées leurs objectifs de performance.  
 Les barres sous titrés 'Q' représentent la charge de travail trimestrielle.  
 \*La norme d'étiquetage n'est pas inclus dans le "Total".

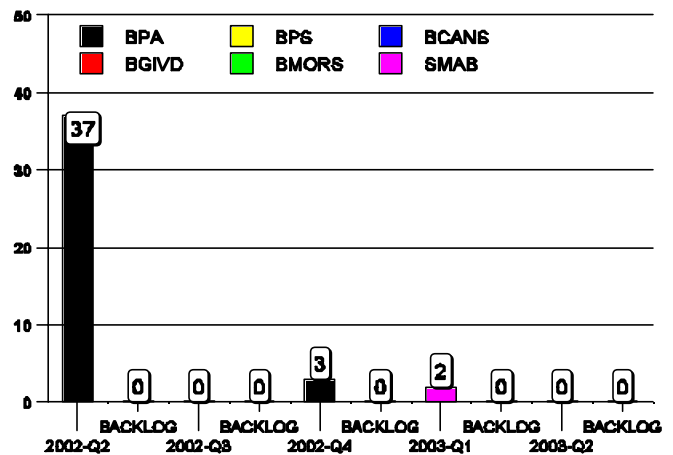


## Screening - Workload/Backlog L'examen préliminaire - Charge de travail/Arriéré

| DINF                                    |                             | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|---|-----------------------------|---------|---------|---------|---------|---------|
| Workload (Backlog)                      | Charge de travail (Arriéré) | 21 (0)  | 45 (0)  | 46 (0)  | 48 (2)  | 95 (20) |
| <b>CLASS / CATÉGORIE</b>                |                             |         |         |         |         |         |
| Labelling Standard / Norme d'étiquetage |                             | 21 (0)  | 45 (0)  | 46 (0)  | 48 (2)  | 95 (20) |



| DINH   |                             | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |
|--|-----------------------------|---------|---------|---------|---------|---------|
| Workload (Backlog)                                   | Charge de travail (Arriéré) | 37 (0)  | 0 (0)   | 3 (0)   | 2 (0)   | 0 (0)   |
| <b>CLASS / CATÉGORIE</b>                             |                             |         |         |         |         |         |
| Form / Formule                                       |                             | 37 (0)  |         | 2 (0)   | 1 (0)   |         |
| Form & Supp. Data / Formule + données justificatives |                             |         |         | 1 (0)   | 1 (0)   |         |
| *Labelling Standard / Norme d'étiquetage             |                             | 10 (0)  | 1 (0)   | 2 (2)   | 1 (0)   |         |

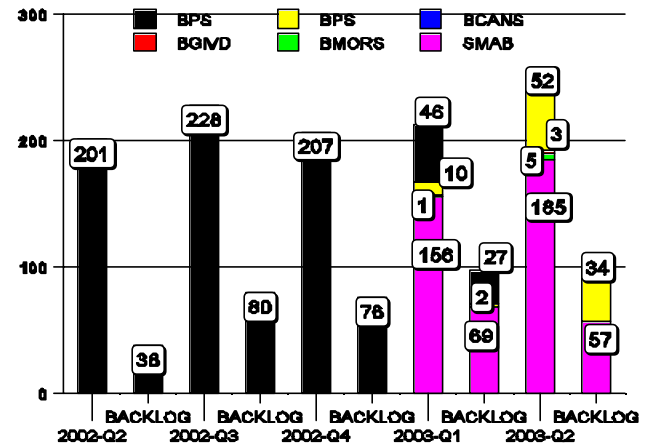


NOTE: "Workload" is a count of all submissions in Screening 1 or Screening 2 on the final day of the quarter.  
 "Backlog" is a subset of Workload and indicates the number of submissions that have exceeded their Performance Targets.  
 Q's in graph represent WORKLOAD totals.  
 \*Labelling Standard is not included in "Total".

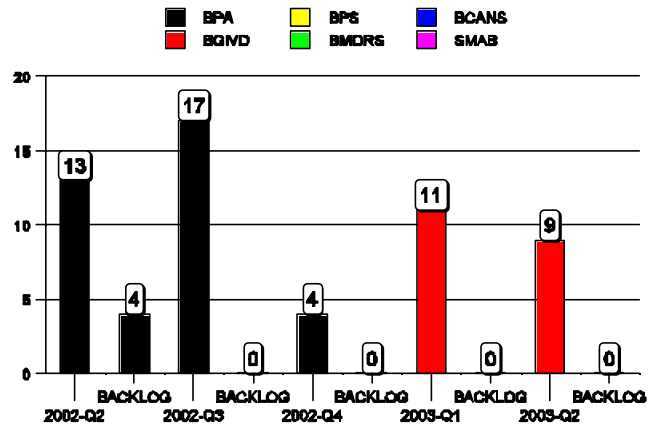
"Charge de travail" est le calcul de toutes les présentations en Examen préliminaire 1 ou 2 au dernier jour du trimestre.  
 "Arriéré" est un sous-ensemble de la Charge de travail qui indique le nombre de présentations qui ont excédées leurs objectifs de performance.  
 Les barres sous titrés 'Q' représentent la charge de travail trimestrielle.  
 \*La norme d'étiquetage n'est pas inclus dans le Total.

## Review - Workload/Backlog / L'examen - Charge de travail/Arrière

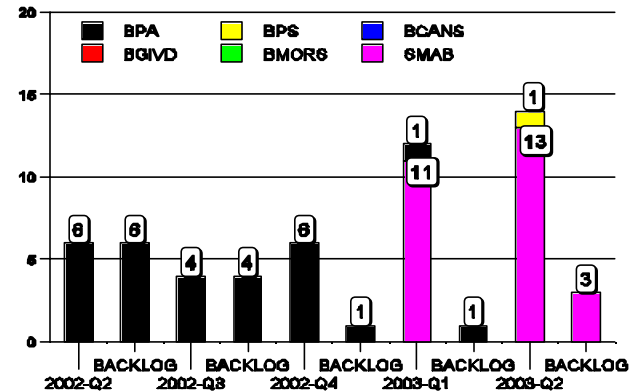
| DINA                     |  | 2002 Q2  | 2002 Q3  | 2002 Q4  | 2003 Q1  | 2003 Q2  |          |
|--------------------------|--|----------|----------|----------|----------|----------|----------|
| Workload (Backlog)       | Charge de travail (Arrière)                          | TOTAL    | 201 (38) | 228 (80) | 207 (76) | 213 (98) | 245 (91) |
| <b>CLASS / CATÉGORIE</b> |  |          |          |          |          |          |          |
|                          | Form / Formule                                       | 125 (14) | 156 (48) | 135 (35) | 141 (62) | 176 (46) |          |
|                          | Form & Supp. Data / Formule + données justificatives | 76 (24)  | 72 (32)  | 72 (41)  | 72 (36)  | 69 (45)  |          |



| DIND                     |  | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 2003 Q2 |       |
|--------------------------|--|---------|---------|---------|---------|---------|-------|
| Workload (Backlog)       | Charge de travail (Arrière)                          | TOTAL   | 13 (4)  | 17 (0)  | 4 (0)   | 11 (0)  | 9 (0) |
| <b>CLASS / CATÉGORIE</b> |  |         |         |         |         |         |       |
|                          | Form / Formule                                       | 4 (2)   | 11 (0)  | 3 (0)   | 9 (0)   | 4 (0)   |       |
|                          | Form & Supp. Data / Formule + données justificatives | 9 (2)   | 6 (0)   | 1 (0)   | 2 (0)   | 5 (0)   |       |



| DINH                     |  | 2002 Q2 | 2002 Q3 | 2002 Q4 | 2003 Q1 | 203 Q2 |        |
|--------------------------|--|---------|---------|---------|---------|--------|--------|
| Workload (Backlog)       | Charge de travail (Arrière)                          | TOTAL   | 6 (6)   | 4 (4)   | 6 (1)   | 12 (1) | 14 (3) |
| <b>CLASS / CATÉGORIE</b> |  |         |         |         |         |        |        |
|                          | Form Formule   | 1 (1)   | 1 (1)   | 2 (1)   | 7 (1)   | 8 (2)  |        |
|                          | Form & Supp. Data / Formule + données justificatives | 5 (5)   | 3 (3)   | 4 (0)   | 5 (0)   | 6 (1)  |        |



NOTE: "Workload" is a count of all submissions in Review 1 or Review 2 on the final day of the quarter.

"Backlog" is a subset of Workload and indicates the number of submissions that have exceeded their Performance Targets.

Q's in graph represent WORKLOAD totals.

"Charge de travail" est le calcul de toutes les présentations en Examen 1 ou Examen 2 au dernier jour du trimestre.

"Arrière" est un sous-ensemble de la Charge de travail qui indique le nombre de présentations qui ont excédées leurs objectifs de performance.

Les barres sous titrés 'Q' représentent la charge de travail trimestrielle.

## **SECTION 4 - Performance/**

## **SECTION 4 - Performance**

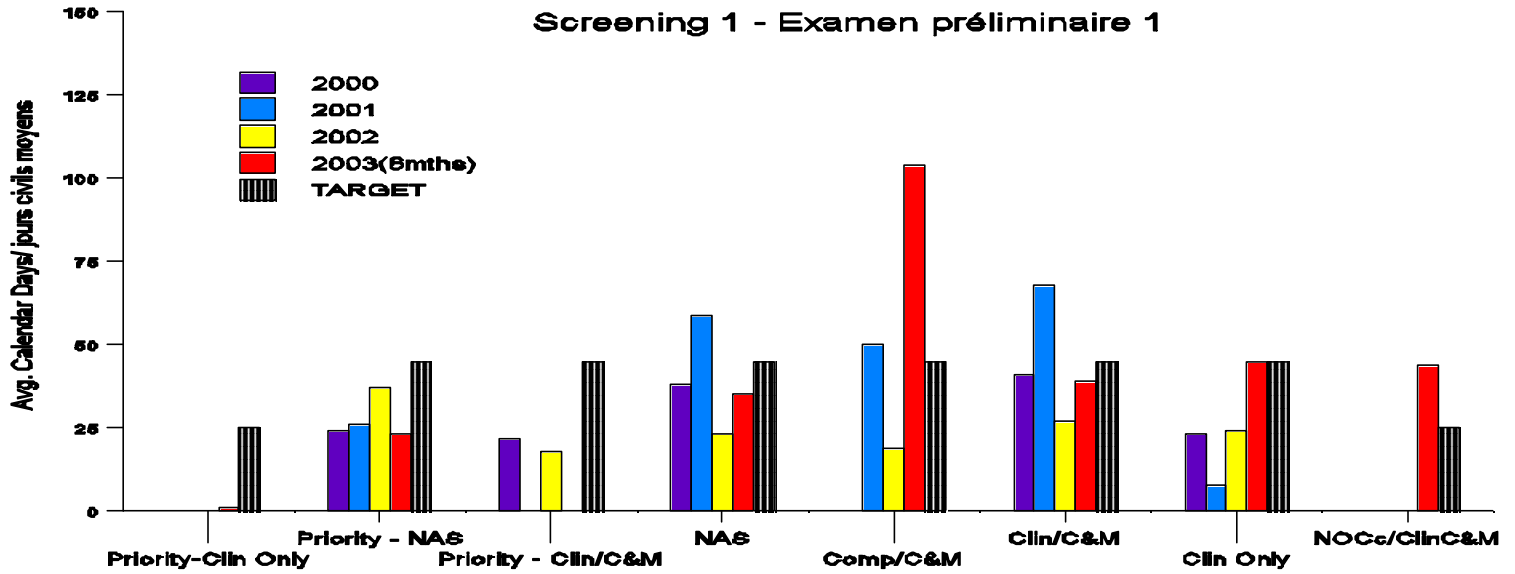
Please note that blanks in the tables represent class descriptions that did not have any submissions to measure performance vs target.

*Veillez noter que les espaces blancs dans les tableuse representent des types de descriptions qui n'avaient aucune soumission pour mesurer le performance vs les object*

ANDS and NDS review performance vs target shows the Bureau breakdown for Q2 only

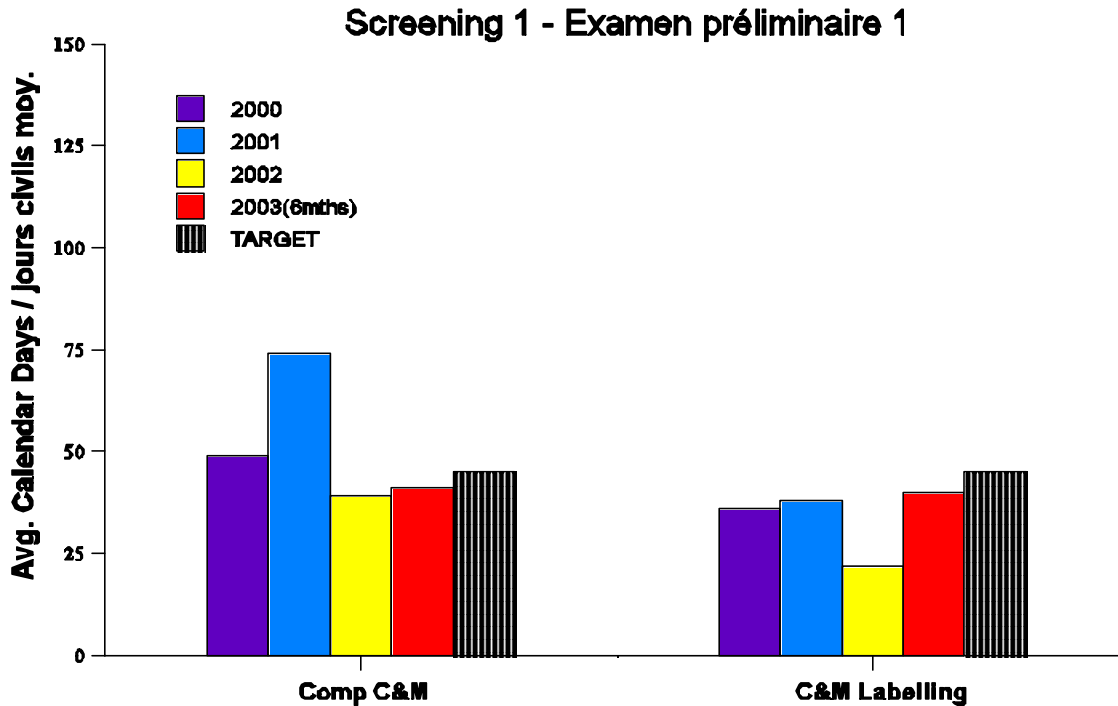
*Les revisions de performance des PADN et PDN ou fonction de la date limite montre les détails du bureau pour Q2 seulement.*

## NDS Screening 0by class - Performance vs Target PND - l'examen préliminaire par catégorie - Performance par rapport aux objectifs, 2000-2003



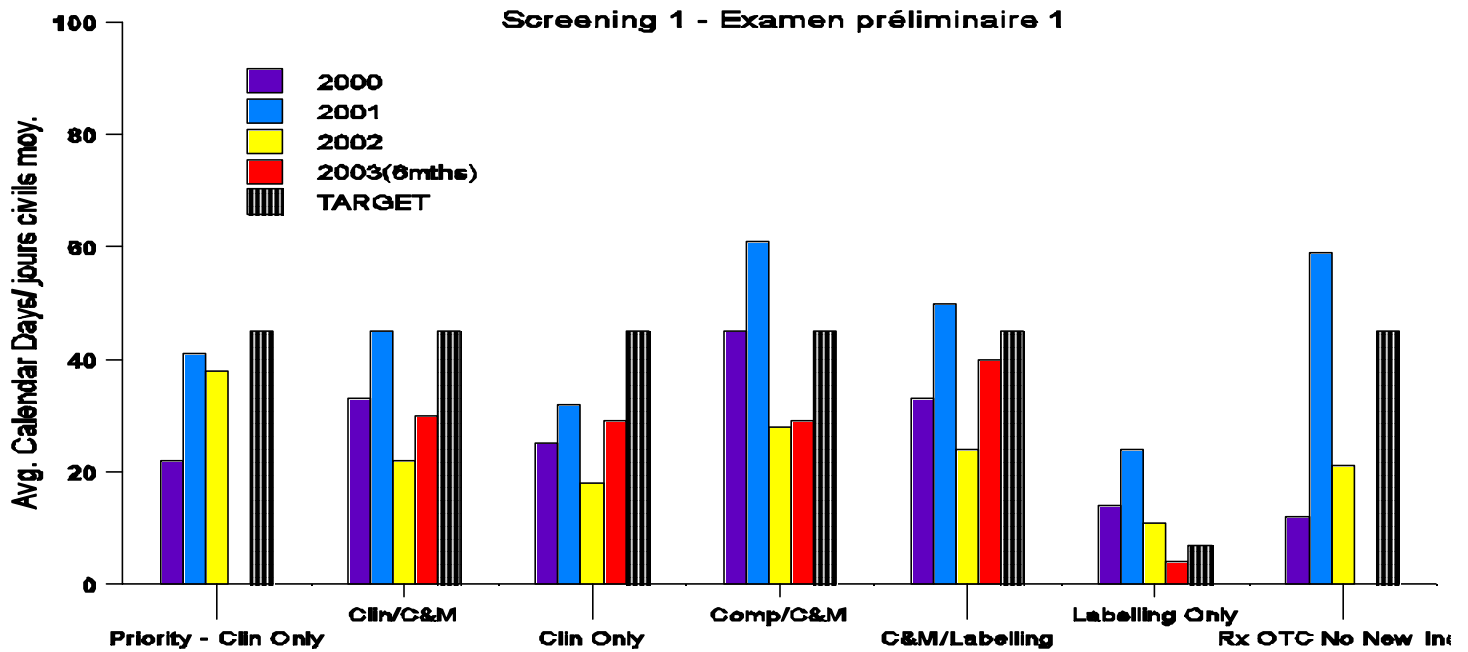
| Class / Catégorie<br>Target (Screening 1 & 2)<br>Objectifs (Ex. pré1.1 & 2) | SCREENING 1/<br>L'EXAMEN PRÉLIMINAIRE 1 |                                |                                |                                 | SCREENING 2/<br>L'EXAMEN PRÉLIMINAIRE 2 |                               |                               |                               |
|---|---|--------------------------------|--------------------------------|---------------------------------|---|-------------------------------|-------------------------------|-------------------------------|
|   | 2000                                    | 2001                           | 2002                           | 2003<br>(6mths/mois)            | 2000                                    | 2001                          | 2002                          | 2003<br>(6mths/mois)          |
| Priority-Clin Only/<br>Priorité-Clin seulement (45/45)                      |   | n=1<br>Avg=28                  | n=3<br>Avg=30<br>Min=8 Max=69  |                                 |   |                               |                               |                               |
| Priority-Clin Only/<br>Priorité-Clin seulement (25/25)                      |   |                                |                                | n=1<br>Avg=1                    |   |                               |                               |                               |
| Priority-NAS /<br>Priorité-NSA (45/45)                                      | n=8<br>Avg=24<br>Min=4Max=49            | n=6<br>Avg=26<br>Min=7 Max=64  | n=5<br>Avg=29<br>Min=3Max=50   | n=1<br>Avg=23                   | n=1<br>Avg=3                            | n=2<br>Avg=45<br>Min=42Max=48 | n=1<br>Avg=18                 |                               |
| Priority-Clin/C&M /<br>Priorité-Clin/C&F (45/45)                            | n=2<br>Avg=22<br>Min=17Max=27           |                                |                                |                                 | n=2<br>Avg=25<br>Min=13 Max=37          |                               |                               |                               |
| NAS /<br>NSA (45/45)  | n=22<br>Avg=38<br>Min=8 Max=74          | n=11<br>Avg=53<br>Min=2Max=112 | n=19<br>Avg=23<br>Min=1 Max=44 | n=11<br>Avg=35<br>Min=1 Max=73  | n=12<br>Avg=22<br>Min=2 Max=50          | n=8<br>Avg=34<br>Min=1Max=68  | n=4<br>Avg=16<br>Min=12Max=24 | n=2<br>Avg=40<br>Min=33Max=47 |
| Clin/C&M /<br>Clin/C&F (45/45)  | n=23<br>Avg=41<br>Min=3Max=101          | n=26<br>Avg=54<br>Min=1Max=222 | n=20<br>Avg=27<br>Min=7 Max=57 | n=12<br>Avg=39<br>Min=2 Max=77  | n=7<br>Avg=20<br>Min=9Max=40            | n=6<br>Avg=24<br>Min=1Max=57  | n=5<br>Avg=13<br>Min=4 Max=24 | n=2<br>Avg=30<br>Min=12Max=47 |
| C&M /Labelling /<br>C&F/Étiquetage (45/45)                                  |   | n=1<br>Avg=42                  | n=1<br>Avg=29                  |                                 |   |                               |                               |                               |
| Comp/C&M /<br>Comp/C&F (45/45)  |   | n=1<br>Avg=50                  | n=3<br>Avg=19<br>Min=7 Max=27  | n=3<br>Avg=104<br>Min=76Max=133 | n=1<br>Avg=44                           |                               |                               |                               |
| Clin Only /<br>Clin seulement (45/45)                                       | n=6<br>Avg=23<br>Min=1 Max=35           | n=2<br>Avg=28<br>Min=8Max=48   | n=5<br>Avg=24<br>Min=3 Max=69  | n=2<br>Avg=45<br>Min=30Max=60   |   | n=1<br>Avg=60                 |                               | n=1<br>Avg=76                 |
| Labelling Only /<br>Étiquetage seulement (7/7)                              | n=2<br>Avg=16<br>Min=11Max=20           | n=1<br>Avg=187                 |                                |                                 |   |                               |                               |                               |
| NOCc Clin/C&M /<br>AC c Clin/C&F (25/25)                                    |   |                                |                                | n=2<br>Avg=44<br>Min=20Max=68   |   |                               |                               |                               |

## ANDS Screening by class - Performance vs Target PADN - l'examen préliminaire par catégorie - Performance par rapport aux objectif 2000-2003



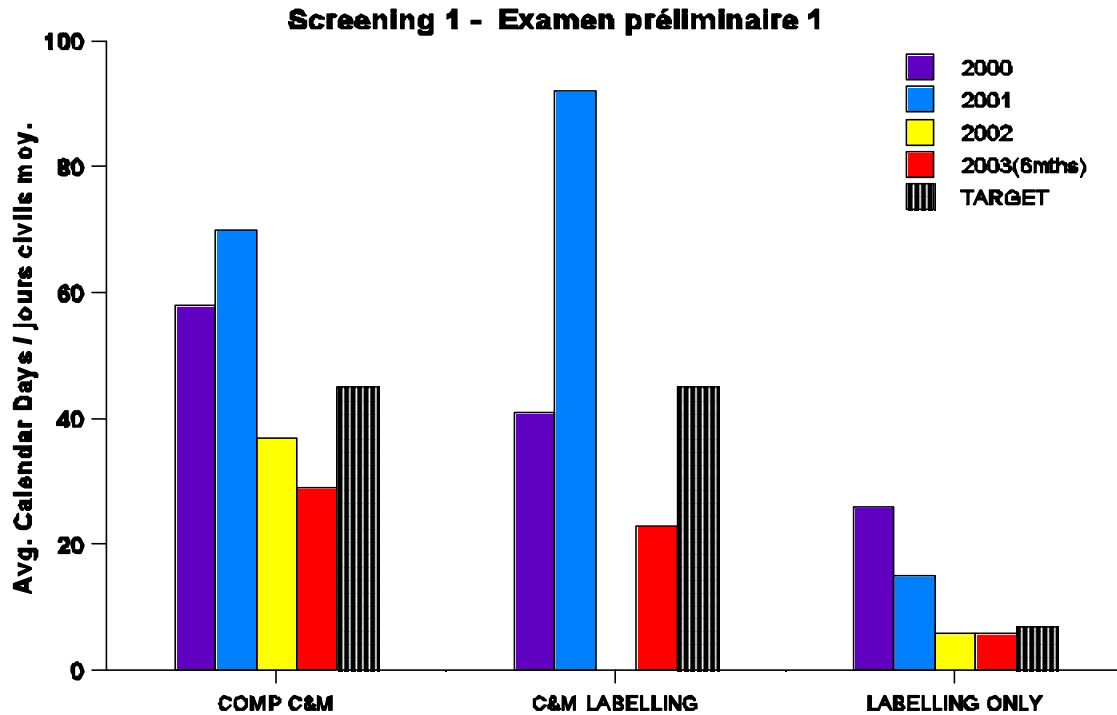
| Class / Catégorie<br>Targets (Screening 1 & 2)<br>Objectifs (Ex. pré. 1 & 2) | SCREENING 1<br>L'EXAMEN PRÉLIMINAIRE 1     |   |                                      |                                       | SCREENING 2<br>L'EXAMEN PRÉLIMINAIRE 2    |  |                                       |                                      |
|--|--|---|--------------------------------------|---------------------------------------|---|--|---------------------------------------|--------------------------------------|
|  | 2000                                       | 2001                                      | 2002                                 | 2003<br>(6mths/mois)                  | 2000                                      | 2001                                       | 2002                                  | 2003<br>(6mths/mois)                 |
| Comp/C&M / Comp/C&F (45/45)  | n = 81<br>Avg = 49<br>Min = 5<br>Max = 133 | n=60<br>Avg=74<br>Min= 1<br>Max = 190     | n=25<br>Avg=39<br>Min= 1<br>Max =279 | n=40<br>Avg=41<br>Min= 9<br>Max =70   | n =16<br>Avg = 42<br>Min = 23<br>Max = 58 | n = 35<br>Avg = 40<br>Min = 0<br>Max = 133 | n=18<br>Avg=33<br>Min= 1<br>Max = 117 | n=3<br>Avg=42<br>Min= 32<br>Max = 52 |
| C&M /Labelling / C&F/Étiquetage (45/45)                                      | n = 28<br>Avg = 36<br>Min = 2<br>Max = 76  | n = 25<br>Avg = 38<br>Min = 3<br>Max = 94 | n=20<br>Avg=22<br>Min= 1<br>Max = 38 | n=14<br>Avg=40<br>Min= 20<br>Max = 54 | n =5<br>Avg = 25<br>Min = 7<br>Max = 47   | n = 13<br>Avg = 26<br>Min = 6<br>Max = 133 | n=5<br>Avg=14<br>Min= 4<br>Max = 26   | n=1<br>Avg=39                        |
| Labelling Only / Étiquetage seulement (7/7)                                  | n =1<br>Avg = 5                            | n=3<br>Avg = 80<br>Min = 80<br>Max = 80   |                                      |                                       |   |  |                                       |                                      |

## SNDS Screening by class - Performance vs Target PDN - l'examen préliminaire par catégorie - Performance par rapport aux objectif 2000-2003



| Class / Catégorie                                      | SCREENING 1<br>EXAMEN PRÉL. 1      |                                  |                               |                               | SCREENING 2<br>EXAMEN PRÉL. 2    |                                  |                              |                              |
|--|------------------------------------|----------------------------------|-------------------------------|-------------------------------|----------------------------------|----------------------------------|------------------------------|------------------------------|
|  | 2000                               | 2001                             | 2002                          | 2003 (6mths)                  | 2000                             | 2001                             | 2002                         | 2003 (6mths/mois)            |
| Targets (Screening1&2)<br>Objectifs (Ex pré1&2)        |                                    |                                  |                               |                               |                                  |                                  |                              |                              |
| Priority-Clin Only/<br>Priorité-Clin seulement (45/45) | n = 4<br>Avg =22<br>Min=7 Max=50   | n=8<br>Avg = 41<br>Min=5 Max=76  | n=2<br>Avg=38<br>Min=19Max=56 |                               |                                  | n=1<br>Avg = 1                   |                              |                              |
| Priority Clin/C&M /<br>Priorité-Clin/C&F (45/45)       |                                    | n=1<br>Avg = 48                  |                               |                               |                                  |                                  |                              |                              |
| Priority-RX-OTC-NNI/<br>Priorité RxàVL- nni (25/25)    |                                    |                                  | n=2<br>Avg=42<br>Min=37Max=47 |                               |                                  |                                  |                              |                              |
| Clin/C&M /<br>Clin/C&F (45/45)                         | n = 20<br>Avg =33<br>Min=7 Max=69  | n=22<br>Avg = 45<br>Min=2Max=112 | n=20<br>Avg=22<br>Min=1Max=44 | n=15<br>Avg=30<br>Min=3Max=70 | n = 4<br>Avg = 8<br>Min=7 Max=9  | n=3<br>Avg = 72<br>Min=7Max=132  | n=2<br>Avg=8<br>Min=3Max=12  | n=1<br>Avg=31                |
| Clin Only /<br>Clin seulement (45/45)                  | n = 65<br>Avg = 25<br>Min=2 Max=86 | n=57<br>Avg = 32<br>Min=1Max=115 | n=78<br>Avg=18<br>Min=1Max=53 | n=52<br>Avg=29<br>Min=1Max=63 | n = 14<br>Avg =26<br>Min=3Max=42 | n=13<br>Avg = 23<br>Min=1Max =70 | n=7<br>Avg=15<br>Min=1Max=35 | n=5<br>Avg=21<br>Min=1Max=36 |
| Comp C&M /<br>Comp/C&F (45/45)                         | n = 25<br>Avg = 45<br>Min=3Max=117 | n=17<br>Avg = 61<br>Min=2Max=139 | n=13<br>Avg=28<br>Min=1Max=57 | n=5<br>Avg=29<br>Min=12Max=43 | n = 6<br>Avg =44<br>Min=15Max=73 | n=5<br>Avg = 37<br>Min=11Max=55  | n=1<br>Avg=37                | n=1<br>Avg=49                |
| C&M/Labeling /<br>C&F/Étiquetage (45/45)               | n = 15<br>Avg =33<br>Min=13Max=85  | n=12<br>Avg = 50<br>Min=1Max=167 | n=11<br>Avg=24<br>Min=3Max=41 | n=5<br>Avg=40<br>Min=14Max=54 | n = 3<br>Avg =53<br>Min=9Max=98  |                                  | n=2<br>Avg=15<br>Min=9Max=20 |                              |
| Labeling Only /<br>Étiquetage seulement (7/7)          | n = 5<br>Avg =14<br>Min=1Max=28    | n=17<br>Avg = 24<br>Min=5 Max=84 | n=8<br>Avg=11<br>Min=1Max=28  | n=13<br>Avg=4<br>Min=1Max=23  |                                  |                                  |                              |                              |
| Rx to OTC-New Ind/<br>Rx à VL ni (45/45)               |                                    |                                  |                               |                               | n=1<br>Avg=28                    |                                  |                              |                              |
| Rx to OTC-No New Ind /<br>Rx à VL pni (45/45)          | n=2<br>Avg=12<br>Min=8Max=15       | n=3<br>Avg = 59<br>Min=14Max=123 | n=2<br>Avg=21<br>Min=13Max=28 |                               |                                  |                                  | n=1<br>Avg=34                | n=1<br>Avg=17                |

## Performance vs Target - Performance par rapport aux objectif SANDS Screening by class / SPADN - l'examen préliminaire par catégories, 2000 - 2003



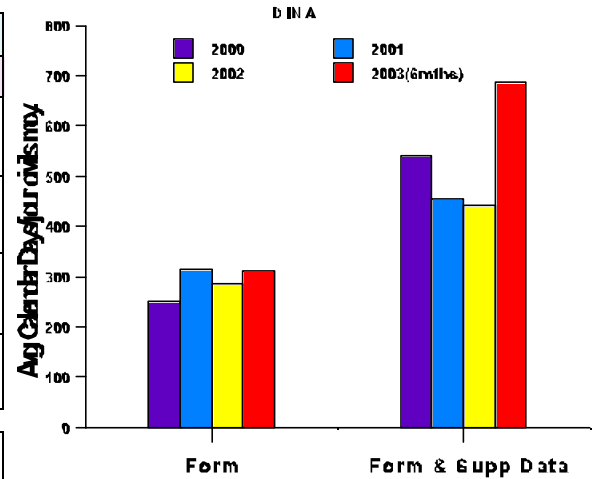
| Class / Catégorie  | Screening 1 / L'examen préliminaire 1 |   |   |                                    | Screening 2 / L'exame préliminaire 2 |      |                 |                   |
|--|---------------------------------------|---|---|------------------------------------|--------------------------------------|------|-----------------|-------------------|
|  | 2000                                  | 2001                                    | 2002                                    | 2003 (6mths/mois)                  | 2000                                 | 2001 | 2002            | 2003 (6mths/mois) |
| Comp/C&M / Comp/C&F (45/45)<br>Targets (Screening 1 & 2)<br>Objectifs (Ex. pré. 1 & 2) | n= 5<br>Avg=58<br>Min=14<br>Max=120   | n=3<br>Avg = 70<br>Min = 6<br>Max = 105 | n=10<br>Avg = 37<br>Min = 8<br>Max = 61 | n=6<br>Avg =29<br>Min=8<br>Max=40  | n=1<br>Avg=55                        |      |                 | n=1<br>Avg=38     |
| C&M /Labelling / C&F/Étiquetage (45/45)  | n=7<br>Avg=41<br>Min=8<br>Max=55      | n=2<br>Avg = 92<br>Min=57<br>Max=127    |   | n=2<br>Avg =23<br>Min=21<br>Max=25 | n=2<br>Avg=24<br>Min=16<br>Max=31    |      | n=1<br>Avg = 23 |                   |
| Clin Only / Clin seulement (45/45)   |                                       |   |   | n=1<br>Avg = 1                     |                                      |      |                 |                   |
| Labelling Only / Étiquetage seulement (7/7)  | n=1<br>Avg=26                         | n=1<br>Avg = 15                         | n=4<br>Avg = 6<br>Min = 1<br>Max = 20   | n=6<br>Avg = 6<br>Min=1<br>Max=15  |                                      |      |                 |                   |

## Performance vs Target - performance vs objectifs

### Average Times\* from Receipt to DIN -Durée moyenne à compter de la date de réception jusqu'à l'émission du DIN

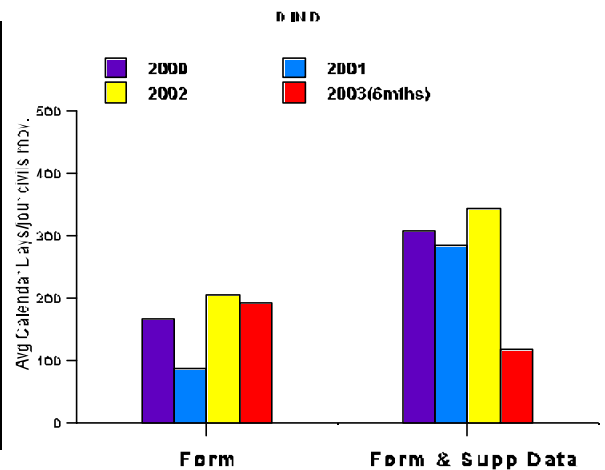
#### DINA: Application / Demande

|   | 2000                               | 2001                                    | 2002                                 | 2003 (6mths/mois)                     |
|---|------------------------------------|---|--------------------------------------|---------------------------------------|
| <b>CLASS / CATÉGORIE</b>                              |                                    |   |                                      |                                       |
| Admin (Non SIPD)<br>Admin (non-DPPR)                  | n=98<br>Avg = 51<br>Min=14Max=101  | n=125<br>Avg = 80<br>Min=9 Max=242      | n=134<br>Avg = 51<br>Min=4 Max=519   | n=42<br>Avg = 80<br>Min=36 Max=323    |
| Form<br>Formule                                       | n=184<br>Avg=250<br>Min=38 Max=713 | n = 168<br>Avg = 313<br>Min=31 Max= 648 | n=156<br>Avg = 285<br>Min=26 Max=777 | n=75<br>Avg = 310<br>Min=65 Max=547   |
| Form & Supp. Data<br>Formule + données justificatives | n=71<br>Avg=541<br>Min=203Max=1318 | n = 21<br>Avg = 454<br>Min=203 Max=864  | n=28<br>Avg = 443<br>Min=241 Max=729 | n=28<br>Avg = 686<br>Min=175 Max=1043 |
| **Labelling Standard<br>Norme d'étiquetage            | n= 388<br>Avg=53<br>Min=27 Max=242 | n = 714<br>Avg = 74<br>Min=13 Max =383  | n=460<br>Avg = 54<br>Min=9 Max=276   | n=193<br>Avg = 94<br>Min=33 Max=635   |
| Admin (SIPD)<br>Admin (DPPR)                          | n= 439<br>Avg=29<br>Min= 1 Max=67  | n = 582<br>Avg = 21<br>Min = 1 Max= 380 | n=246<br>Avg = 11<br>Min=1 Max=104   | n=141<br>Avg = 17<br>Min=1 Max=380    |



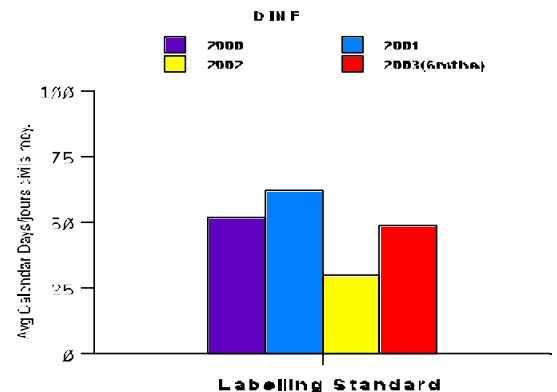
#### DIND: Disinfectants / Désinfectants

|  | 2000                               | 2001                                  | 2002                                | 2003 (6mths/mois)                   |
|--|------------------------------------|---------------------------------------|-------------------------------------|-------------------------------------|
| <b>CLASS / CATÉGORIE</b>                           |                                    |                                       |                                     |                                     |
| Admin (Non SIPD)<br>Admin (non-DPPR)               | n= 12<br>Avg = 45<br>Min=14Max=101 | n = 13<br>Avg = 51<br>Min =20Max =169 | n=131<br>Avg = 38<br>Min=8 Max=113  | n=51<br>Avg = 73<br>Min=44 Max=205  |
| Form<br>Formule                                    | n= 22<br>Avg=167<br>Min=56Max=392  | n = 10<br>Avg = 87<br>Min=29Max= 191  | n=23<br>Avg = 204<br>Min=32 Max=673 | n=13<br>Avg = 191<br>Min=69 Max=267 |
| Form & Supp. Data<br>Form + données justificatives | n= 6<br>Avg=306<br>Min=210Max=458  | n = 3<br>Avg = 284<br>Min=230Max=379  | n=25<br>Avg = 344<br>Min=119Max=679 | n=6<br>Avg = 117<br>Min=65 Max=261  |
| **Labelling Standard<br>Norme d'étiquetage         | n=3<br>Avg=102<br>Min=53Max=153    | n = 2<br>Avg = 51<br>Min=26Max = 29   | n=5<br>Avg = 42<br>Min=28 Max=89    |                                     |
| Admin (SIPD)<br>Admin (DPPR)                       | n= 24<br>Avg=31<br>Min= 6Max=56    | n = 4<br>Avg = 20<br>Min =20Max = 20  | n=20<br>Avg = 14<br>Min=5 Max=41    | n=9<br>Avg = 11<br>Min=3 Max=19     |



#### DINF: Category IV / Catégorie IV

|  | 2000                             | 2001                                    | 2002                               | 2003 (6mths/mois)                   |
|--|----------------------------------|---|------------------------------------|-------------------------------------|
| <b>CLASS / CATÉGORIE</b>                   |                                  |   |                                    |                                     |
| **Labelling Standard<br>Norme d'étiquetage | n=336<br>Avg=52<br>Min=20Max=131 | n = 507<br>Avg = 62<br>Min =8 Max = 339 | n=437<br>Avg = 30<br>Min=8 Max=199 | n=205<br>Avg = 49<br>Min=27 Max=139 |



\* Times are calculated as calendar days from date of receipt in TPD to date of DIN issuance, including any company time.  
Durée calculée en jours civils à compter de la date de réception par le Direction des produits thérapeutiques jusqu'à l'émission du DIN, y compris le temps de la compagnie.

\*\* Statistics on DINs classified as Labelling Standard are calculated as calendar days from date of receipt or date of response to Labelling Standard Letter in Therapeutic Products Directorate to date of DIN Issuance, including any company time.  
Les données statistiques sur les DIN relevant de la catégorie Norme d'étiquetage sont calculées en jours civils depuis la date de réception ou le date de réponse à la lettre Norme d'étiquetage au Direction de produits thérapeutiques jusqu'à la date de délivrance du DIN, y compris le temps de la compagnie.



## Approved DIN's by year of issuance: Average Screening and Review Times\* DIN approuvées: Durée moyenne des examens\* - par l'année de notification

| DINA<br><br>CLASS / CATÉGORIE<br>Targets / Objectifs                  | 2001               |                  |                    |                 | 2002               |                  |                    |                 | 2003 (6 MONTHS)    |                 |                    |                 |
|---|--------------------|------------------|--------------------|-----------------|--------------------|------------------|--------------------|-----------------|--------------------|-----------------|--------------------|-----------------|
|   | SCR<br>Ex Pré<br>1 | REV<br>EXA<br>1  | SCR<br>Ex Pré<br>2 | REV<br>EXM<br>2 | SCR<br>Ex Pré<br>1 | REV<br>EXA<br>1  | SCR<br>Ex Pré<br>2 | REV<br>EXM<br>2 | SCR<br>Ex Pré<br>1 | REV<br>EXA<br>1 | SCR<br>Ex Pré<br>2 | REV<br>EXM<br>2 |
| Form (45/180/45/120)<br>Formule                                       | n=187<br>Avg=84    | n=158<br>Avg=181 | n=26<br>Avg=63     | n=25<br>Avg=120 | n=178<br>Avg=33    | n=148<br>Avg=221 | n=17<br>Avg=43     | n=16<br>Avg=166 | n=81<br>Avg=20     | n=73<br>Avg=257 | n=8<br>Avg=36      | n=8<br>Avg=171  |
| Form & Supp. Data (45/180/45/150)<br>Formule + données justificatives | n=24<br>Avg=68     | n=21<br>Avg=281  | n=5<br>Avg=34      | n=6<br>Avg=175  | n=30<br>Avg=83     | n=28<br>Avg=253  | n=7<br>Avg=89      | n=7<br>Avg=237  | n=32<br>Avg=91     | n=26<br>Avg=380 | n=10<br>Avg=68     | n=10<br>Avg=293 |

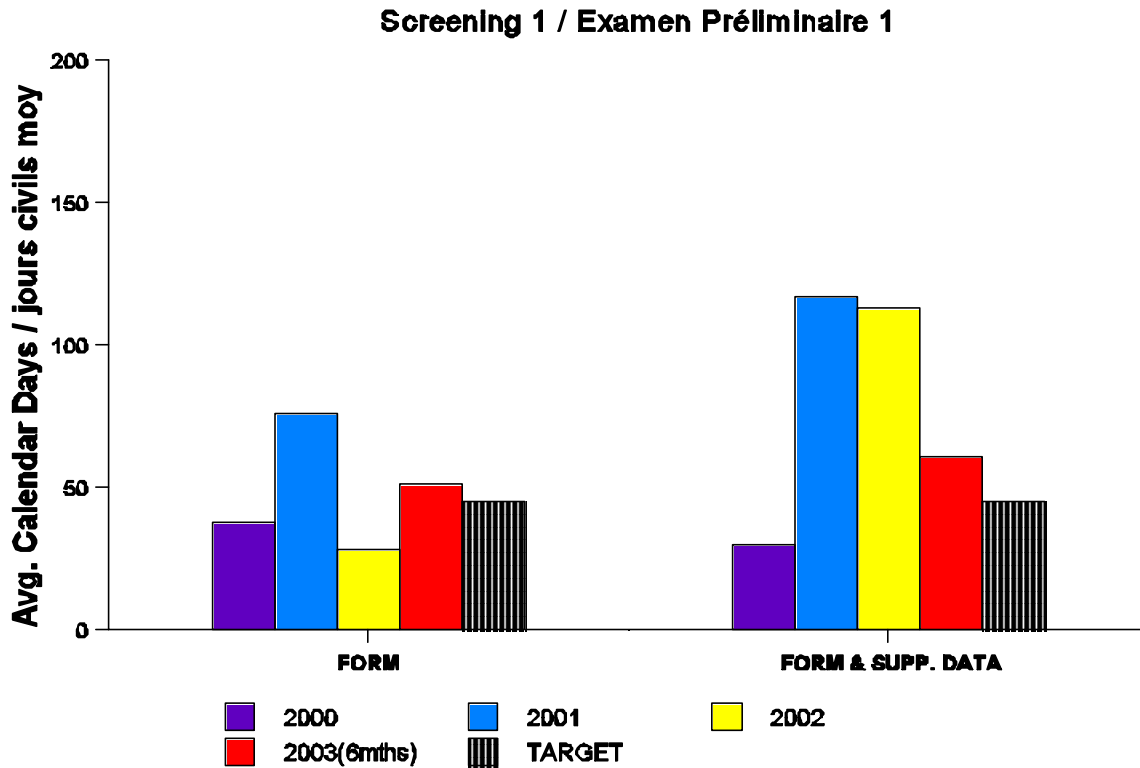
| DIND<br><br>CLASS / CATÉGORIE<br>Targets / Objectifs                  | 2001               |                 |                    |                 | 2002               |                 |                    |                 | 2003 (6 MONTHS)    |                 |                    |                 |
|---|--------------------|-----------------|--------------------|-----------------|--------------------|-----------------|--------------------|-----------------|--------------------|-----------------|--------------------|-----------------|
|   | SCR<br>Ex Pré<br>1 | REV<br>EXA<br>1 | SCR<br>Ex Pré<br>2 | REV<br>EXM<br>2 | SCR<br>Ex Pré<br>1 | REV<br>EXA<br>1 | SCR<br>Ex Pré<br>2 | REV<br>EXM<br>2 | SCR<br>Ex Pré<br>1 | REV<br>EXA<br>1 | SCR<br>Ex Pré<br>2 | REV<br>EXM<br>2 |
| Form (45/180/45/120)<br>Formule                                       | n=12<br>Avg=62     |                 |                    |                 | n=26<br>Avg=29     | n=15<br>Avg=162 | n=4<br>Avg=21      | n=4<br>Avg=104  | n=13<br>Avg=42     | n=15<br>Avg=52  | n=7<br>Avg=87      | n=7<br>Avg=38   |
| Form & Supp. Data (45/180/45/150)<br>Formule + données justificatives | n=3<br>Avg=84      | n=3<br>Avg=183  |                    |                 | n=26<br>Avg=30     | n=25<br>Avg=225 | n=9<br>Avg=19      | n=10<br>Avg=131 | n=6<br>Avg=45      | n=6<br>Avg=42   | n=1<br>Avg=88      | n=1<br>Avg=32   |

| DINH<br><br>CLASS / CATÉGORIE<br>Targets / Objectifs                  | 2001               |                 |                    |                 | 2002               |                 |                    |                 | 2003 (6 MONTHS)    |                 |                    |                 |
|---|--------------------|-----------------|--------------------|-----------------|--------------------|-----------------|--------------------|-----------------|--------------------|-----------------|--------------------|-----------------|
|   | SCR<br>Ex Pré<br>1 | REV<br>EXA<br>1 | SCR<br>Ex Pré<br>2 | REV<br>EXM<br>2 | SCR<br>Ex Pré<br>1 | REV<br>EXA<br>1 | SCR<br>Ex Pré<br>2 | REV<br>EXM<br>2 | SCR<br>Ex Pré<br>1 | REV<br>EXA<br>1 | SCR<br>Ex Pré<br>2 | REV<br>EXM<br>2 |
| Form (45/180/45/120)<br>Formule                                       | n=1<br>Avg=331     |                 |                    |                 |                    |                 |                    |                 |                    |                 |                    |                 |
| Form & Supp. Data (45/180/45/150)<br>Formule + données justificatives | n=3<br>Avg=15      | n=3<br>Avg=323  | n=1<br>Avg=56      |                 | n=4<br>Avg=28      | n=4<br>Avg=373  |                    |                 |                    |                 |                    |                 |

NOTE: This is the breakdown of issued DINs grouped by the year of the DIN issuance. Labelling Standard and Administrative are not included.

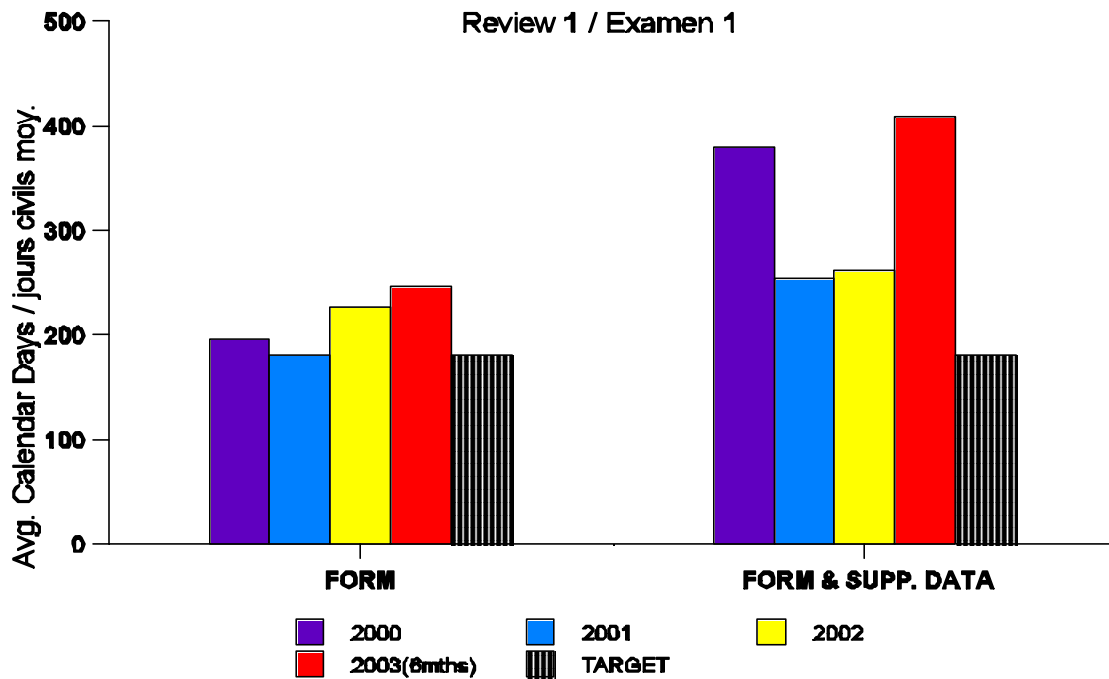
Ce tableau décrit le temps au les DIN approuvés. Les statistiques sur les DIN classés comme norme d'étiquetage & présentation administrative ne sont pas incluses puisqu'elles ne sont pas soumis à la phase Examen.

Performance vs Target - Performance vs objectifs  
DINA- Screening by class, DINA - Examen préliminaire par catégorie,  
2000 - 2003



| Class / Catégorie                                     | Targets (Screening 1 & 2)<br>Objectifs ( Examen prélim.1 & 2) | SCREENING 1<br>EXAMEN PRÉLIMINAIRE 1 |                      |                      |                      | SCREENING 2<br>EXAMEN PRÉLIMINAIRE 2 |                    |                    |                      |
|---|---|--------------------------------------|----------------------|----------------------|----------------------|--------------------------------------|--------------------|--------------------|----------------------|
|   |   | 2000                                 | 2001                 | 2002                 | 2003<br>(6mths/mois) | 2000                                 | 2001               | 2002               | 2003<br>(6mths/mois) |
| Form<br>Formule                                       | (45)  | n = 229<br>Avg = 38                  | n = 354<br>Avg = 76  | n = 288<br>Avg = 28  | n = 179<br>Avg = 51  | n = 45<br>Avg = 22                   | n = 31<br>Avg = 74 | n = 24<br>Avg = 23 | n = 3<br>Avg = 24    |
| Form & Supp. Data<br>Formule + données justificatives | (45)  | n = 82<br>Avg = 30                   | n = 159<br>Avg = 117 | n = 101<br>Avg = 113 | n = 50<br>Avg = 61   | n = 8<br>Avg = 34                    | n = 8<br>Avg = 106 | n = 29<br>Avg = 58 |                      |

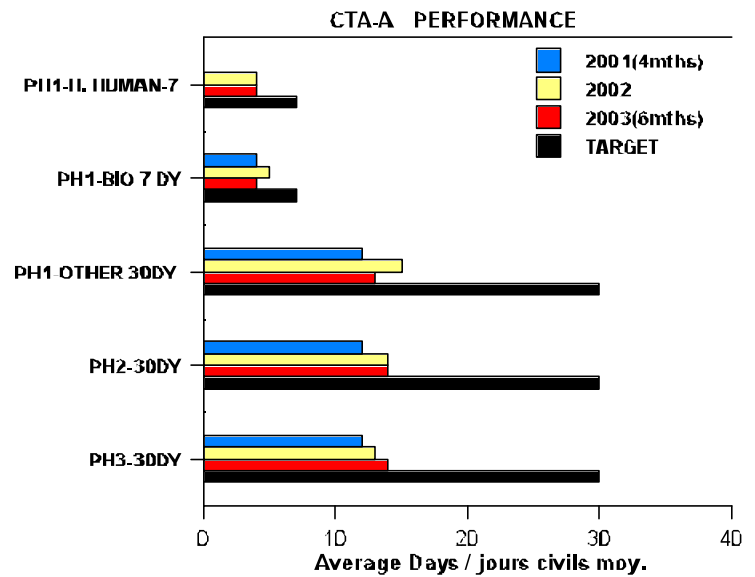
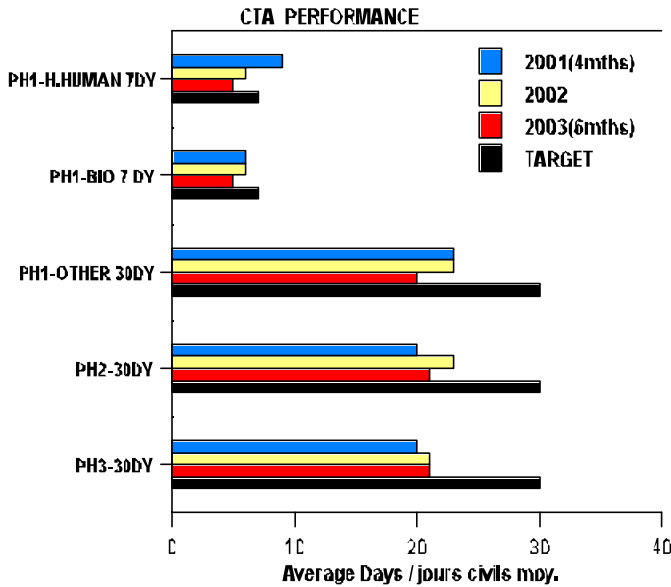
Performance vs Target - Performance vs objectifs  
DINA- Review by class, DINA - Examen préliminaire par catégorie,  
2000 - 2003



| Class / Catégorie                                     | Targets (Review 1 & 2)<br>Objectifs ( Examen 1 & 2) | REVIEW 1<br>EXAMEN 1 |                      |                      |                       | REVIEW 2<br>EXAMEN 2 |                     |                     |                       |
|---|---|----------------------|----------------------|----------------------|-----------------------|----------------------|---------------------|---------------------|-----------------------|
|   |   | 2000                 | 2001                 | 2002                 | 2003<br>(6 mths/mois) | 2000                 | 2001                | 2002                | 2003<br>(6 mths/mois) |
| Form<br>Formule                                       | (180/120)   | n = 235<br>Avg =196  | n = 184<br>Avg = 180 | n = 210<br>Avg = 227 | n = 80<br>Avg =247    | n = 40<br>Avg =148   | n = 32<br>Avg = 138 | n = 19<br>Avg = 158 | n = 10<br>Avg = 172   |
| Form & Supp. Data<br>Formule + données justificatives | (180/150)   | n =122<br>Avg = 380  | n = 43<br>Avg = 254  | n = 53<br>Avg = 261  | n = 13<br>Avg =408    | n =14<br>Avg = 294   | n = 6<br>Avg = 198  | n = 19<br>Avg = 178 | n = 9<br>Avg = 291    |

## Performance vs Target - Performance vs objectifs

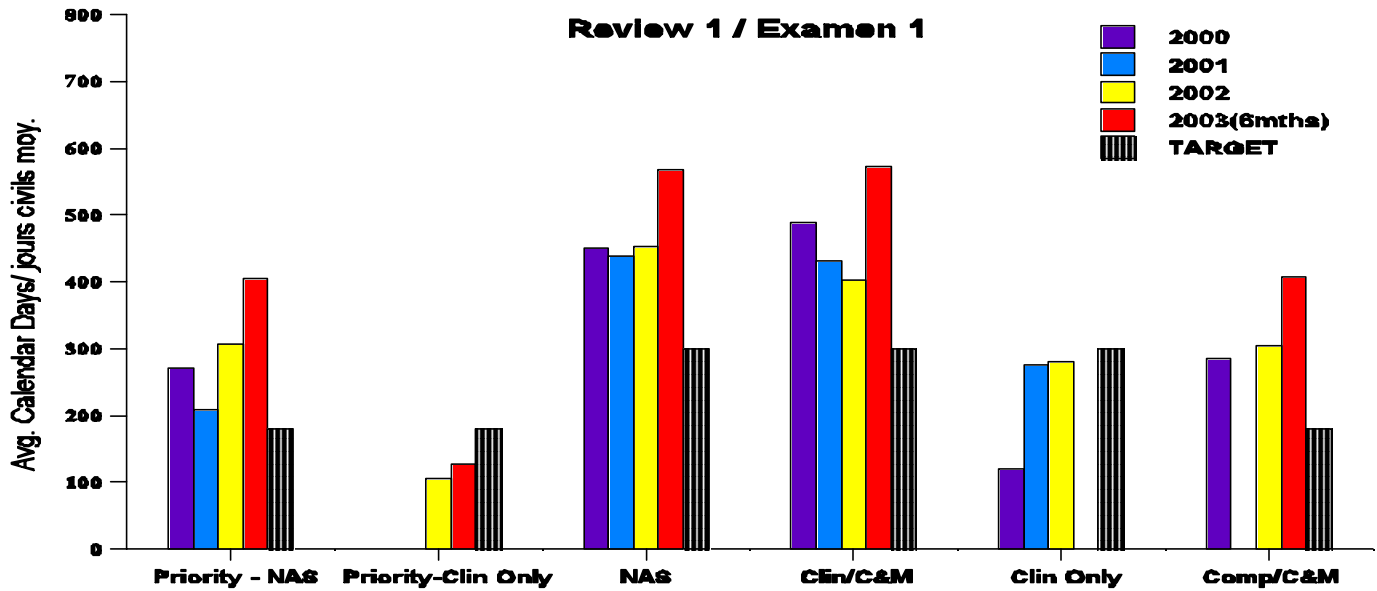
### CTA and CTA-A / DEC et MDEC



| Class / Catégorie<br>Targets Review 1<br>Objectifs Examen 1 | CTA - DEC            |                 |                      | CTA-A / M-DEC        |                 |                      |
|---|----------------------|-----------------|----------------------|----------------------|-----------------|----------------------|
|   | 2001<br>(4mths/mois) | 2002            | 2003<br>(6mths/mois) | 2001<br>(4mths/mois) | 2002            | 2003<br>(6mths/mois) |
| PH1 BIOEQUIVALENCE-7 /<br>PH1 de bioéquivalence-7           | n=119<br>Avg=6       | n=640<br>Avg=6  | n=307<br>Avg=5       | n=7<br>Avg=4         | n=38<br>Avg=5   | n=16<br>Avg=4        |
| PH1 HEALTHY HUMAN-7/<br>PH1 des humains en santé-7          | n=8<br>Avg=9         | n=45<br>Avg=6   | n=20<br>Avg=5        |                      | n=3<br>Avg=4    | n=2<br>Avg=4         |
| PH1 Healthy Human-30 /<br>PH1 des humains en santé-30       |                      | n=7<br>Avg=17   | n=1<br>Avg=15        |                      | n=50<br>Avg=17  | n=1<br>Avg=6         |
| PH1 OTHER - 30Days /<br>PH1 autre - 30 jours                | n=7<br>Avg=23        | n=29<br>Avg=23  | n=27<br>Avg=20       | n=6<br>Avg=12        | n=27<br>Avg=15  | n=17<br>Avg=13       |
| PH2 - 30 Days /<br>PH2 - 30 jours                           | n=43<br>Avg=20       | n=201<br>Avg=23 | n=111<br>Avg=21      | n=33<br>Avg=12       | n=144<br>Avg=14 | n=103<br>Avg=14      |
| PH3 - 30 Days /<br>PH3 - 30 jour                            | n=75<br>Avg=20       | n=335<br>Avg=21 | n=140<br>Avg=21      | n=84<br>Avg=13       | n=431<br>Avg=13 | n=195<br>Avg=14      |
| Phase 1 / 2- 30 Days/<br>phase 1 / 2- 30 jours              | n=4<br>Avg=20        | n=6<br>Avg=23   | n=3<br>Avg=22        | n=2<br>Avg=17        | n=9<br>Avg=14   | n=3<br>Avg=14        |
| Phase 2 / 3 - 30 Days /<br>phase 2 / 3 - 30 jours           | n=3<br>Avg=15        | n=11<br>Avg=25  | n=1<br>Avg=13        | n=3<br>Avg=21        | n=6<br>Avg=18   | n=5<br>Avg=17        |
| Phase Unassign-30/<br>indéterminé phase-30                  | n=7<br>Avg=21        | n=18<br>Avg=24  | n=16<br>Avg=15       | n=1<br>Avg=8         | n=25<br>Avg=16  | n=14<br>Avg=13       |

\*Note: The new CTA and CTA-A regulations became effective September 2001.  
Les DEC et les MDEC l'application du nouveau règlement commence septembre 2001.

Performance vs Target / Performance vs objectifs  
NDS - Review by class / PDN - Examen par catégorie  
2000-2003



| Class / Catégorie<br>Targets/Objectifs<br>(Review / Examen 1 & 2) | REVIEW / EXAMEN 1                         |   |  |   | REVIEW / EXAMEN 2                        |  |  |  |
|---|---|---|--|---|--|--|--|--|
|   | 2000                                      | 2001  | 2002                                       | 2003<br>(6 Mths/mois)                     | 2000                                     | 2001   | 2002   | 2003<br>(6 Mths/mois)                    |
| Priority-NAS/<br>Priorité-NSA (180/90)                            | n = 9<br>Avg = 272<br>Min=180<br>Max=575  | n = 5<br>Avg = 210<br>Min=171<br>Max=238    | n = 4<br>Avg = 308<br>Min=246<br>Max=366   | n=1<br>Avg=406                            | n = 2<br>Avg = 292<br>Min=90<br>Max=494  | n = 2<br>Avg = 101<br>Min = 94<br>Max = 107  | n = 1<br>Avg = 180                           |  |
| Priority Clin Only/<br>Priorité-Clin seulement (180/90)           |   |   | n = 5<br>Avg = 106<br>Min=33*<br>Max=257   | n=1<br>Avg=127                            |  |  |  | n=1<br>Avg=11                            |
| NAS / NSA (300/150)   | n = 28<br>Avg = 451<br>Min=113<br>Max=715 | n = 26<br>Avg = 439<br>Min =99<br>Max =636  | n = 15<br>Avg = 454<br>Min=203<br>Max=1013 | n = 9<br>Avg = 567<br>Min=246<br>Max=1083 | n = 4<br>Avg = 355<br>Min=7<br>Max=471   | n= 10<br>Avg = 334<br>Min = 219<br>Max = 462 | n= 10<br>Avg = 248<br>Min = 106<br>Max = 465 | n=1<br>Avg=275                           |
| Clin/C&M /<br>Clin/C&F (300/150)                                  | n = 30<br>Avg = 489<br>Min=113<br>Max=966 | n = 21<br>Avg = 431<br>Min =198<br>Max =786 | n = 13<br>Avg = 403<br>Min=242<br>Max=537  | n = 13<br>Avg = 572<br>Min=337<br>Max=815 | n = 9<br>Avg = 258<br>Min=129<br>Max=372 | n = 8<br>Avg = 280<br>Min = 158<br>Max =434  | n = 2<br>Avg = 220<br>Min = 188<br>Max = 252 | n = 4<br>Avg = 364<br>Min=151<br>Max=553 |
| Clin Only /<br>Clin Seulement (300/150)                           | n = 2<br>Avg = 121<br>Min=69<br>Max=336   | n = 5<br>Avg = 277<br>Min =55<br>Max =380   | n = 3<br>Avg = 281<br>Min=173<br>Max=408   |   |  |  |  |  |
| Comp/C&M /<br>Comp/C&F (180/150)                                  | n = 1<br>Avg = 285                        |   | n = 2<br>Avg = 304<br>Min=168<br>Max=439   | n=1<br>Avg=407                            | n = 1<br>Avg = 260                       | n = 1<br>Avg = 400                           | n = 1<br>Avg = 108                           |  |
| C&M/Labeling /<br>C&F/Étiquetage (180/150)                        |   | n = 2<br>Avg = 226<br>Min=225<br>Max=227    | n = 1<br>Avg = 287                         |   |  |  |  |  |

\*Medical Device submission/Équipement médical présentations

cont'd

**Performance vs Target  
Performance vs objectifs**

**NDS - Review by Bureau \* and class  
PDN - Examen par Bureau \* et catégorie**

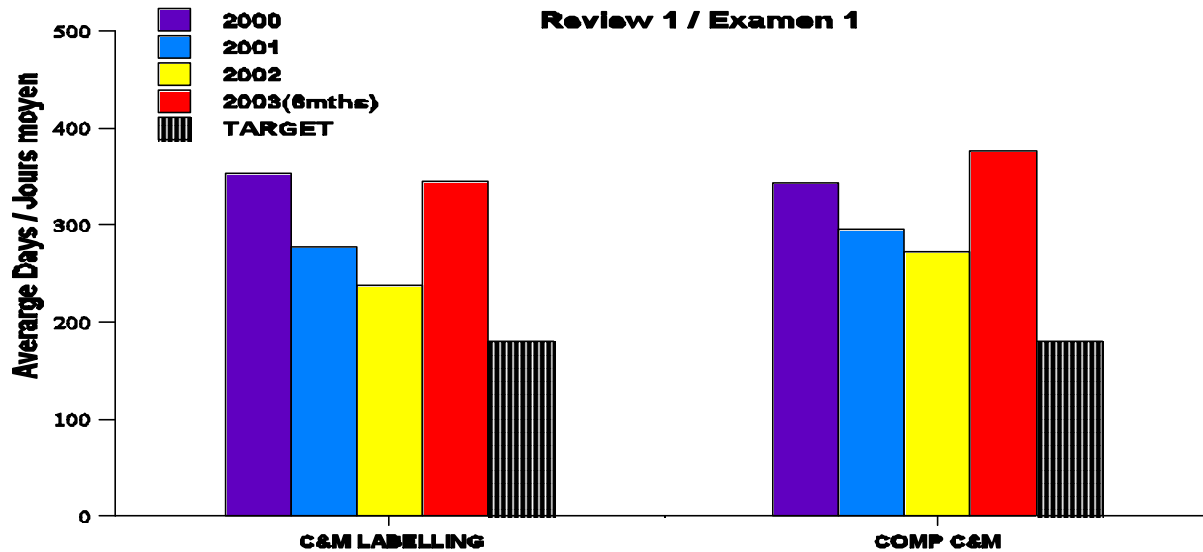
| Class / Catégorie<br>Targets/Objectifs<br>(Review / Examen 1 & 2) | 2003 - 6 MONTHS/MOIS<br>REVIEW / EXAMEN 1 |                                      |                                       |                                      |                                      | 2003 - 6 MONTHS/MOIS<br>REVIEW / EXAMEN 2 |                |                |                                      |      |
|---|---|--------------------------------------|---------------------------------------|--------------------------------------|--------------------------------------|---|----------------|----------------|--------------------------------------|------|
|   | BPS                                       | BCANS                                | BGIVD                                 | BMORS                                | SMAB                                 | BPS                                       | BCANS          | BGIVD          | BMORS                                | SMAB |
| Priority-NAS/<br>Priorité-NSA (180/90)                            |   |                                      | n=1<br>Avg=406                        |                                      |                                      |   |                |                |                                      |      |
| Priority Clin Only/<br>Priorité-Clin seulement (180/90)           |   | n=1<br>Avg=127                       |                                       |                                      |                                      |   | n=1<br>Avg=11  |                |                                      |      |
| NAS /<br>NSA (300/150)  |   | n=7<br>Avg=482<br>Min=246<br>Max=808 | n=2<br>Avg=862<br>Min=641<br>Max=1083 |                                      |                                      |   |                |                | n=1<br>Avg=275                       |      |
| Clin/C&M /<br>Clin/C&F (300/150)                                  |   | n=5<br>Avg=646<br>Min=476<br>Max=815 | n=4<br>Avg=494<br>Min=337<br>Max=708  | n=2<br>Avg=577<br>Min=553<br>Max=600 | n=2<br>Avg=542<br>Min=501<br>Max=583 |   | n=1<br>Avg=151 | n=1<br>Avg=364 | n=2<br>Avg=471<br>Min=389<br>Max=553 |      |
| Comp/C&M /<br>Comp/C&F (180/150)                                  |   |                                      |                                       | n=1<br>Avg=407                       |                                      |   |                |                |                                      |      |

\* This table represents a breakdown of performance vs target for Q-2 only (2003 - 6 months) by Bureau.

\* Le tableau représente les détails de la performance vs objectifs (2003-6mois) par bureau.

## Performance vs Target - Performance vs objectifs ANDS - Review by Bureau and Class - PADN - Examen par Bureau et catégorie,

2000 - 2003

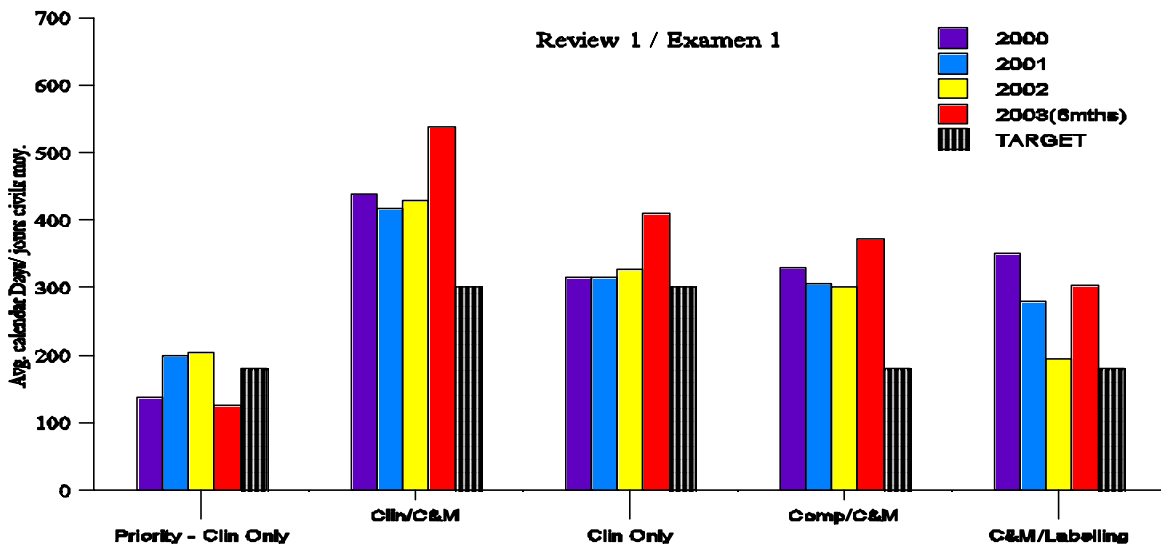


| Class / Catégorie<br>Targets (Review 1 & 2)<br>Objectifs (Examen 1 & 2) | REVIEW 1<br>EXAMEN 1                          |  |   |   | REVIEW 2<br>EXAMEN 2                         |  |   |   |
|---|---|--|---|---|--|--|---|---|
|   | 2000  | 2001   | 2002  | 2003<br>(6mths/mois)                          | 2000   | 2001   | 2002  | 2003<br>(6mths/mois)                          |
| C&M/Labelling /<br>C&F/Étiquetage<br>(180/150)                          | n = 20<br>Avg = 354<br>Min = 199<br>Max = 500 | n = 38<br>Avg = 277<br>Min = 70<br>Max = 465 | n = 11<br>Avg = 238<br>Min = 5<br>Max = 428   | n = 7<br>Avg = 345<br>Min = 261<br>Max = 431  | n = 4<br>Avg = 242<br>Min = 195<br>Max = 280 | n = 8<br>Avg = 187<br>Min = 126<br>Max = 341 | n = 12<br>Avg = 203<br>Min = 154<br>Max = 294 |   |
| Comp/C&M /<br>Comp/C&F<br>(180/150)                                     | n = 54<br>Avg = 343<br>Min = 160<br>Max = 630 | n = 67<br>Avg = 295<br>Min = 92<br>Max = 504 | n = 43<br>Avg = 273<br>Min = 172<br>Max = 941 | n = 21<br>Avg = 377<br>Min = 220<br>Max = 728 | n = 6<br>Avg = 207<br>Min = 18<br>Max = 392  | n = 33<br>Avg = 199<br>Min = 2<br>Max = 418  | n = 20<br>Avg = 187<br>Min = 1<br>Max = 287   | n = 10<br>Avg = 294<br>Min = 162<br>Max = 651 |

| Class / Catégorie<br>Targets/Objectifs<br>(Review / Examen 1 & 2) | 2003 - 6 MONTHS<br>REVIEW / EXAMEN 1  |       |                                      |       |      | 2003 - 6 MONTHS<br>REVIEW / EXAMEN 2  |       |       |       |      |
|---|---------------------------------------|-------|--------------------------------------|-------|------|---------------------------------------|-------|-------|-------|------|
|   | BPS                                   | BCANS | BGIVD                                | BMORS | SMAB | BPS                                   | BCANS | BGIVD | BMORS | SMAB |
| C&M/Labelling /<br>C&F/Étiquetage<br>(180/150)                    | n=5<br>Avg=342<br>Min=261<br>Max=431  |       | n=2<br>Avg=354<br>Min=322<br>Max=385 |       |      |                                       |       |       |       |      |
| Comp/C&M /<br>Comp/C&F<br>(180/150)                               | n=19<br>Avg=367<br>Min=220<br>Max=728 |       | n=2<br>Avg=476<br>Min=468<br>Max=484 |       |      | n=10<br>Avg=294<br>Min=162<br>Max=651 |       |       |       |      |

\* This table represents a breakdown of performance vs target for Q-2 only (2003 - 6 months) by Bureau.

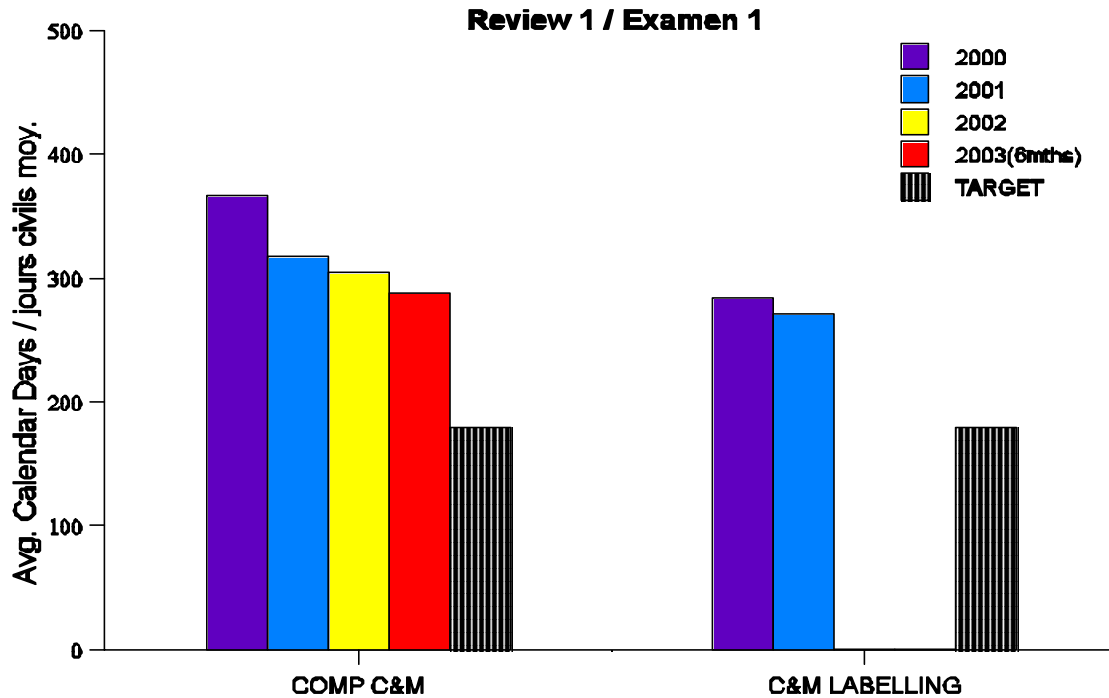
## Performance vs Target - Performance vs objectifs SNDS Review by class - SPDN Examen par catégorie, 2000 - 2003



| Class / Catégorie<br>Targets / Objectifs<br>(Review / Examen 1 & 2) | REVIEW / EXAMEN 1                     |                                       |                                       |                                      | REVIEW / EXAMEN 2                     |                                      |                                      |                                      |
|---|---------------------------------------|---------------------------------------|---------------------------------------|--------------------------------------|---------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
|   | 2000                                  | 2001                                  | 2002                                  | 2003<br>(6 Mths/mois)                | 2000                                  | 2001                                 | 2002                                 | 2003<br>(6 Mths/mois)                |
| Priority-Clin Only /<br>Priorité/Clin seulement<br>(180/90)         | n=2<br>Avg=137<br>Min=71<br>Max=202   | n=6<br>Avg=200<br>Min=56<br>Max=286   | n=6<br>Avg=203<br>Min=152<br>Max=296  | n=1<br>Avg=125                       |                                       |                                      | n=1<br>Avg=382                       |                                      |
| Priority Clin/C&M/<br>Priorité-Clin/C&F<br>(180/90)                 | n=1<br>Avg=307                        | n=1<br>Avg=448                        |                                       |                                      |                                       |                                      |                                      |                                      |
| Priority Rx-OTC-NNI/<br>Priorité Rx à VL nni<br>(120/90)            |                                       |                                       | n=1<br>Avg=81                         | n=1<br>Avg=183                       |                                       |                                      |                                      |                                      |
| Clin/C&M/<br>Clin / C&F<br>(300/150)                                | n=20<br>Avg=439<br>Min=300<br>Max=564 | n=23<br>Avg=416<br>Min=266<br>Max=628 | n=14<br>Avg=429<br>Min=266<br>Max=875 | n=9<br>Avg=538<br>Min=325<br>Max=870 | n=4<br>Avg=216<br>Min=133<br>Max=307  | n=6<br>Avg=202<br>Min=158<br>Max=266 | n=2<br>Avg=319<br>Min=165<br>Max=472 | n=2<br>Avg=368<br>Min=162<br>Max=574 |
| Clin Only /<br>Clin seulement<br>(300/150)                          | n=60<br>Avg=316<br>Min=46<br>Max=1250 | n=63<br>Avg=314<br>Min=55<br>Max=804  | n=50<br>Avg=328<br>Min=26<br>Max=649  | n=29<br>Avg=411<br>Min=8<br>Max=888  | n=12<br>Avg=194<br>Min=119<br>Max=379 | n=10<br>Avg=200<br>Min=99<br>Max=342 | n=12<br>Avg=184<br>Min=56<br>Max=358 | n=5<br>Avg=299<br>Min=181<br>Max=621 |
| Comp/C&M /<br>Comp/C&F<br>(180/150)                                 | n=21<br>Avg=330<br>Min=218<br>Max=446 | n=16<br>Avg=306<br>Min=216<br>Max=384 | n=8<br>Avg=301<br>Min=258<br>Max=372  | n=7<br>Avg=373<br>Min=152<br>Max=504 | n=5<br>Avg=239<br>Min=172<br>Max=375  | n=8<br>Avg=180<br>Min=112<br>Max=302 | n=2<br>Avg=216<br>Min=188<br>Max=243 |                                      |
| C&M/Labeling /<br>C&F/Étiquetage<br>(180/150)                       | n=10<br>Avg=351<br>Min=237<br>Max=447 | n=14<br>Avg=279<br>Min=182<br>Max=385 | n=9<br>Avg=195<br>Min=74<br>Max=263   | n=1<br>Avg=304                       | n=3<br>Avg=231<br>Min=199<br>Max=276  | n=1<br>Avg=315                       |                                      | n=1<br>Avg=253                       |
| Labeling Only/<br>Étiquetage seulement<br>(60)                      | n=2<br>Avg=94<br>Min=56<br>Max=131    | n=14<br>Avg=77<br>Min=59<br>Max=102   | n=7<br>Avg=60<br>Min=1<br>Max=122     | n=9<br>Avg=99<br>Min=23<br>Max=359   |                                       |                                      |                                      |                                      |
| Rx-OTC-No New Indication<br>Rx à VL pni<br>(180/150)                | n=2<br>Avg=256<br>Min=244<br>Max=267  | n=3<br>Avg=212<br>Min=184<br>Max=228  | n=1<br>Avg=203                        | n=1<br>Avg=216                       |                                       |                                      |                                      |                                      |



## Performance vs Target - Performance vs objectifs SANDS Review by class - SPADN Examen par catégorie, 2000 - 2003



| Class / Catégorie<br>Targets / Objectifs (Review/ Examen1 & 2) | REVIEW 1<br>EXAMEN 1                 |                                      |                                      |                                      | REVIEW 2<br>EXAMEN 2                |      |      |                      |
|--|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|-------------------------------------|------|------|----------------------|
|  | 2000                                 | 2001                                 | 2002                                 | 2003<br>(6Mths/mois)                 | 2000                                | 2001 | 2002 | 2003<br>(6Mths/mois) |
| Comp/C&M / Comp/C&F (180/150)                                  | n=3<br>Avg=367<br>Min=326<br>Max=434 | n=5<br>Avg=318<br>Min=256<br>Max=399 | n=3<br>Avg=305<br>Min=272<br>Max=364 | n=6<br>Avg=288<br>Min=206<br>Max=344 | n=1<br>Avg=233                      |      |      | n=1<br>Avg=271       |
| C&M/Labeling / C&F/Étiquetage (180/150)                        | n=3<br>Avg=284<br>Min=225<br>Max=366 | n=6<br>Avg=271<br>Min=195<br>Max=328 |                                      |                                      | n=2<br>Avg=153<br>Min=56<br>Max=250 |      |      | n=1<br>Avg=348       |
| Labeling Only / Étiquetage seuleMent (60)                      |                                      | n=2<br>Avg=76<br>Min=70<br>Max=81    | n=3<br>Avg=64<br>Min=64<br>Max=64    | n=6<br>Avg=83<br>Min=12<br>Max=197   |                                     |      |      |                      |