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Natural and Non-Prescription Health Products Directorate

Drug Submission Performance
Quarterly Report
January - March
2019



Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high quality health services are accessible, and works to reduce health risks.

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Direction des produits de santé naturels et sans ordonnance – Rapport trimestriel du rendement des présentations de drogue – janvier – mars 2019

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OVERVIEW

The NNHPD Quarterly Drug Submission Performance Report reflects Non-Prescription and Disinfectant Drug submission review activity over five consecutive quarters from January – March 2018 to January – March 2019. Statistics are provided by Submission Type and show the number received, the number in workload and the number of licensing decisions issued over that period.

Some of the highlights of the January – March 2019 report are:

Non-Prescription (Over the Counter - OTC) Drugs:

- There was a slight increase (3%) in the number of DINA submissions received: from 35 in October-December 2018 to 36 in this quarter (January-March 2019).
- There was a 30% increase in the number of DINF submissions received: from 43 in October-December 2018 to 56 in this quarter (January-March 2019).
- The number of PDC submissions received decreased slightly (8%): from 71 in October-December 2018 to 65 in this quarter (January-March 2019).
- There was 1 NDS received in this quarter (January-March 2019) while 2 were received in October-December 2018. However, there was a doubling (50%) in the number of SNDS received this quarter (20 in January-March 2019) when compared to the 10 received in the last quarter.
- The number of NCs received during this past quarter increased slightly (17%): from 6 in October-December 2018 to 7 in January-March 2019.

Overall, the total non-prescription drug submissions received increased by 15% during this past quarter (185) compared to last quarter (161). This increase brings the total number of non-prescription drug submissions up to the highest levels as compared to the 4 quarters of 2018 (i.e., 36 in January-March 2018; 151 in April-June 2018; 111 in July-September 2018; and 161 in October-December 2018).

Disinfectant Drugs:

- The number of DIND submissions received decreased (33%): from 57 in October-December 2018 to 38 in this quarter (i.e., January-March 2019).
- The number of PDC submissions received decreased (31%) from 16 in October-December 2018 to 11 in this quarter (January-March 2019).

Overall, the total disinfectant drug submissions received decreased by 34% during this past quarter (49) compared to last quarter (74). However, this decrease brings the total number of disinfectant drug submissions back to levels more consistent with those received in the first 3 quarters of 2018 (i.e., 48 in January-March 2018; 48 in April-June 2018; and 42 in October-December 2018).

General Information

There are several steps involved in the drug submission review¹ and approval process:

- administrative processing,
- regulatory and scientific screening and
- in-depth scientific review.

When deficiencies or non-compliance issues are found, a company may submit responses before a final decision can be reached and thus multiple review cycles may be required. A submission's approval time can vary depending on the number and type of review cycles needed.

Submissions Received are counts of submissions received during the year using the filing date (CR date) which is the date the submission is considered administratively complete by Health Canada.

Workload is the number of submissions “under active review” on the last day of the quarter. “**Backlog**” is the proportion of the workload that is over target. Often the term workload is used to mean the amount of work received over a period of time and is a common source of confusion.

For new drugs, **approvals** are Notice of Compliances (NOC) Issued or Issuable which are reported in the Decisions’ section. An NOC issuable is when a submission’s NOC is placed “on hold” awaiting authorization to market, due to changes from Prescription to Non-Prescription or due to Patented Medicines (NOC) Regulations.

¹ For further clarification refer to the [Guidance for Industry: Management of Drug Submissions](#).

A **review cycle completion** is counted upon the conclusion of a scientific review that then results in a decision of approval or non-approval. The time taken is compared to a set [performance standard](#)² which is based on the type of submission, class and cycle (status). Health Canada has set a goal of 90% of review cycle completions to be rendered within performance standards.

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

Office of Submissions and Intellectual Property, Resource Management and Operations
Directorate
Finance Building, A.L. # 0202A1
101 Tunney's Pasture Driveway, Tunney's Pasture
Ottawa, Ontario, K1A 0K9

Tel: (613) 941-7281 Fax: (613) 941-0825

Email: hc.osip-bppi.sc@canada.ca

² Performance continues to be measured against performance standards for Submission Type/Submission Class/ Status combinations as set out in Appendix 3 of the [Guidance for Industry: Management of Drug Submissions](#). This is not to be confused with the 'UF Review 1 (iteration 1)' performance standards that are employed to measure performance to meet the *User Fees Act* reporting Requirements in the 'Health Canada Departmental Performance Report (DPR)'.

ACRONYMS

Submission Types

ANDS	-	Abbreviated New Drug Submission
DINA	-	Application for a Drug Identification Number
DIND	-	Application for a Drug Identification Number – Disinfectant Product
DINF	-	Application for a Drug Identification Number - Category IV Product – (Labelling Standard)
MPNDS		Pre-NDS Meeting
NC	-	Notifiable Change – New Drug
NDS	-	New Drug Submission
NDS-D		New Drug Submission - Disinfectants
PDC	-	Post-DIN Changes
SNDS	-	Supplemental New Drug Submission

Documents

NOC	-	Notice of Compliance
NOC-c	-	Notice of Compliance with Conditions
Issuable NOC (Patent)	-	NOC on Hold due to Patented Medicines (NOC) Regulations
Issuable NOC (Rx to OTC)	-	NOC on Hold due to changes (Prescription to Non-Prescription)
NON	-	Notice of Non-Compliance
NOD	-	Notice of Deficiency
NON Withdrawal	-	Notice of Non-Compliance Withdrawal Letter
NOD Withdrawal	-	Notice of Deficiency Withdrawal Letter

Fee Categories

Fee Category	Fee Category Description
New Active Substance (NAS)	Submission in support of a drug, excluding a disinfectant, that contains a medicinal ingredient not previously approved in a drug for sale in Canada, and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. For biologics, this submission class does not include an NDS in support of a subsequent entry biologic or an SNDS in support of changes to the manufacturing process of biologics.
Clinical or Non-Clinical Data and Chemistry and Manufacturing data	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a NAS.
Clinical or Non-Clinical Data Only	Submissions based only on clinical or non-clinical data for a drug that does not include a NAS.
Comparative Studies	Submissions based on comparative studies with or without chemistry and manufacturing data for a drug that does not include a NAS. It excludes superiority and non-inferiority studies since they are clinical studies. It also excludes pharmaceutical equivalence studies since they are captured by the chemistry and manufacturing fee.
Chemistry and Manufacturing Data Only	Submissions based only on chemistry and manufacturing data for a drug that does not include a NAS.
Published Data Only	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS.
Switch from Prescription to Nonprescription Status	Submissions based only on data that support the modification or removal of a medicinal ingredient on the Prescription Drug List . This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
Labelling Only³	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission	Submissions in support of a manufacturer or product name change.
Disinfectants⁴	Submissions and applications that include data in support of a disinfectant.
Drug Identification Number (DIN) - Labelling Standards	Applications attesting to compliance with a labelling standard or Category IV Monograph (DINF) for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.

For further information, please refer to the [Guidance Document - Fees for the Review of Drug Submissions and Applications](#)

³ For more information, please consult the [Guidance Document: Question and Answers about Plain Language Labelling](#)

⁴ The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from TPD to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported on in a separate NNHPD Drug Submission Performance Report.

PART 1: NON-PRESCRIPTION DRUGS

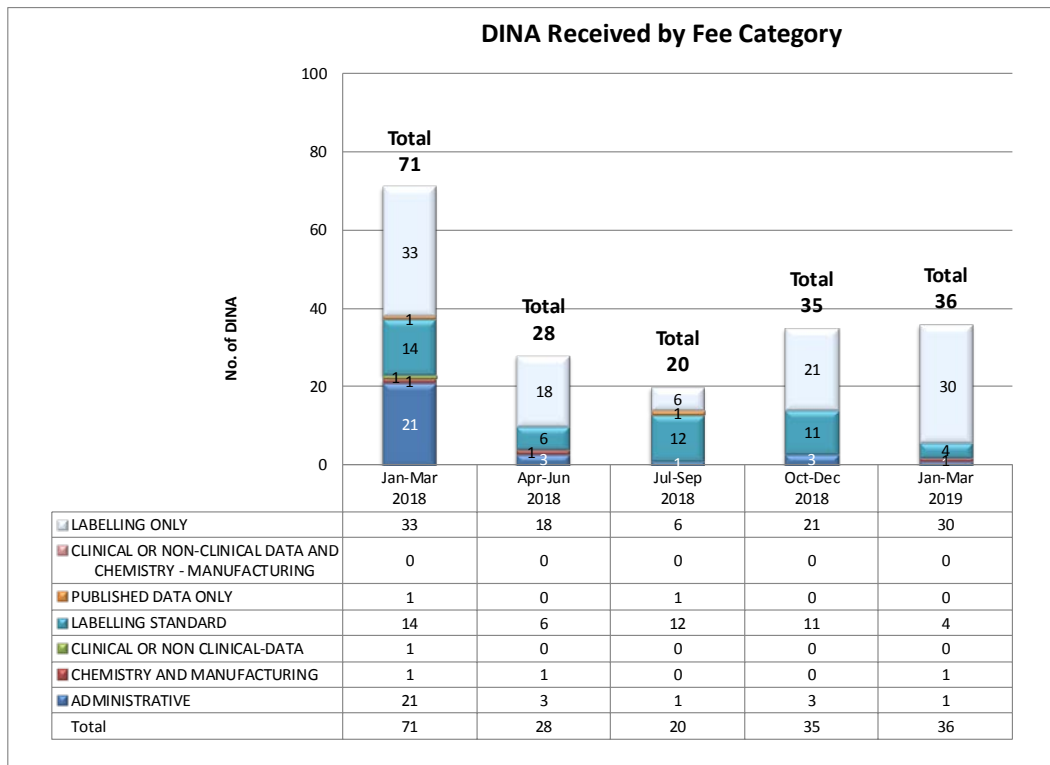
Over the counter (OTC) Drugs

NON PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the Food and Drug Regulations

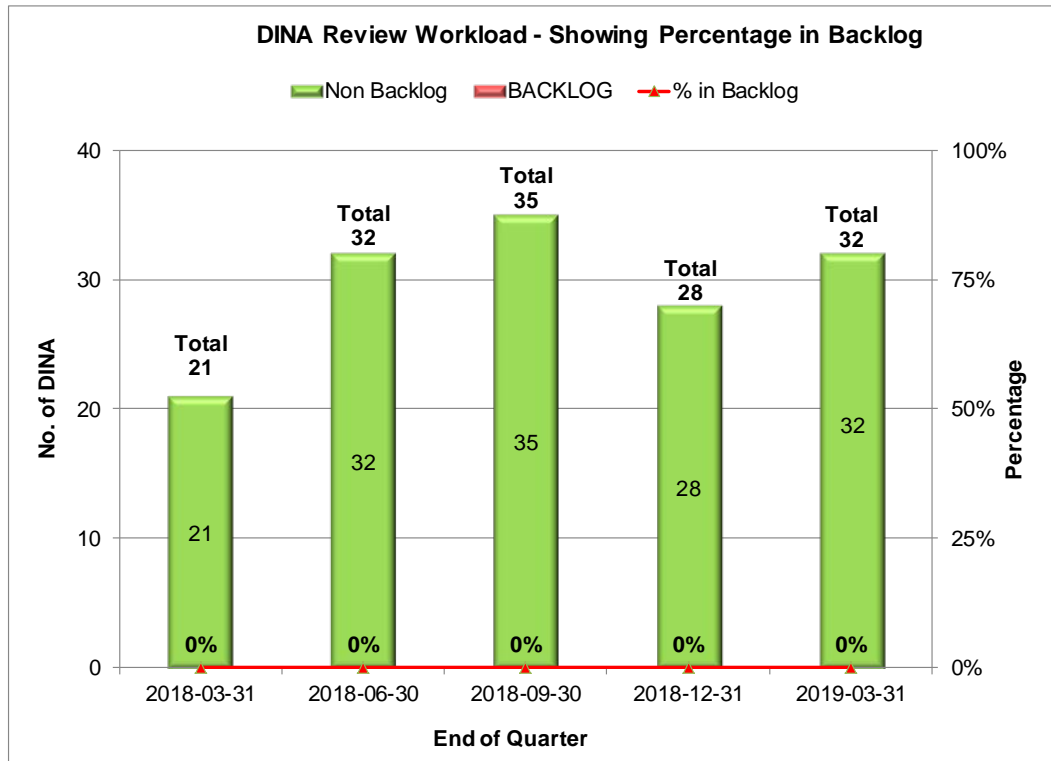
DINA: DRUG IDENTIFICATION NUMBER APPLICATIONS SUBMISSIONS RECEIVED

DINA: Received by Fee Category



WORKLOAD

DINA: Review Workload Showing Percentage in Backlog

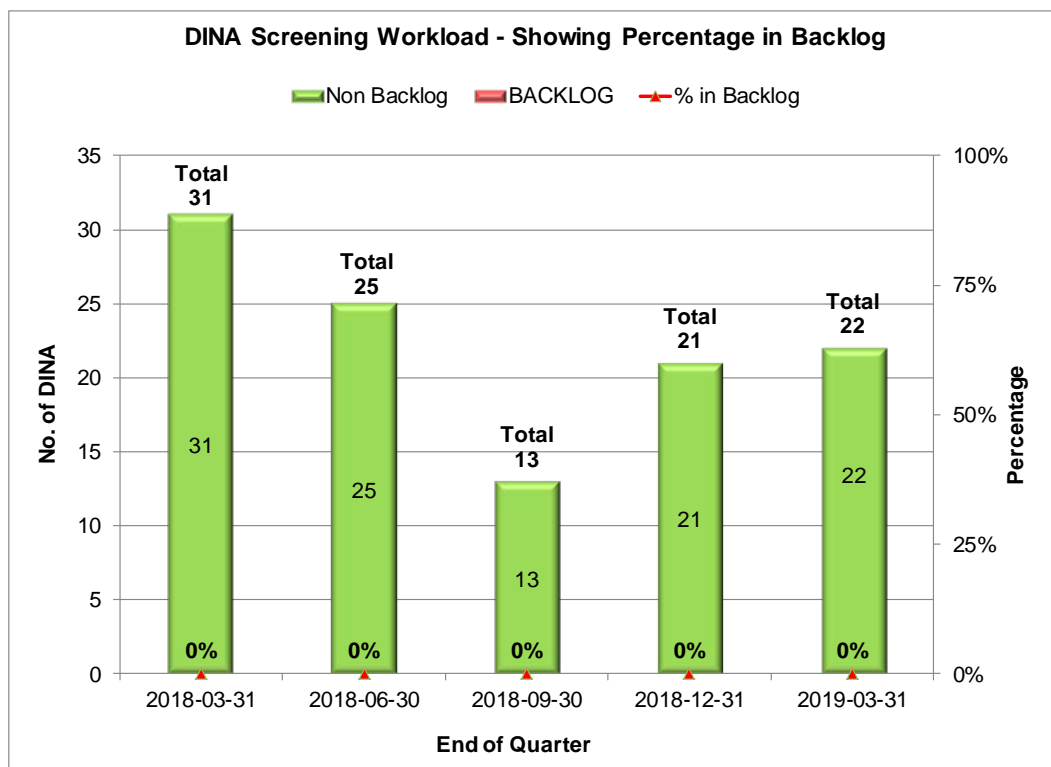


DINA: Review Workload by Fee Category

NNHPD DINA REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Chemistry and Manufacturing	1	1	1	1	0
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clinical Data	0	1	1	1	0
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clinical Data and Chemistry -	1	0	1	1	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	19	30	31	24	32
<i>Backlog</i>	0	0	0	0	0
Published Data	0	0	1	1	0
<i>Backlog</i>	0	0	0	0	0
Total	21	32	35	28	32
Non Backlog	21	32	35	28	32
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

DINA: Screening Workload Showing Percentage in Backlog

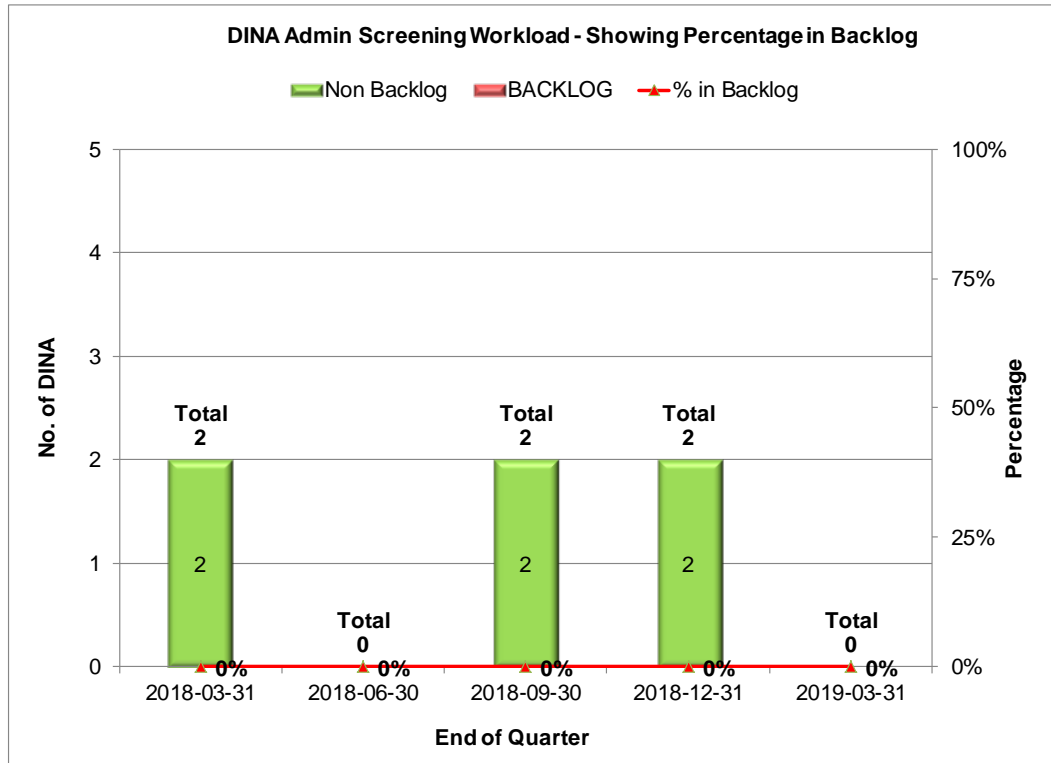


DINA: Screening Workload by Fee Category

NNHPD DINA SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Chemistry and Manufacturing	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clinical	0	0	0	0	1
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clinical Data and Chemistry -	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	21	13	8	9	15
<i>Backlog</i>	0	0	0	0	0
Labelling Standard	10	12	5	12	6
<i>Backlog</i>	0	0	0	0	0
Published Data	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	31	25	13	21	22
Non Backlog	31	25	13	21	22
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

DINA: Administrative-Screening Workload Showing Percentage in Backlog



DINA: Administrative-Screening Workload by Fee Category

NNHPD DINA ADMIN SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Administrative	2	0	2	2	0
<i>Backlog</i>	0	0	0	0	0
Total	2	0	2	2	0
Non Backlog	2	0	2	2	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

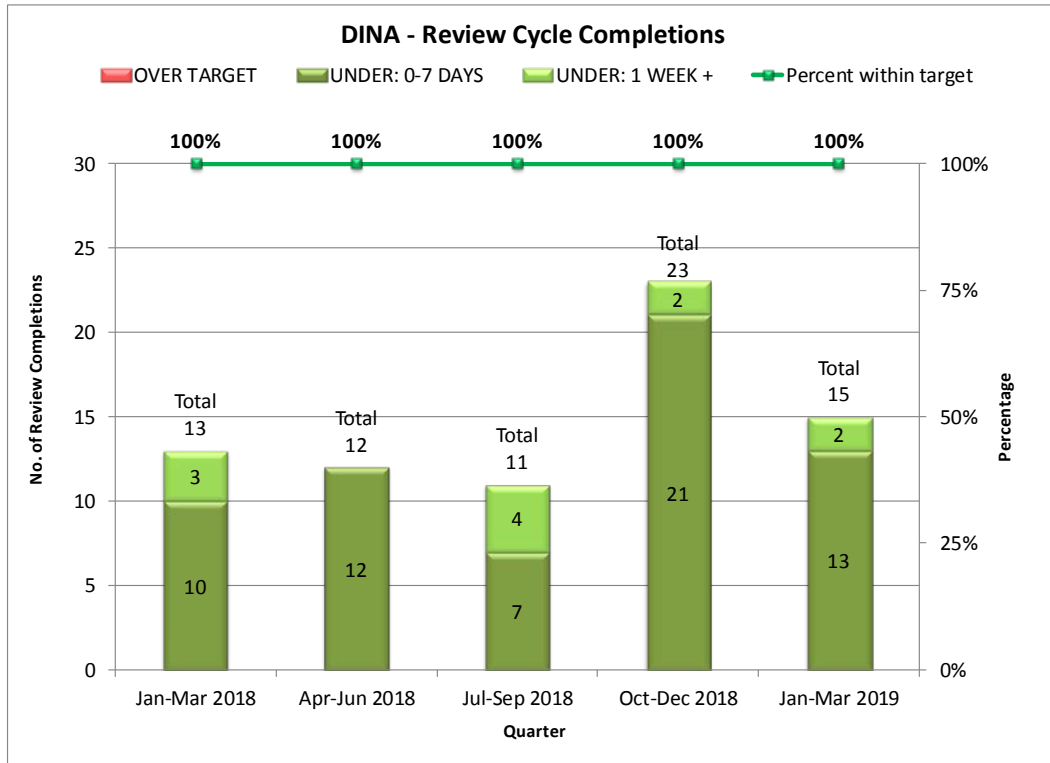
DECISION DOCUMENTS

DINA: Decision Documents by Fee Category

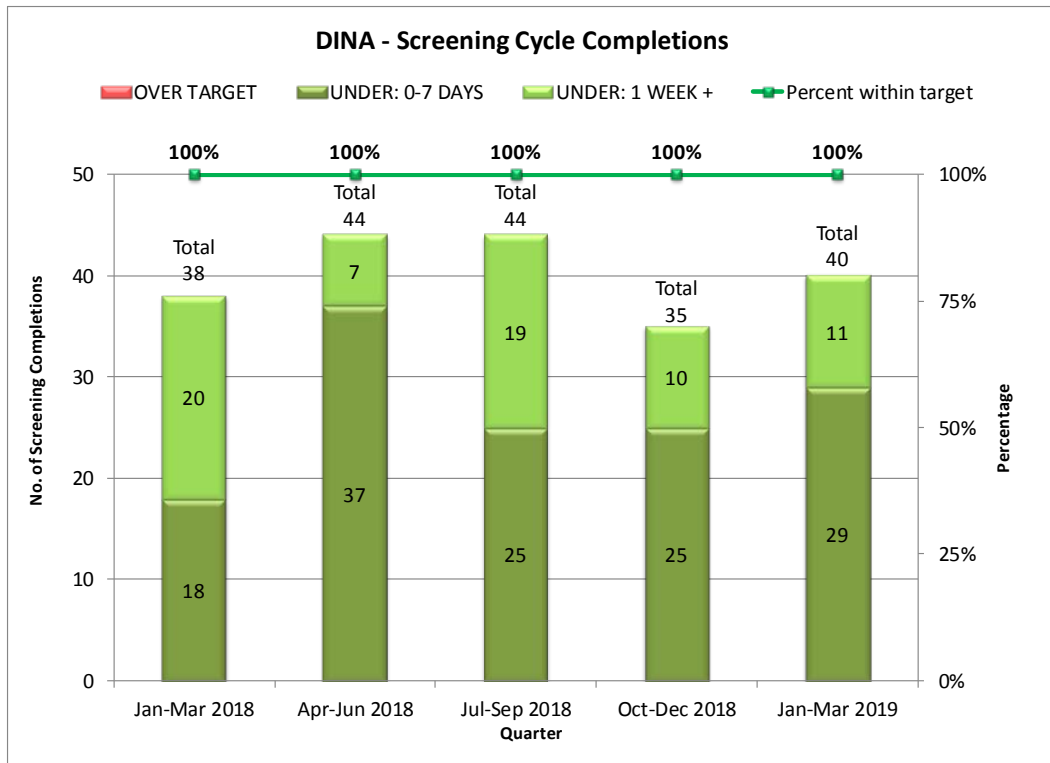
User Fee Category	Decision	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
ADMINISTRATIVE	CANCELLATION LETTER	18	5	1	1	3
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	REJECTION LETTER (SCR)	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	2
	NO OBJECTION LETTER	0	0	0	0	0
CHEMISTRY AND MANUFACTURING	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	NO OBJECTION LETTER	0	1	1	0	1
	CANCELLATION LETTER	2	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	1
	WITHDRAWAL NO RESP TO NON	0	0	0	0	0
CLINICAL OR NON-CLINICAL DATA	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	1
	NO OBJECTION LETTER	1	0	0	0	0
	SCREENING DEFICIENCY NOTICE	1	0	0	0	0
	CANCELLATION LETTER	0	1	0	0	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	1	0	0	0
	NOTIFICATION FORM DIN SUB	0	0	0	0	1
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTIFICATION FORM DIN SUB	0	0	0	0	0
LABELLING ONLY	CANCELLATION LETTER	8	4	0	0	0
	NO OBJECTION LETTER	0	0	1	0	2
	NOTICE OF NON-COMPLIANCE	0	3	2	0	1
	NOTICE OF DEFICIENCY	0	1	1	0	0
	NOTIFICATION FORM DIN SUB	11	7	7	23	8
	REJECTION LETTER (SCR)	1	0	2	5	0
	SCREENING DEFICIENCY NOTICE	5	5	6	2	11
	WITHDRAWAL NO RESP TO NOD	0	0	1	0	0
	WITHDRAWAL NO RESP TO NON	0	1	0	0	0
LABELLING STANDARD	CANCELLATION LETTER	0	1	3	1	0
	NO OBJECTION LETTER	0	0	0	0	
	NOTIFICATION FORM DIN SUB	10	4	13	7	6
	REJECTION LETTER (SCR)	0	0	1	0	0
	SCREENING DEFICIENCY NOTICE	1	9	7	5	4
PUBLISHED DATA	SCREENING DEFICIENCY NOTICE	1	0	0	0	
	NOTICE OF NON-COMPLIANCE	0	0	0	0	
	CANCELLATION LETTER	0	1	0	0	0
	NON WITHDRAWAL LETTER	0	0	0	0	
	NOTIFICATION FORM DIN SUB	1	0	0	0	1

PERFORMANCE

DINA: Review Cycle Completions Showing Percentage within Target

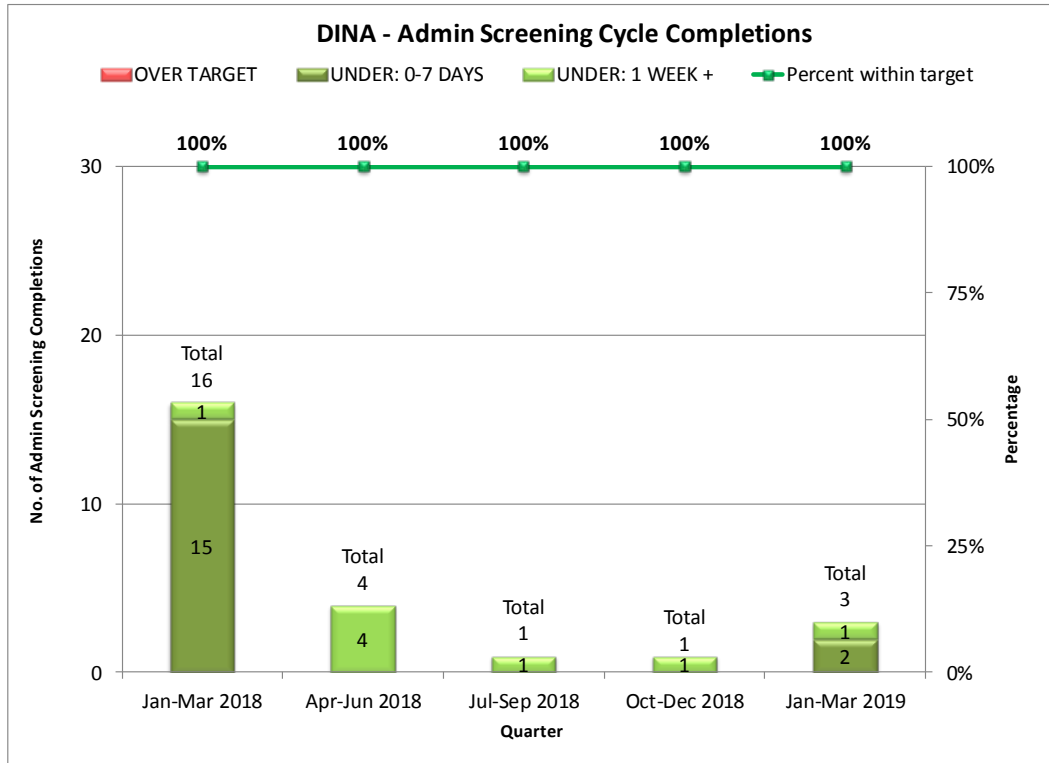


DINA: Screening Cycle Completions Showing Percentage within Target



PERFORMANCE

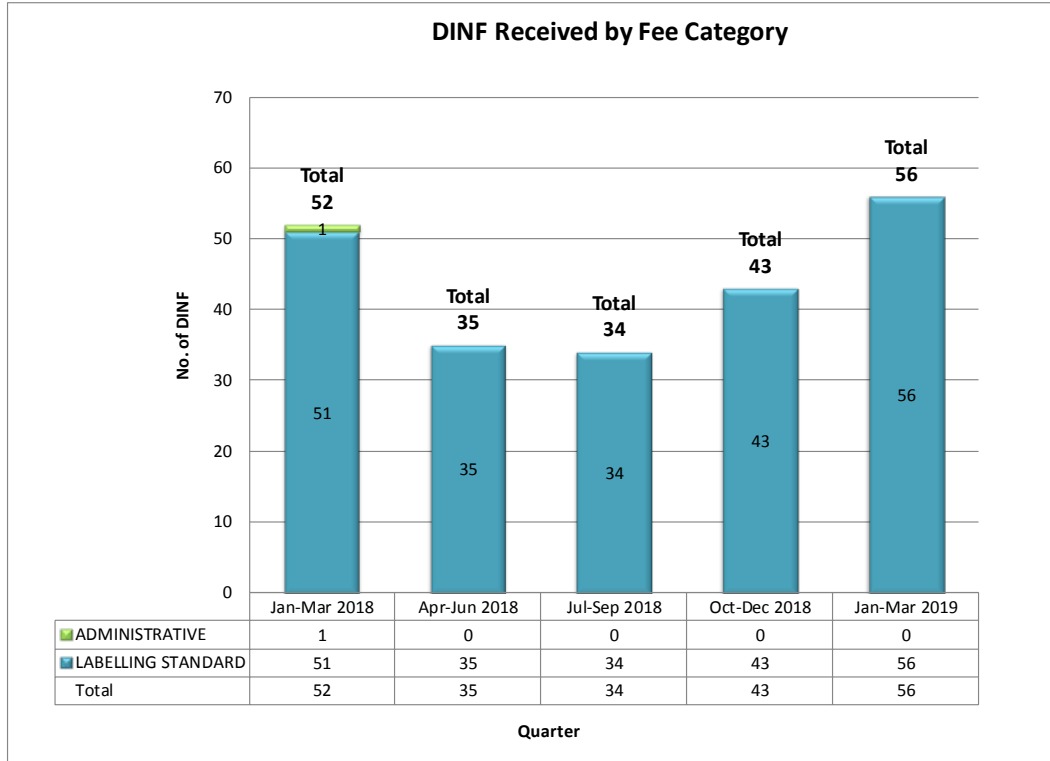
DINA: Administrative-Screening Cycle Completions Showing Percentage within Target



DINF: CATEGORY FOUR DIN APPLICATIONS

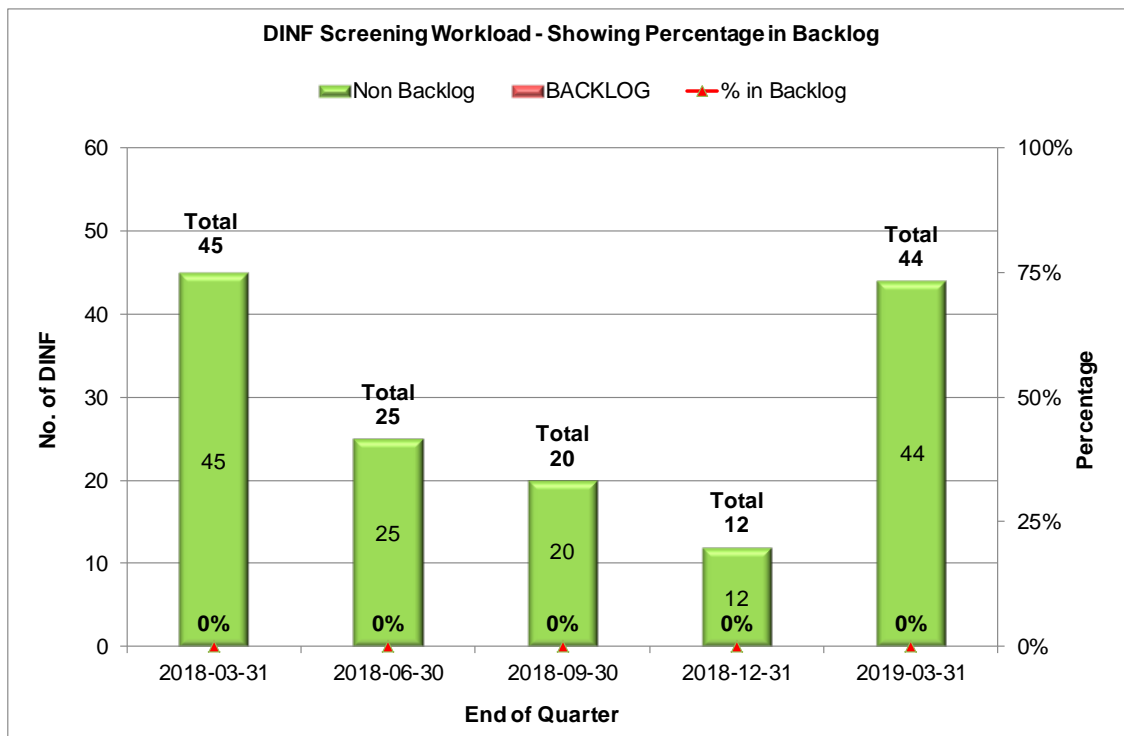
SUBMISSIONS RECEIVED

DINF: Received by Fee Category



WORKLOAD

DINF: Screening Workload Showing Percentage in Backlog



DINF: Screening Workload by Fee Category

NNHPD DINF SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Labelling Standard	45	25	20	12	44
<i>Backlog</i>	0	0	0	0	0
Administrative	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	45	25	20	12	44
Non Backlog	45	25	20	12	44
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

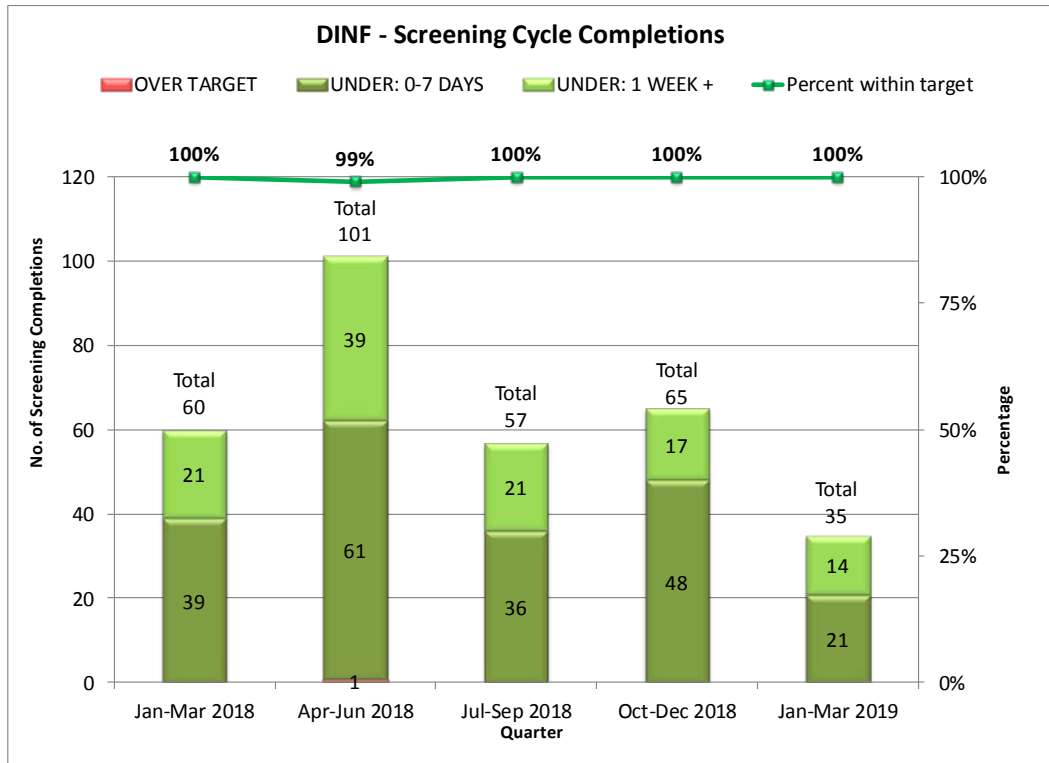
DECISION DOCUMENTS

DINF: Decision Documents by Fee Category

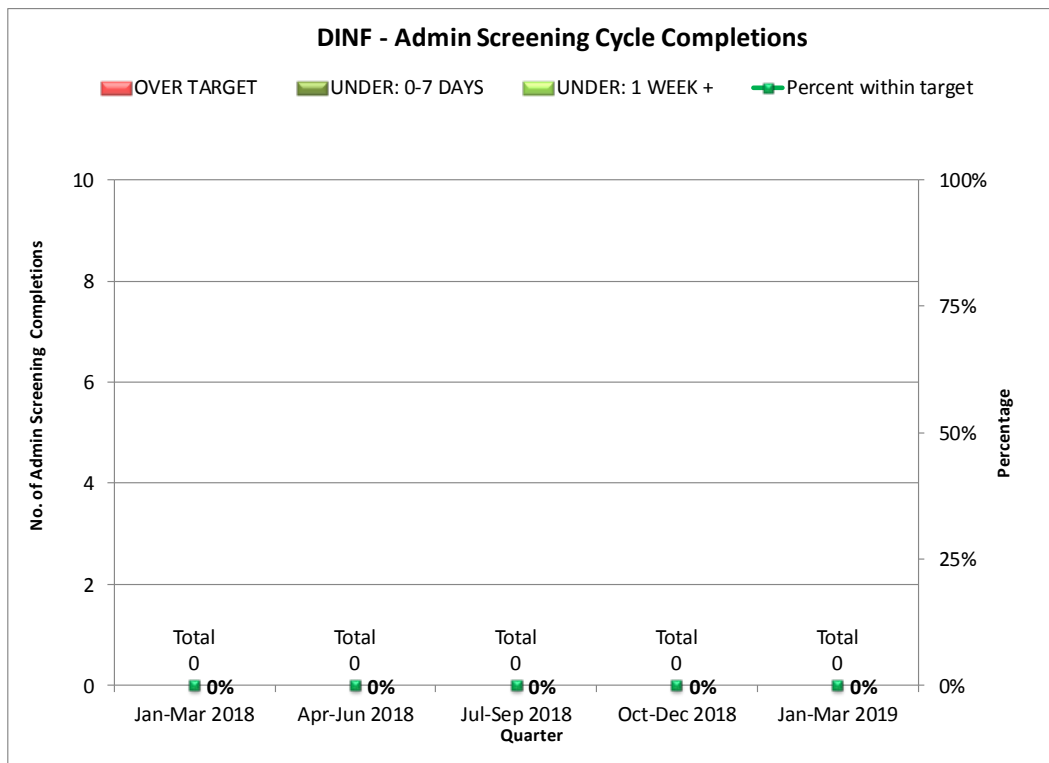
User Fee Category	Decision	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
LABELLING STANDARD	CANCELLATION LETTER	1	5	2	4	2
	NO OBJECTION LETTER	0	0	2	0	0
	NEW DRUG LETTER SCREEN	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	29	53	39	29	22
	REJECTION LETTER (SCR)	0	6	2	4	1
	SCREENING DEFICIENCY NOTICE	31	43	16	34	12
ADMINISTRATIVE	REJECTION LETTER (SCR)	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	CANCELLATION LETTER	1	0	0	0	0

PERFORMANCE

DINF: Screening Cycle Completions



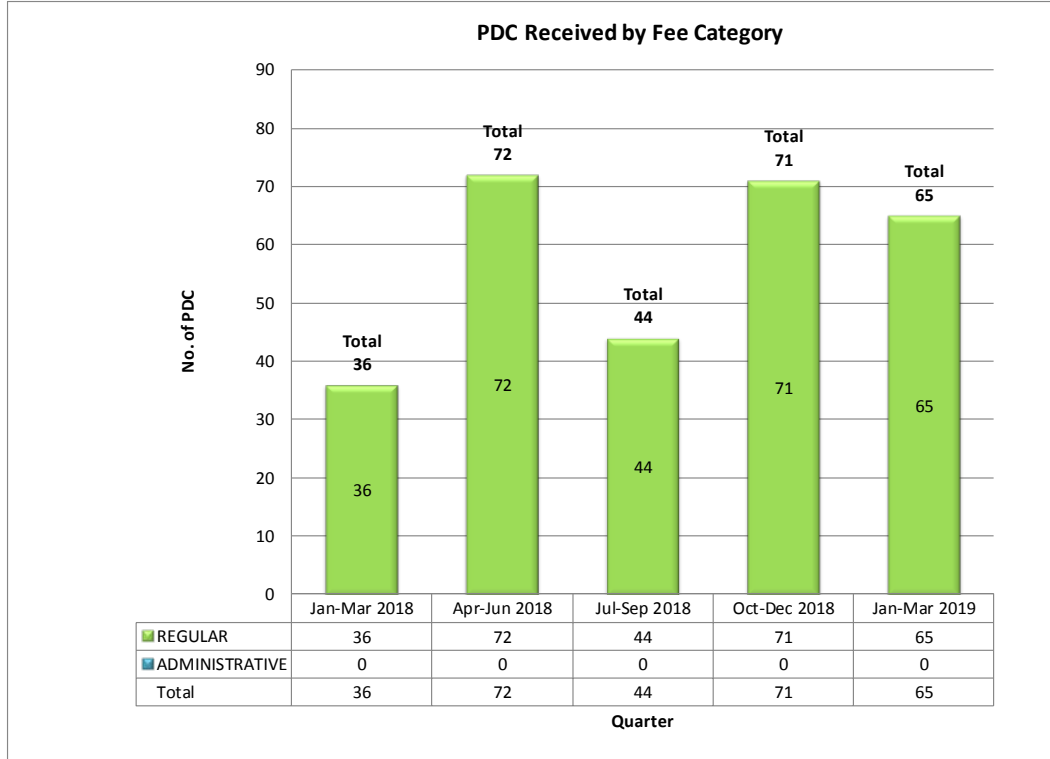
DINF: Admin-Screening Cycle Completions



PDC: POST AUTHORIZATION DIVISION 1 CHANGES

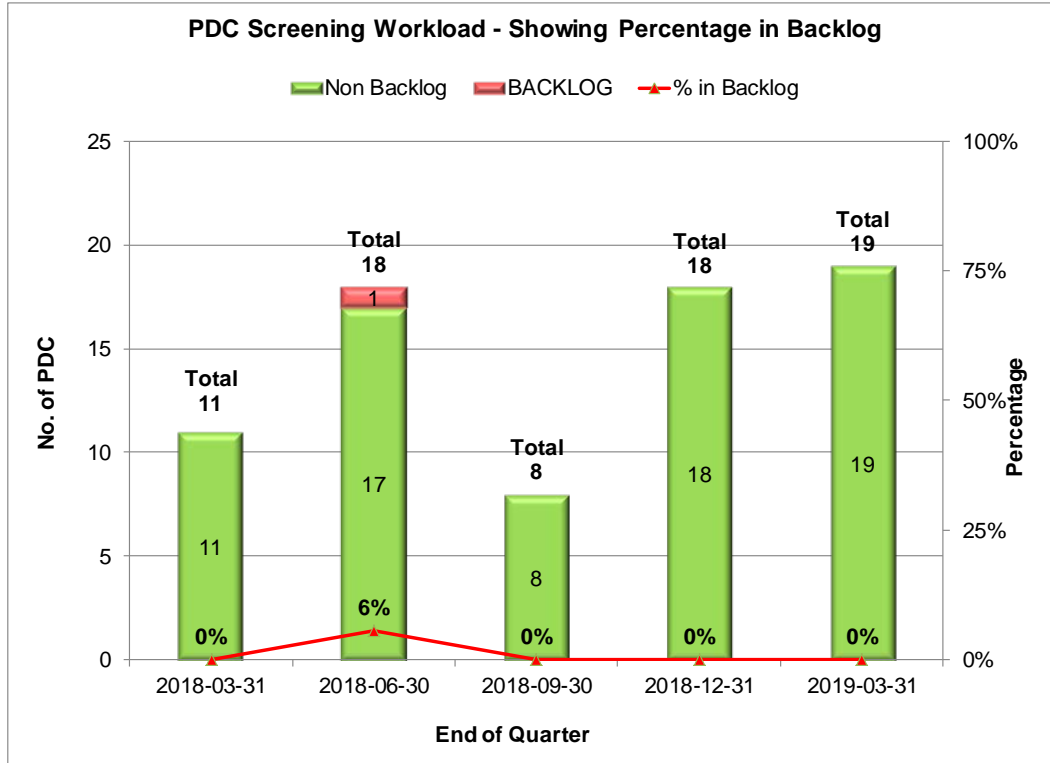
SUBMISSIONS RECEIVED

PDC: Received by Fee Category



WORKLOAD

PDC: Screening Workload Showing Percentage in Backlog



PDC: Screening Workload by Fee Category

NNHPD PDC SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Regular	11	18	8	18	19
<i>Backlog</i>	<i>0</i>	<i>1</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	11	18	8	18	19
Non Backlog	11	17	8	18	19
BACKLOG	0	1	0	0	0
% in Backlog	0%	6%	0%	0%	0%

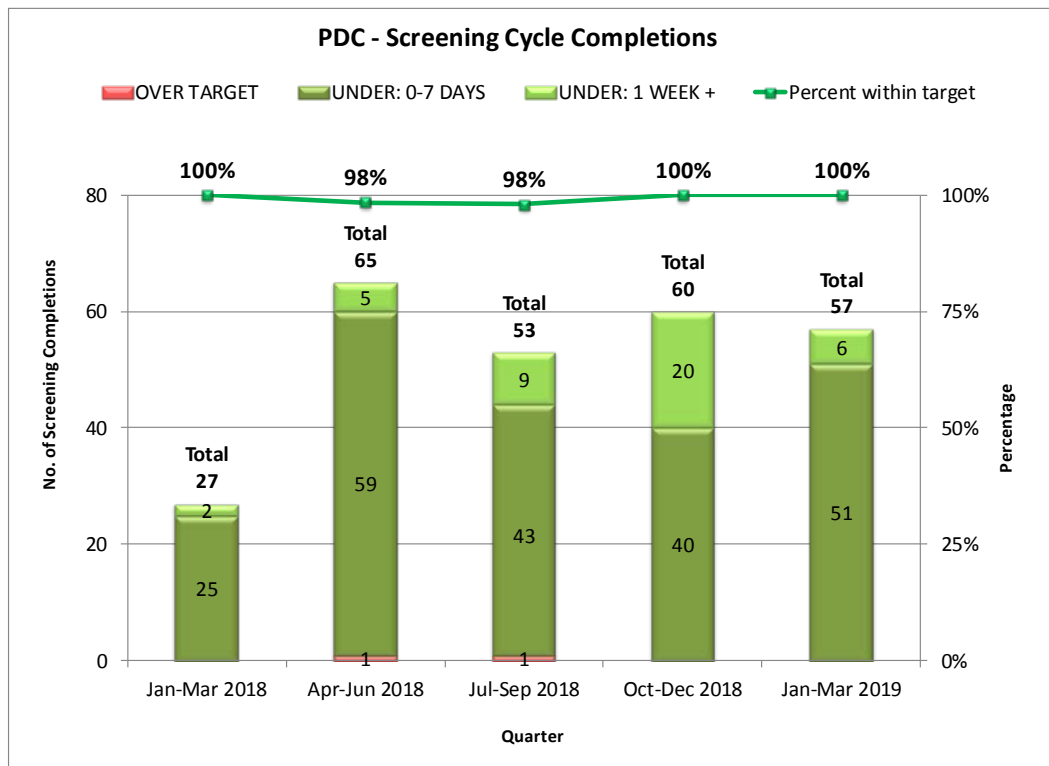
DECISION DOCUMENTS

PDC: Decision Documents by Fee Category

User Fee Category	Decision	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
REGULAR	CANCELLATION LETTER	0	3	6	12	5
	NO OBJECTION LETTER	24	56	40	34	45
	NOT SATISFACTORY NOTICE	3	7	6	13	9
	REJECTION LETTER (SCR)	0	0	0	1	0
	SCREENING DEFICIENCY NOTICE	0	0	1	0	0

PERFORMANCE

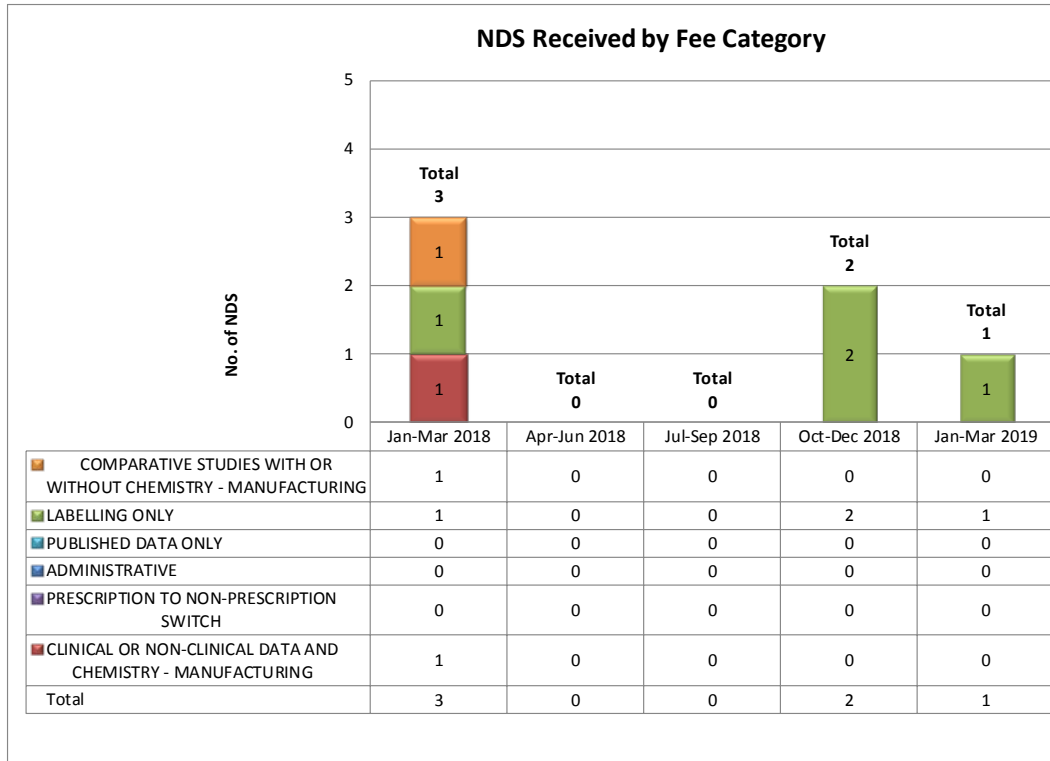
PDC: Screening Cycle Completions



**NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 8
in Part C of the *Food and Drug Regulations***

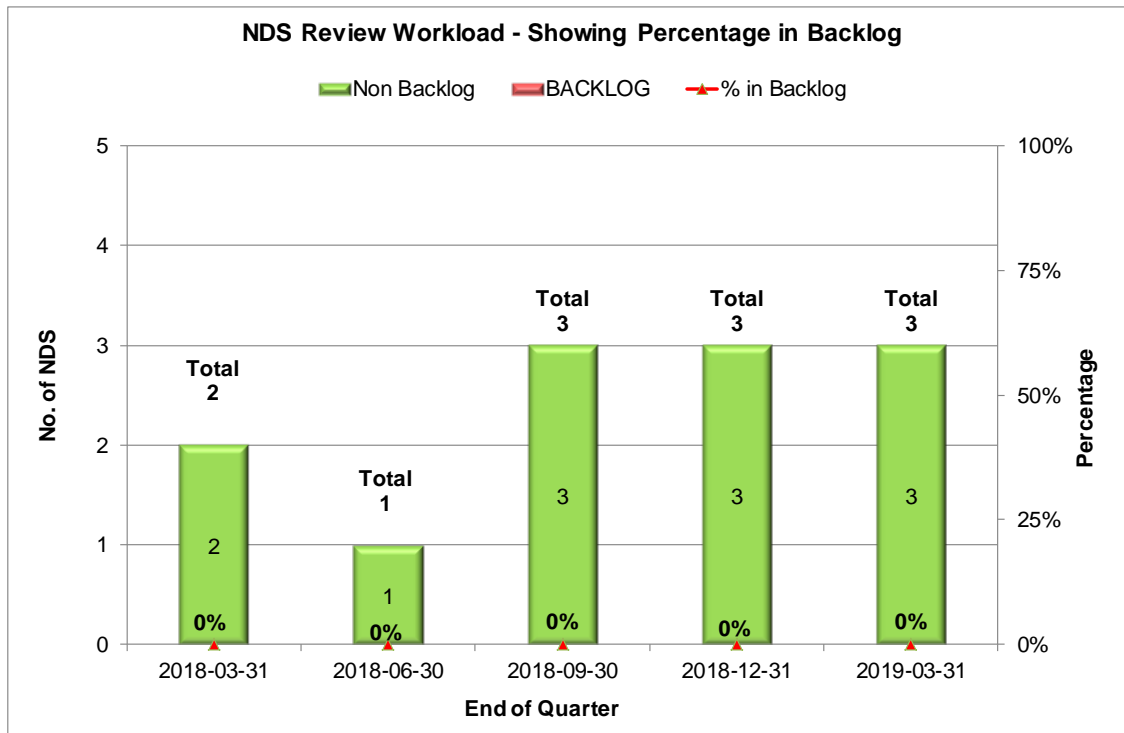
NDS: NEW DRUG SUBMISSIONS SUBMISSIONS RECEIVED

NDS: Received by Fee Category



WORKLOAD

NDS: Review Workload Showing Percentage in Backlog

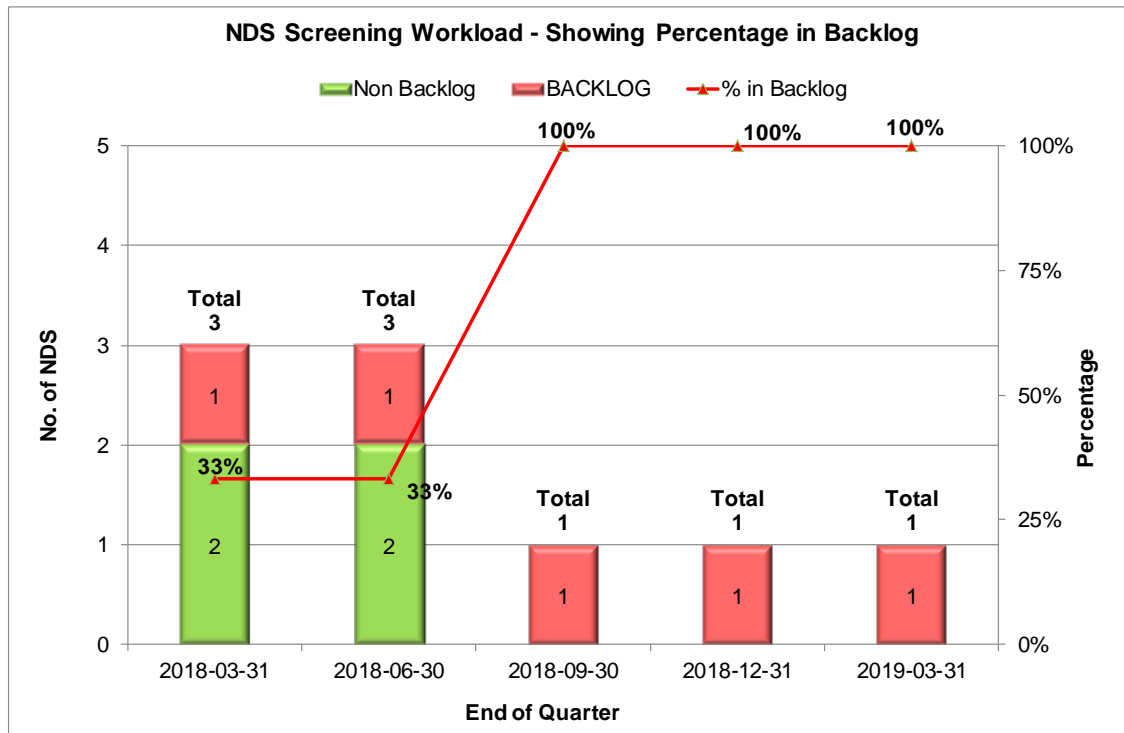


NDS: Review Workload by Fee Category

NNHPD NDS REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Clinical or Non-Clinical Data and Chemistry -	1	1	2	1	1
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	1	1	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	1	0	0	1	2
<i>Backlog</i>	0	0	0	0	0
Total	2	1	3	3	3
Non Backlog	2	1	3	3	3
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

NDS: Screening Workload Showing Percentage in Backlog



NDS: Screening Workload by Fee Category

NNHPD NDS SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Prescription to Non-Prescription Switch	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Published Data	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clinical Data and Chemistry -	1	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	1	1	1	1	1
<i>Backlog</i>	1	1	1	1	1
Comparative Studies with or without Chemistry - Manufacturing	1	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	3	3	1	1	1
Non Backlog	2	2	0	0	0
BACKLOG	1	1	1	1	1
% in Backlog	33%	33%	100%	100%	100%

DECISION DOCUMENTS

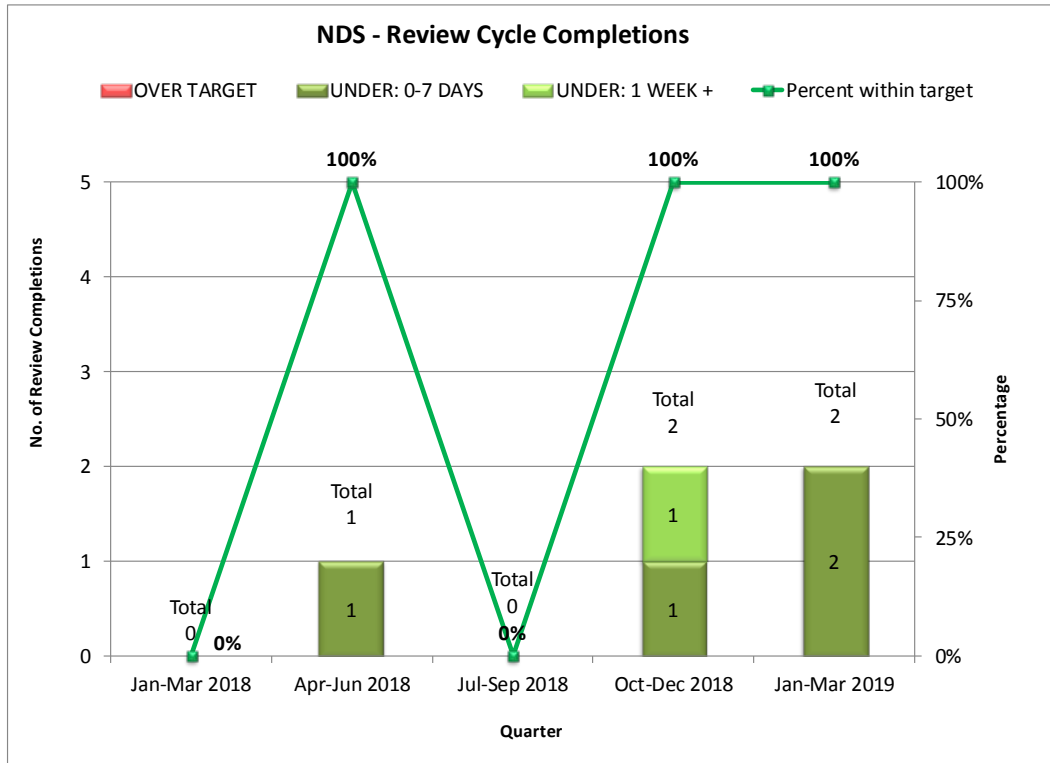
NDS: Decision Documents by Fee Category

User Fee Category	Decision	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	0	1	0	0	0
	NOD WITHDRAWAL LETTER	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	1	0
	NOC ON HOLD (SWITCH)*	0	0	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	1	0	0	0
LABELLING ONLY	NOTICE OF COMPLIANCE*	0	1	0	1	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	0	0	0	1	0
	CANCELLATION LETTER	0	0	0	0	0
PUBLISHED DATA ONLY	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
PRESCRIPTION TO NON-PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH)*	0	0	0	0	0

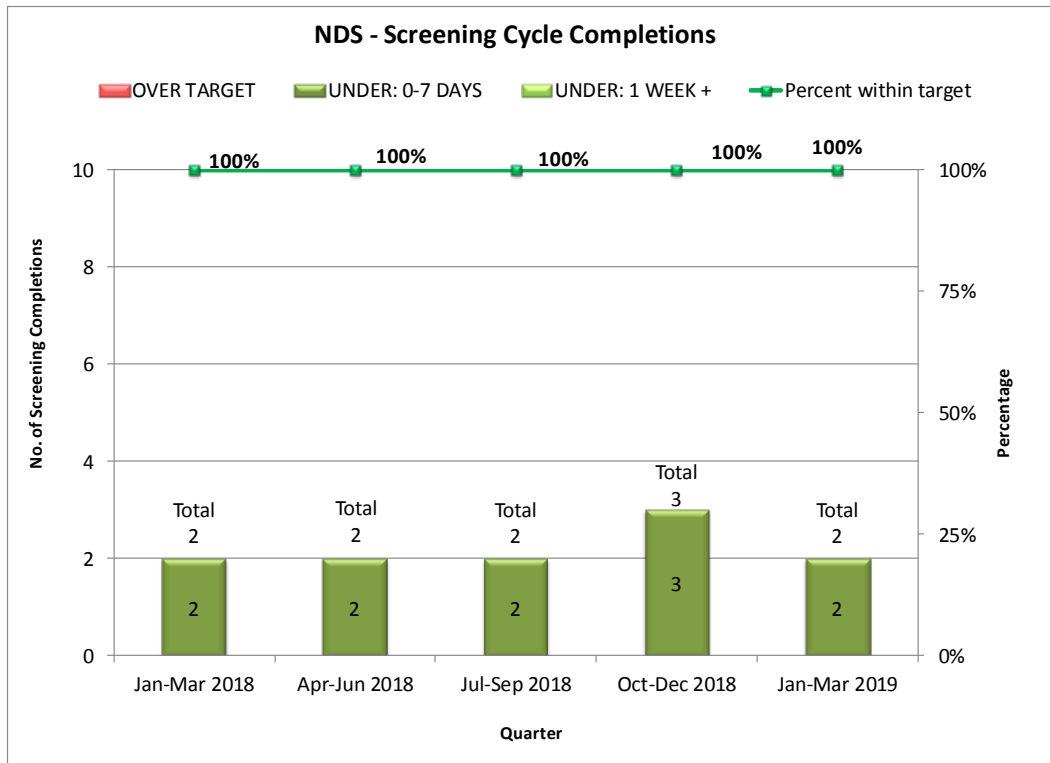
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

NDS: Review Cycle Completions Showing Percentage within Target

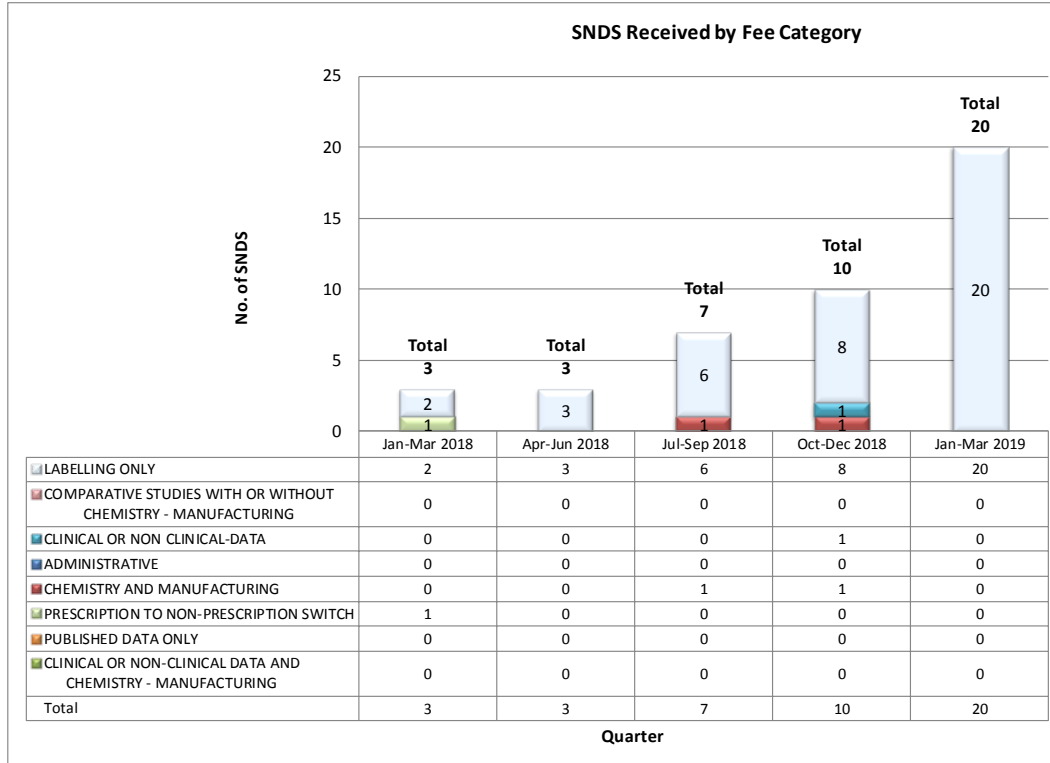


NDS: Screening Cycle Completions Showing Percentage within Target



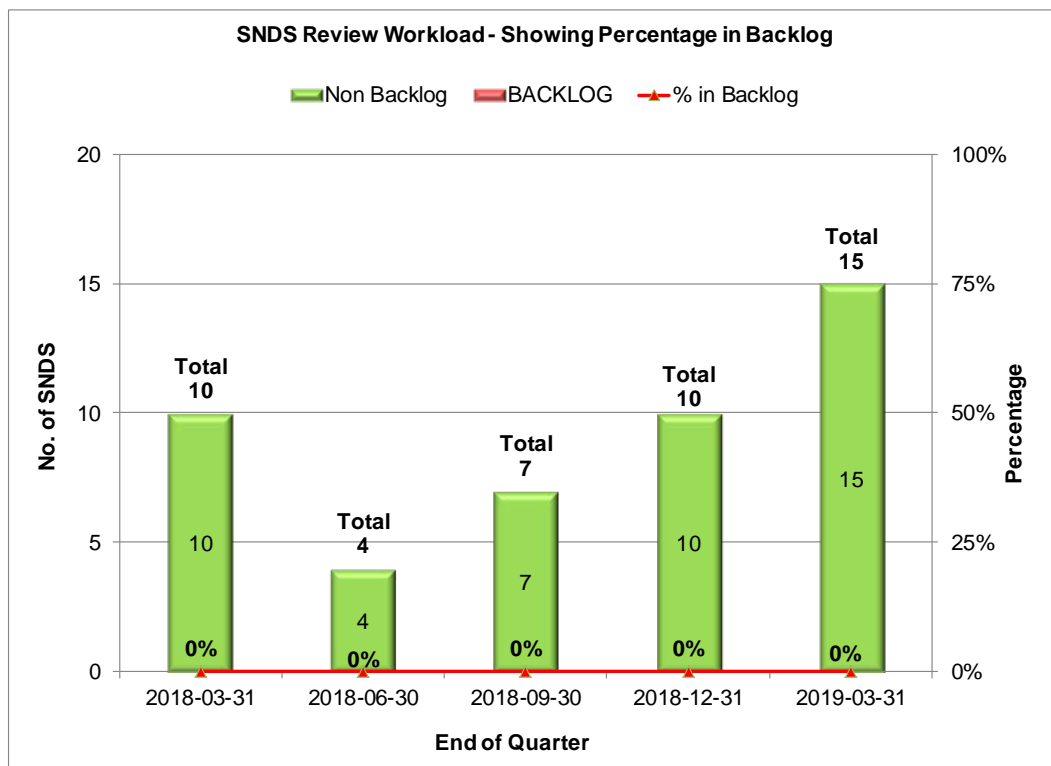
SNDS: SUPPLEMENTAL NEW DRUG SUBMISSIONS SUBMISSIONS RECEIVED

SNDS: Received by Fee Category



WORKLOAD

SNDS: Review Workload Showing Percentage in Backlog

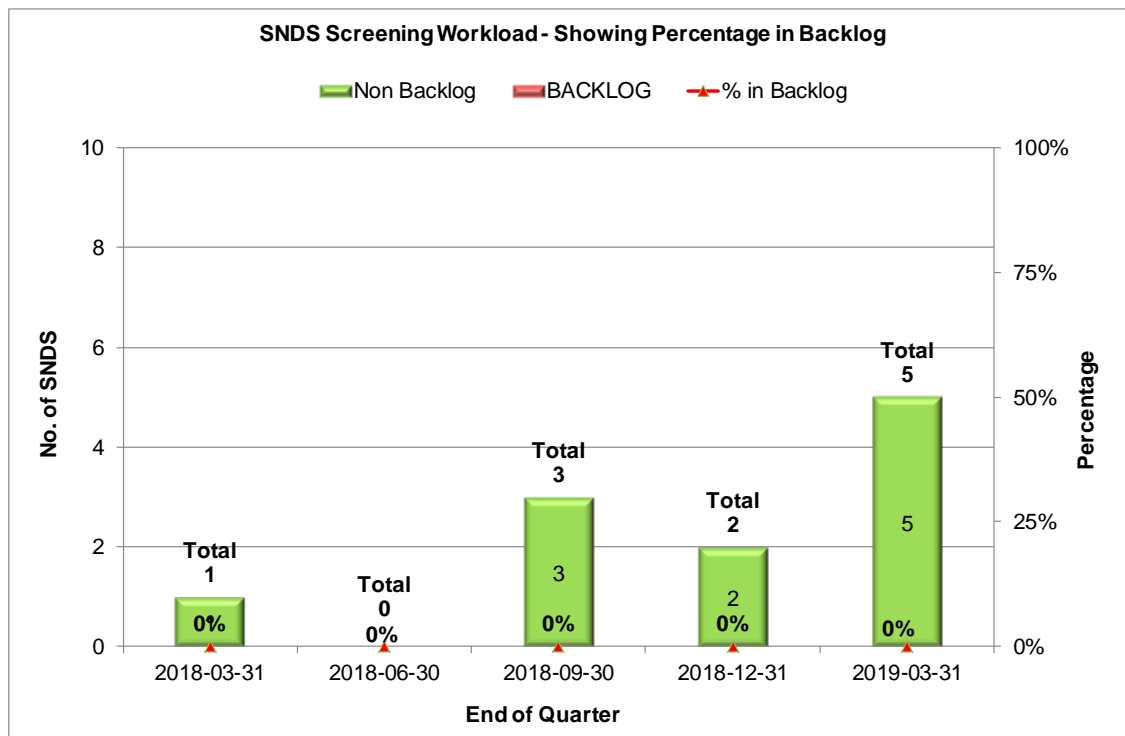


SNDS: Review Workload by Fee Category

NNHPD SNDS REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Clinical or Non-Clinical Data	1	0	0	1	1
<i>Backlog</i>	0	0	0	0	0
and Chemistry - Manufacturing	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	2	1	5	6	12
<i>Backlog</i>	0	0	0	0	0
Published Data	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Prescription to Non-Prescription Switch	1	1	0	0	0
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	2	1	1	1	0
<i>Backlog</i>	0	0	0	0	0
Chemistry and Manufacturing	4	1	1	2	2
<i>Backlog</i>	0	0	0	0	0
Total	10	4	7	10	15
Non Backlog	10	4	7	10	15
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

SNDS: Screening Workload Showing Percentage in Backlog



SNDS: Screening Workload by Fee Category

NNHPD SNDS SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Chemistry and Manufacturing	1	0	2	1	0
<i>Backlog</i>	0	0	0	0	0
Clinical or Non-Clinical Data	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Labelling Only	0	0	1	1	5
<i>Backlog</i>	0	0	0	0	0
Published Data	0	0	0	0	0
<i>Backlog</i>	0	0	0	0	0
Total	1	0	3	2	5
Non Backlog	1	0	3	2	5
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISION DOCUMENTS

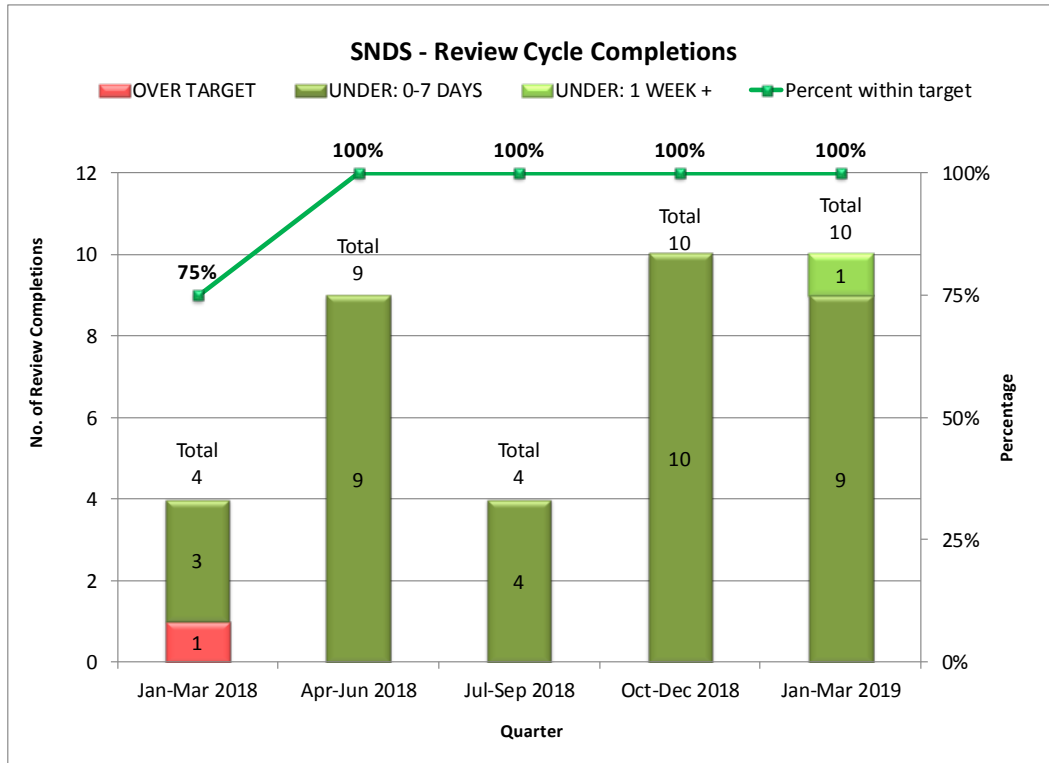
SNDS: Decision Documents by Fee Category

User Fee Category	Decision	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
CLINICAL OR NON-CLINICAL DATA	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	1	0	0	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	0	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	0	1	0	1
	NOTICE OF NON-COMPLIANCE	0	1	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
LABELLING ONLY	NOC ON HOLD (SWITCH)*	0	0	0	1	0
	NOTICE OF COMPLIANCE*	2	2	1	5	5
	SCREENING DEFICIENCY NOTICE	1	0	2	1	2
	CANCELLATION LETTER	0	0	0	1	2
	NOTICE OF DEFICIENCY	0	0	0	1	0
	NOTICE OF NON-COMPLIANCE	0	1	1	2	3
PRESCRIPTION TO NON-PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH) *	0	0	1	0	0
	CANCELLATION LETTER	0	0	0	0	1
PUBLISHED DATA ONLY	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	0	0
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CHEMISTRY AND MANUFACTURING	NOTICE OF NON-COMPLIANCE	0	1	0	0	0
	NOTICE OF COMPLIANCE*	2	3	0	1	1
	SCREENING DEFICIENCY NOTICE	1	0	0	2	0

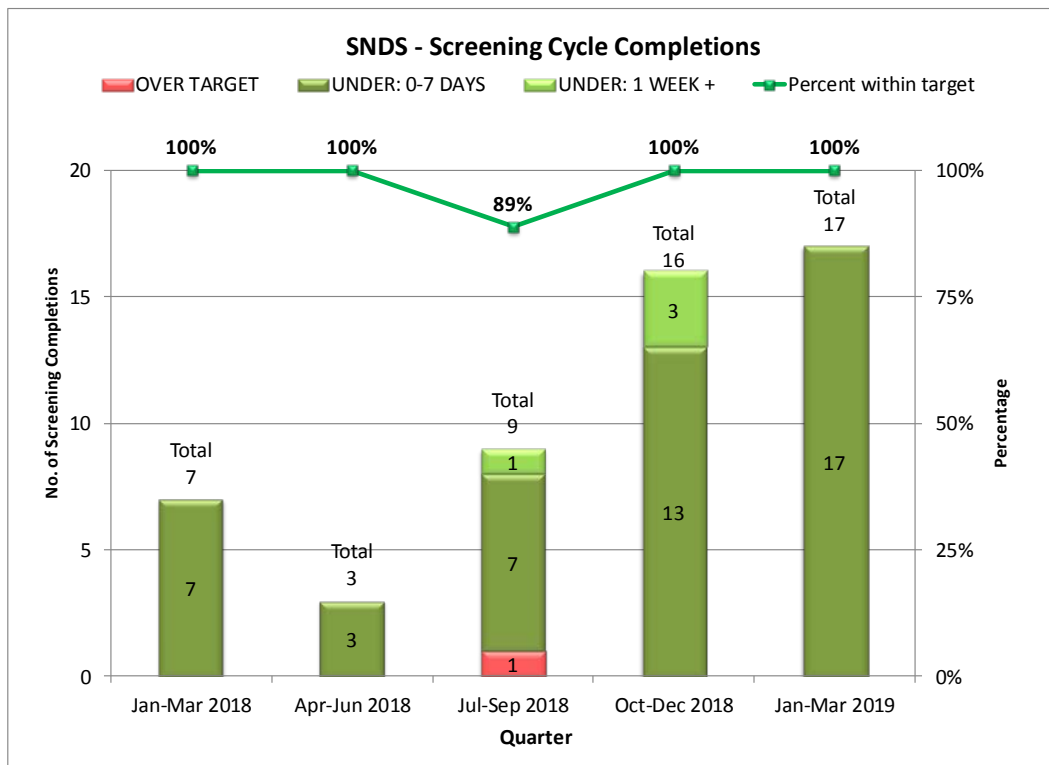
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE

SNDS: Review Cycle Completions Showing Percentage within Target



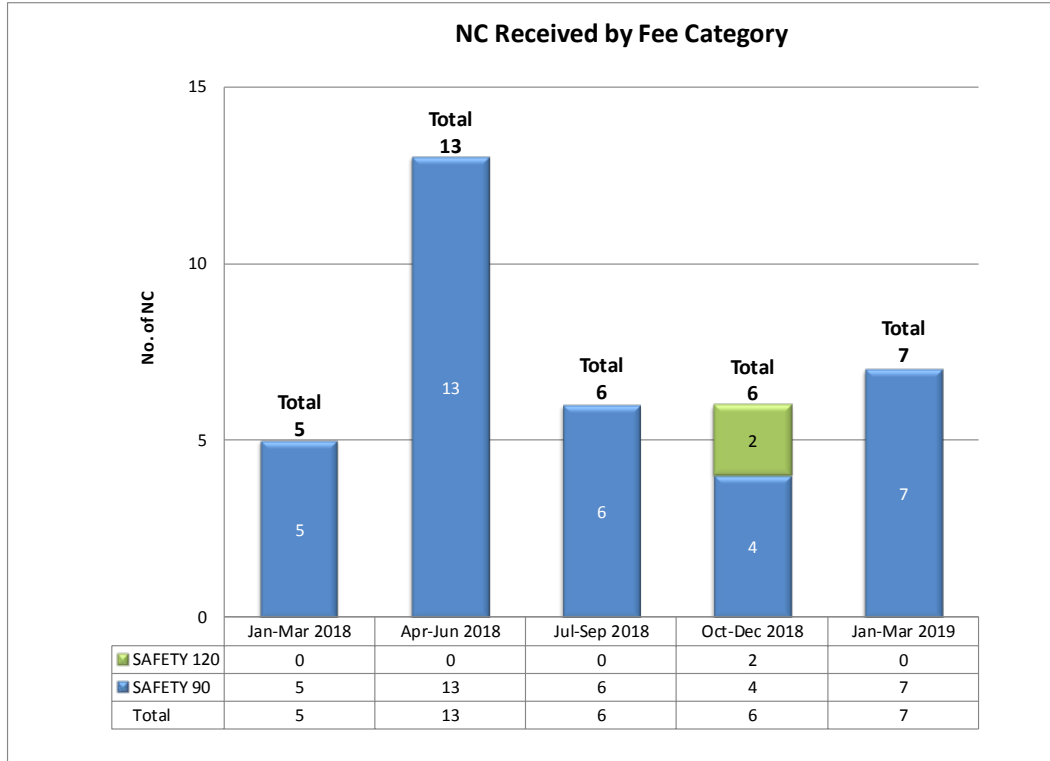
SNDS: Screening Cycle Completions Showing Percentage within Target



NC: NOTIFIABLE CHANGES

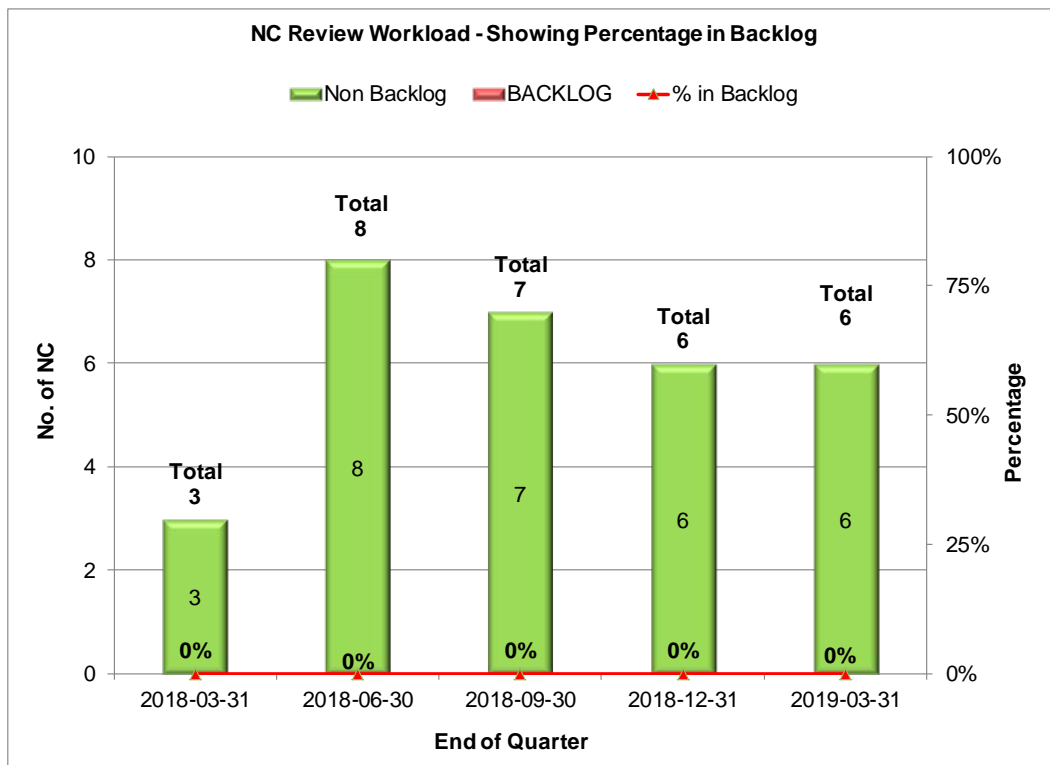
SUBMISSIONS RECEIVED

NC: Received by Fee Category



WORKLOAD

NC: Review Workload Showing Percentage in Backlog

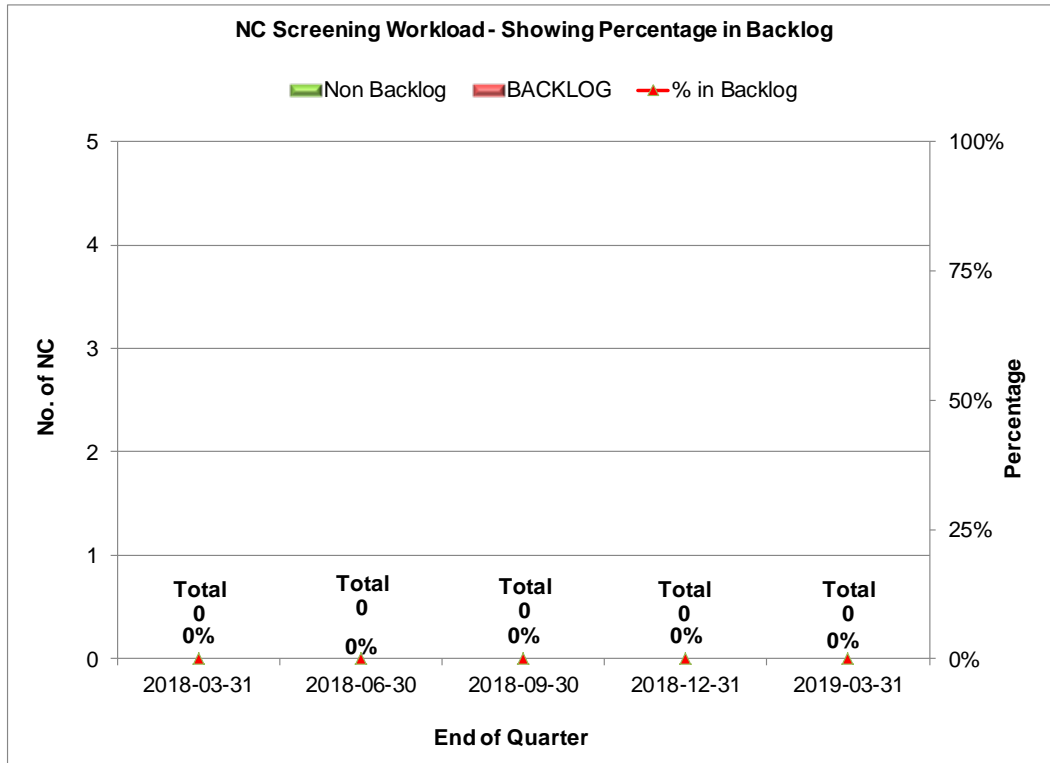


NC: Review Workload by Fee Category

NNHPD NC REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Safety 90	3	8	7	4	4
<i>Backlog</i>	0	0	0	0	0
Safety 120	0	0	0	2	2
<i>Backlog</i>	0	0	0	0	0
Total	3	8	7	6	6
Non Backlog	3	8	7	6	6
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

WORKLOAD

NC: Screening Workload Showing Percentage in Backlog



NC: Screening Workload by Fee Category

NNHPD NC SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Safety 90	0	0	0	0	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	0	0	0	0	0
Non Backlog	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

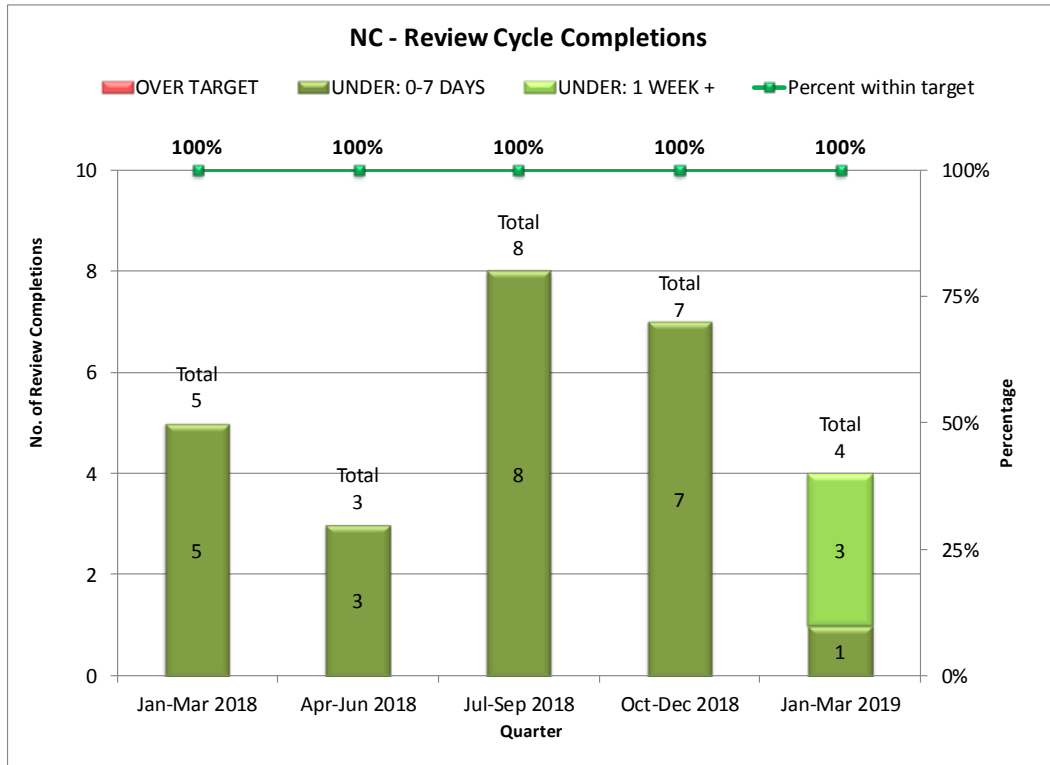
DECISION DOCUMENTS

NC: Decision Documents by Fee Category

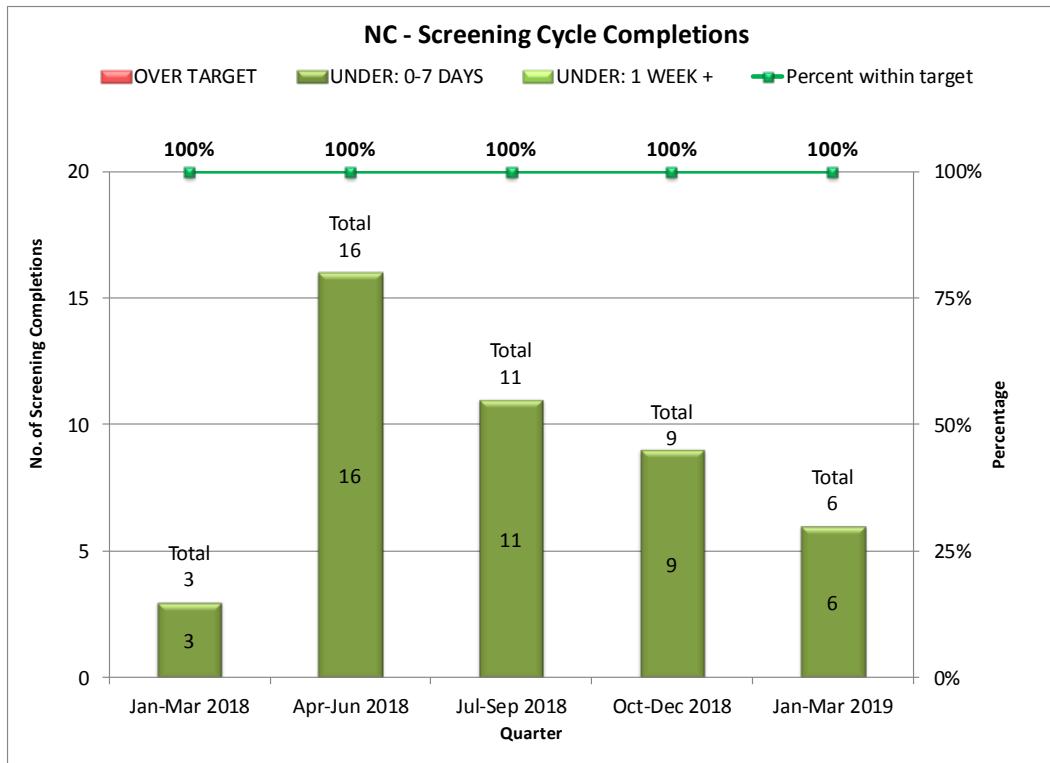
User Fee Category	Decision	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
SAFETY 90	NO OBJECTION LETTER	5	3	8	7	1
	NC-HOLD (SWITCH)	0	0	0	0	0
	NOT SATISFACTORY NOTICE	0	0	0	0	0
	REJECTION LETTER (SCR)	0	1	0	0	0
	CANCELLATION LETTER	0	1	4	0	3
	SCREENING DEFICIENCY NOTICE	0	7	4	3	2
SAFETY 120	CANCELLATION LETTER	0	0	0	0	0

PERFORMANCE

NC: Review Cycle Completions Showing Percentage within Target



NC: Screening Cycle Completions Showing Percentage within Target



MPDIN: PRE-DIN MEETING**MPDIN – Pre-DIN Meeting Received by Fee Category**

PRE - DIN MEETING (MPDIN)	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA	0	0	1	0	0
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	0	1	2
<i>Total</i>	<i>0</i>	<i>0</i>	<i>1</i>	<i>1</i>	<i>2</i>

MPNDS: PRE-NDS MEETING**MPNDS – Pre-NDS Meeting Received by Fee Category**

PRE - NDS MEETING (MPNDS)	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	2	1	0

MPSNDS: PRE-SNDS MEETING**MPSNDS – Pre-SNDS Meeting Received by Fee Category**

PRE - SNDS MEETING (MPSNDS)	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA	0	1	0	0	0

PART 2: DISINFECTANT DRUGS

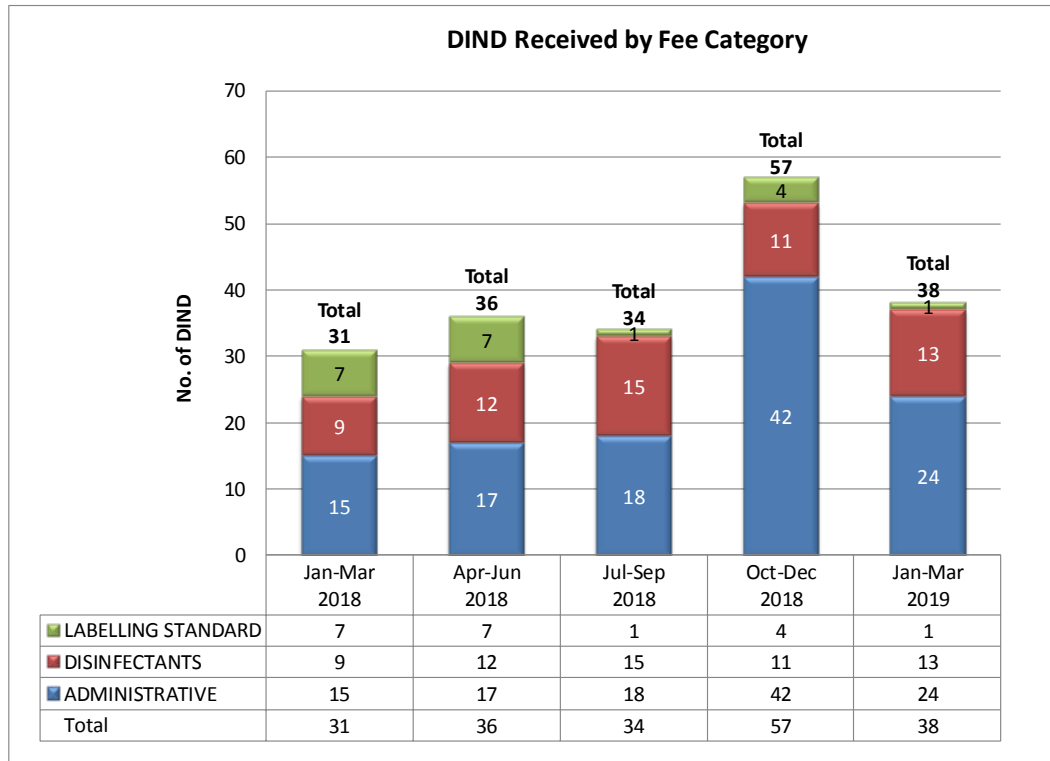
DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the *Food and Drug Regulations*

DIND: DIN APPLICATION – DISINFECTANT DRUGS

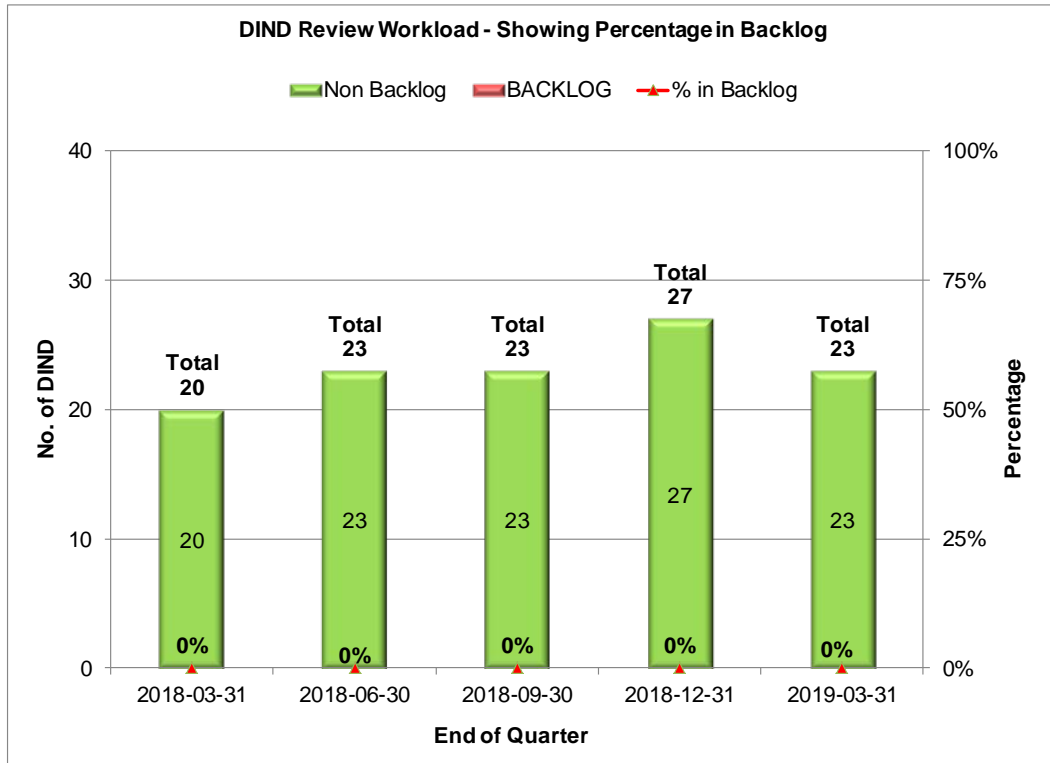
SUBMISSIONS RECEIVED

DIND: Received by Fee Category

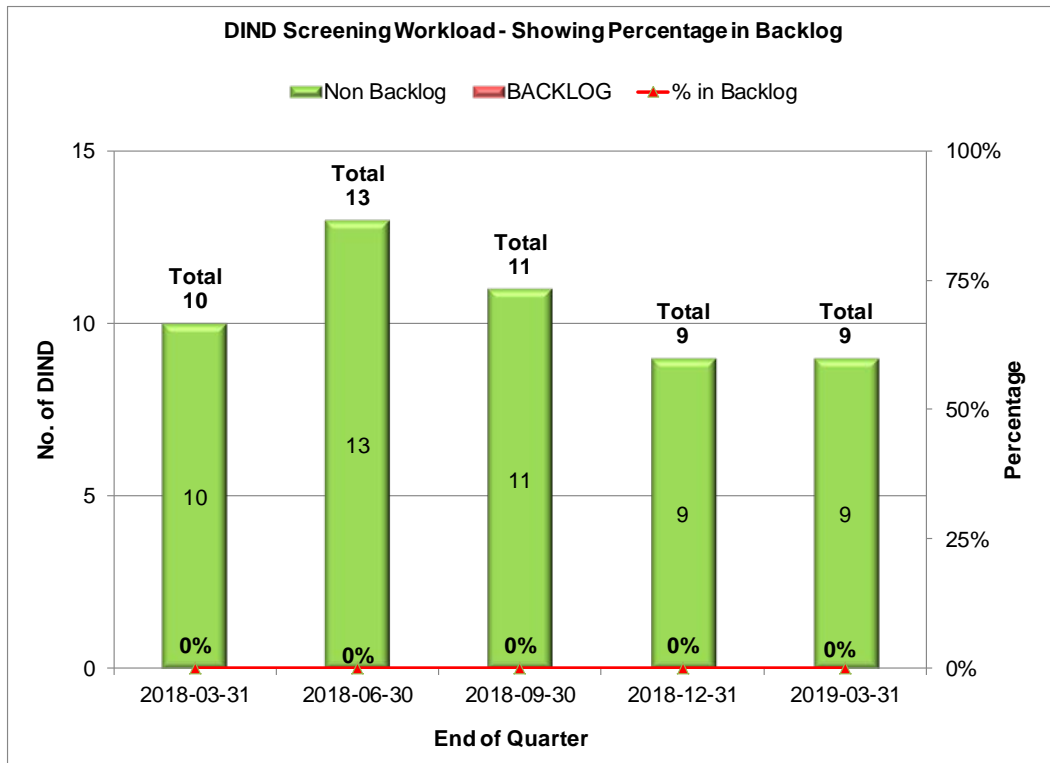


WORKLOAD

DIND: Review Workload Showing Percentage in Backlog

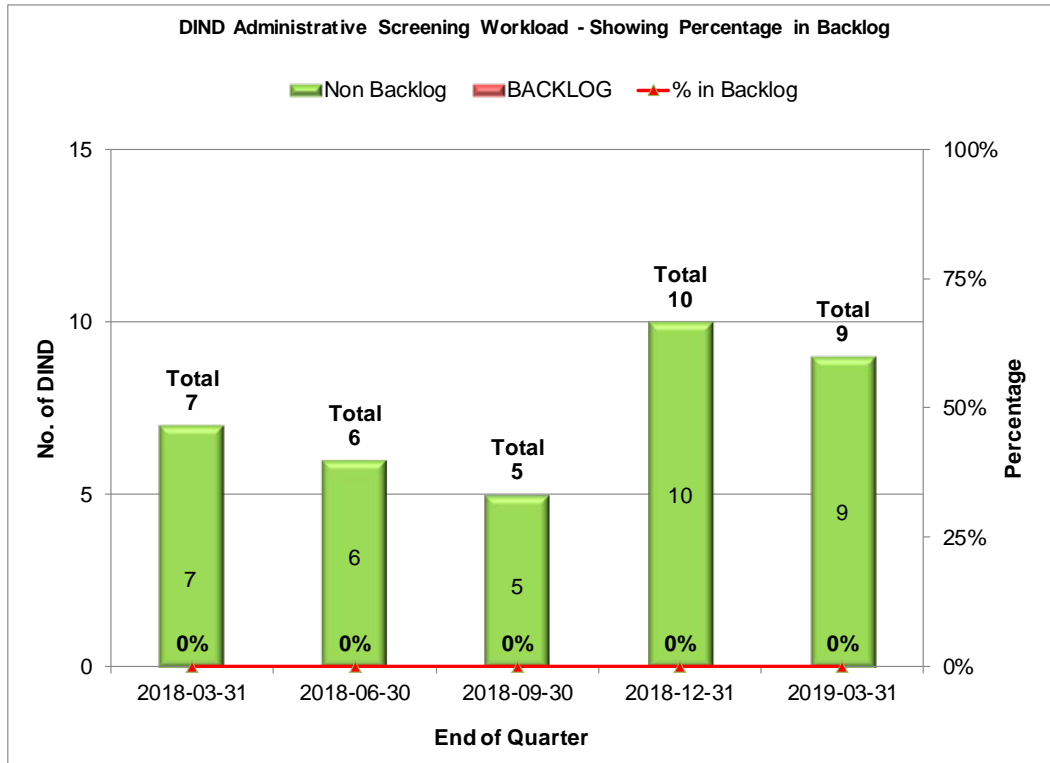


DIND: Screening Workload Showing Percentage in Backlog



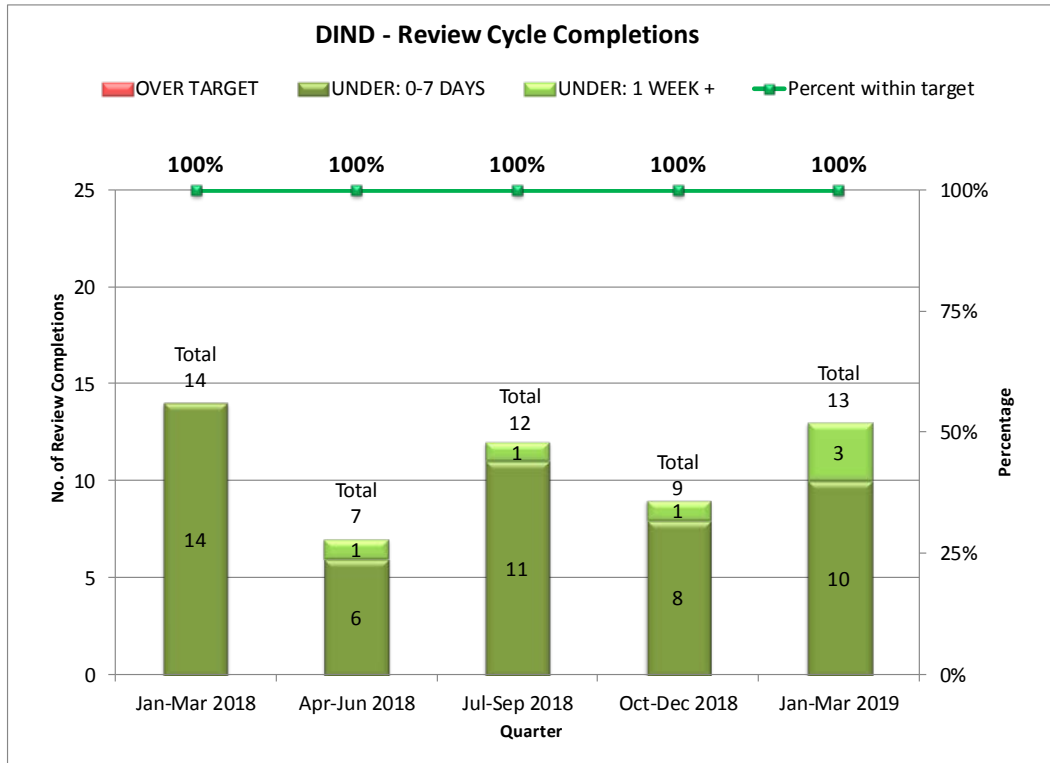
WORKLOAD

DIND: Administrative-Screening Workload Showing Percentage in Backlog

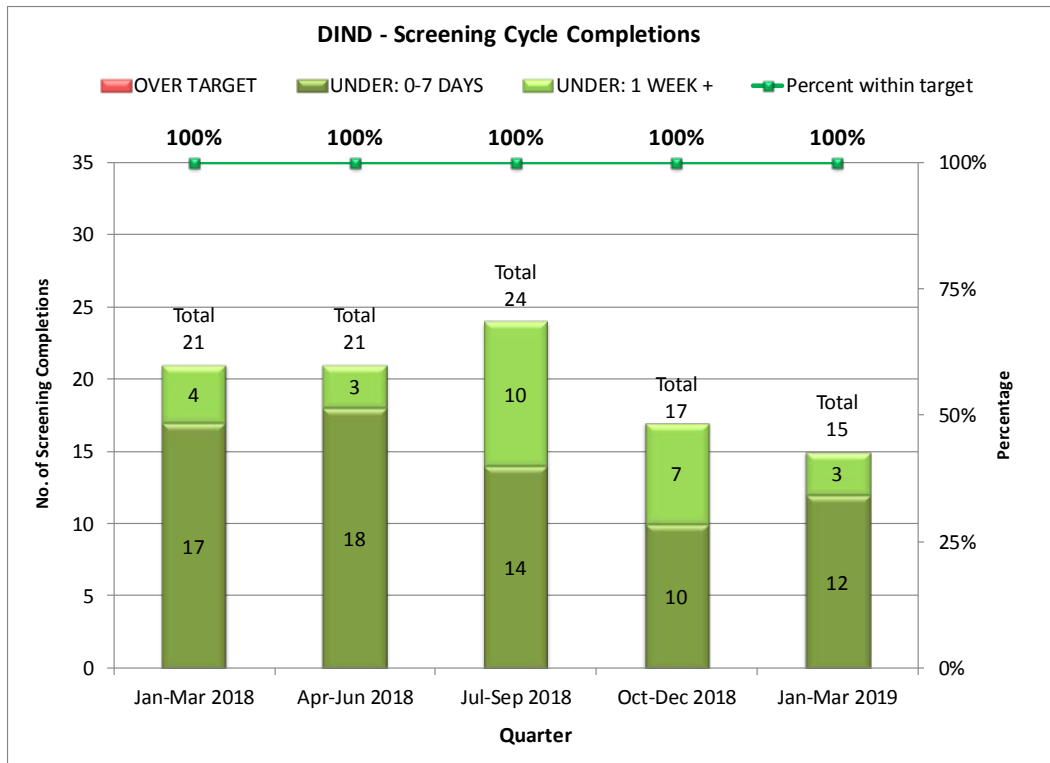


PERFORMANCE

DIND: Review Performance Showing Percentage within Target

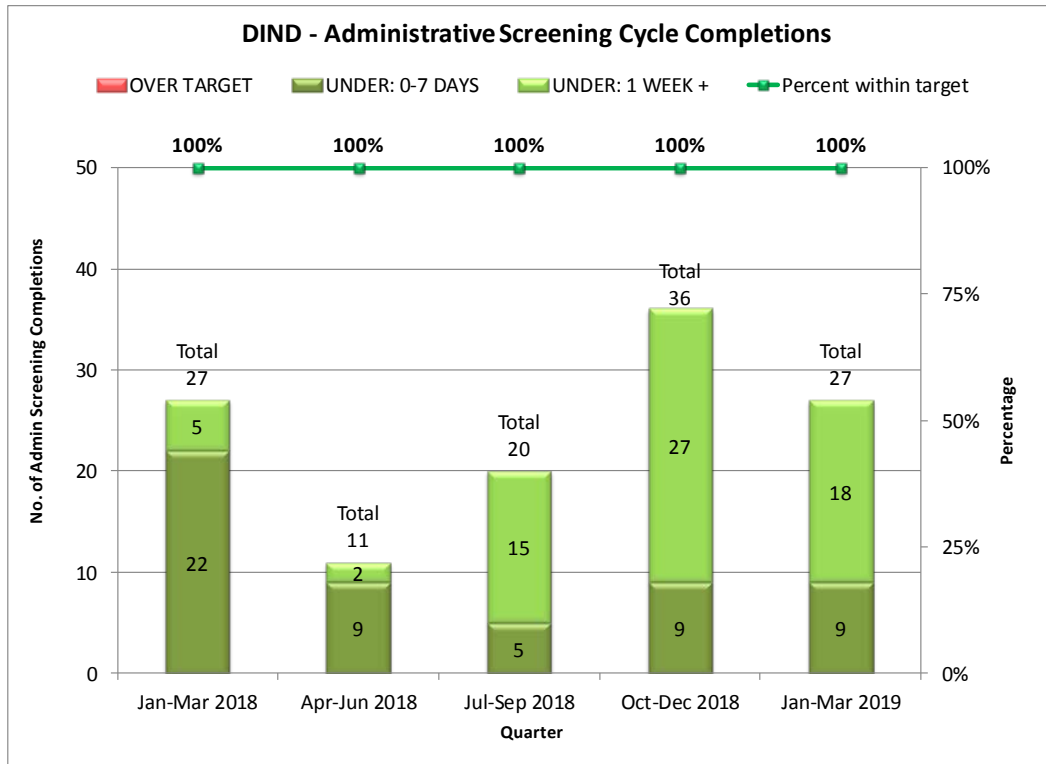


DIND: Screening Performance Showing Percentage within Target



PERFORMANCE

DIND: Administrative-Screening Performance Showing Percentage within Target



DECISION DOCUMENTS

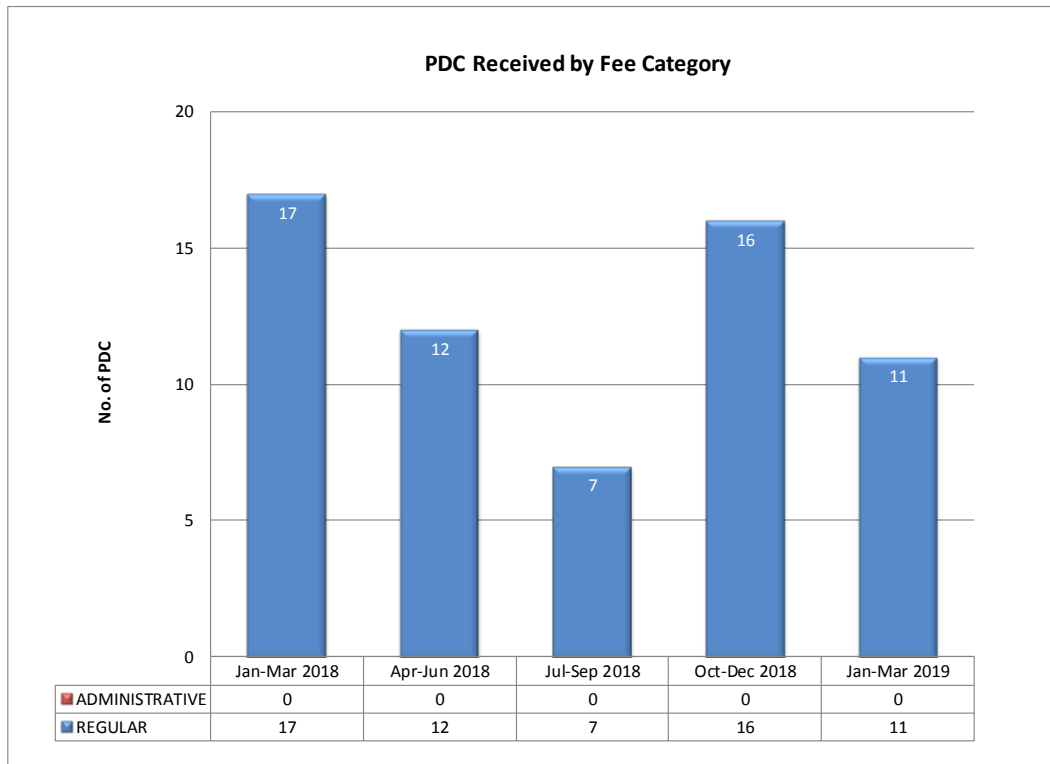
DIND: Decisions Documents by Fee Category

User Fee Category	Decision	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
ADMINISTRATIVE	CANCELLATION LETTER	0	7	0	0	1
	NO OBJECTION LETTER	0	0	1	5	3
	DIN IN CORR SUBTYPE-CLASS	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	27	11	12	20	19
	REJECTION LETTER (SCR)	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	1	0	7	11	4
DISINFECTANTS	DIN IN CORR SUBTYPE-CLASS	0	0	0	0	0
	NO OBJECTION LETTER	7	0	0	3	5
	CANCELLATION LETTER	0	0	1	1	2
	NEW DRUG LETTER SCREEN	0	0	0	0	0
	NOD WITHDRAWAL LETTER	0	0	0	0	0
	NON WITHDRAWAL LETTER	0	0	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	7	7	12	6	8
	SCREENING DEFICIENCY NOTICE	2	2	2	2	2
	REJECTION LETTER (SCR)	0	0	0	0	0
	WITHDRAWAL NO RESP TO NON	0	0	0	0	0
	LABELLING STANDARD	NOTIFICATION FORM DIN SUB	6	5	5	1
NO OBJECTION LETTER		0	0	0	0	0
SCREENING DEFICIENCY NOTICE		5	1	3	0	1
REJECTION LETTER (SCR)		0	3	1	0	0

PDC: POST AUTHORIZATION DIVISION 1 CHANGES

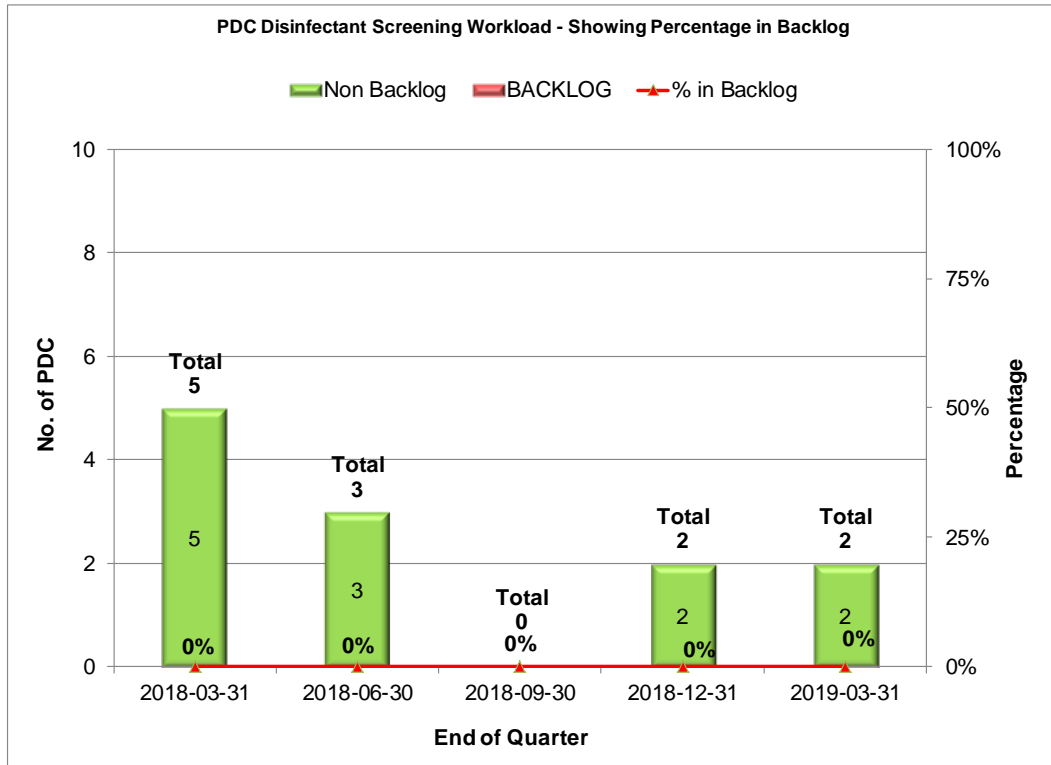
SUBMISSIONS RECEIVED

PDC: Received by Fee Category



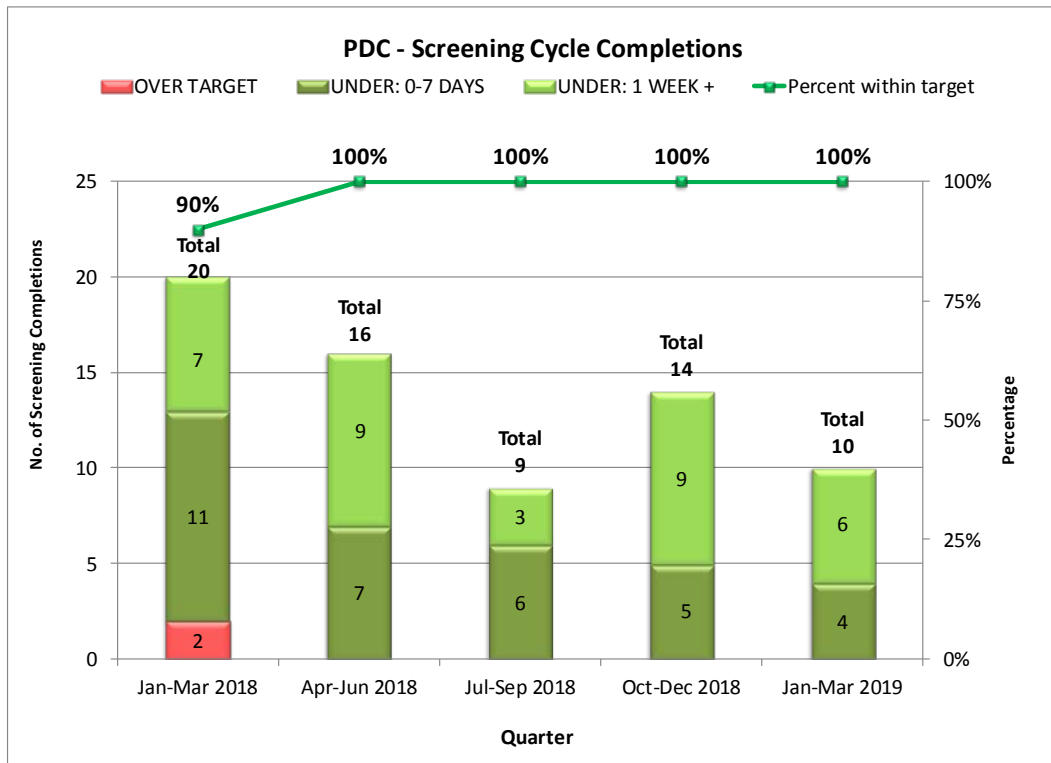
WORKLOAD

PDC: Screening Workload Showing Percentage in Backlog



PERFORMANCE

PDC: Screening Performance Showing Percentage within Target



DECISION DOCUMENTS

PDC: Decision Documents by Fee Category

User Fee Category	Decision	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
ADMINISTRATIVE	CANCELLATION LETTER	1	0	0	0	0
REGULAR	CANCELLATION LETTER	0	0	0	0	0
	NO OBJECTION LETTER	15	15	4	13	7
	NOT SATISFACTORY NOTICE	0	1	5	0	3
	NOTIFICATION FORM DIN SUB	3	0	0	0	0
	REJECTION LETTER (SCR)	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	1	0

DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 8
in Part C of the *Food and Drug Regulations*

NDS-D: NEW DRUG SUBMISSIONS-DISINFECTANT DRUGS

SUBMISSIONS RECEIVED

NDS-D: Received by Fee Category

NDS-D - NEW DRUG SUBMISSION-DISINFECTANTS	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Submission Type - User Fee Category					
ADMINISTRATIVE	0	0	1	0	0
DISINFECTANTS	0	0	0	1	0
<i>Total</i>	0	0	1	1	0

WORKLOAD

NDS-D: Review Workload/Backlog at End of Quarter

NNHPD NDS-D REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Disinfectants	2	1	1	1	1
<i>Backlog</i>	0	0	0	0	0
Total	2	1	1	1	1
Non Backlog	2	1	1	1	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NDS-D: Screening Workload/Backlog at End of Quarter

NNHPD NDS-D SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Disinfectants	0	0	0	0	1
<i>Backlog</i>	0	0	0	0	0
Total	0	0	0	0	1
Non Backlog	0	0	0	0	1
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NDS-D: Administrative-Screening Workload/Backlog at End of Quarter

NNHPD NDS-D ADMIN SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
Administrative	0	0	1	0	0
<i>Backlog</i>	0	0	0	0	0
Total	0	0	1	0	0
Non Backlog	0	0	1	0	0
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE

NDS-D: Review Performance

REVIEW Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Jan-Mar 2018	0	0	0	-	0
Apr-Jun 2018	0	1	0	100%	1
Jul-Sep 2018	0	0	0	-	0
Oct-Dec 2018	0	0	1	100%	1
Jan-Mar 2019	0	0	0	-	0

NDS-D: Screening Performance

SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent with Target	Total
Jan-Mar 2018	0	5	0	100%	5
Apr-Jun 2018	0	0	0	-	0
Jul-Sep 2018	0	0	0	-	0
Oct-Dec 2018	0	1	0	100%	1
Jan-Mar 2019	0	0	0	-	0

NDS-D: Administrative-Screening Performance

ADMIN SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent with Target	Total
Jan-Mar 2018	0	0	0	-	0
Apr-Jun 2018	0	0	0	-	0
Jul-Sep 2018	0	1	0	100%	1
Oct-Dec 2018	0	1	0	100%	1
Jan-Mar 2019	0	0	0	-	0

DECISION DOCUMENTS

NDS-D: Decision Documents by Fee Category

User Fee Category	Decision	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	1	0	0
	NOTICE OF COMPLIANCE*	0	0	0	1	0
DISINFECTANTS	NOTICE OF NON-COMPLIANCE	0	0	0	1	0
	NOTICE OF DEFICIENCY	1	0	0	0	0
	NOD WITHDRAWAL LETTER	1	0	0	0	0
	NOTICE OF COMPLIANCE*	0	1	0	0	0
	CANCELLATION LETTER	0	0	0	0	0
	REJECTION LETTER (SCR)	1	0	0	0	0
	SCREENING DEFICIENCY NOTICE	1	0	0	0	0

*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

NC: NOTIFIABLE CHANGES**SUBMISSIONS RECEIVED****NC – Disinfectant Drugs: Received by Fee Category**

NOTIFIABLE CHANGE - NEW DRUG (NC)	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Submission Type - User Fee Category					
SAFETY 90	0	0	0	0	0

WORKLOAD**NC – Disinfectant Drugs: Review Workload/Backlog at End of Quarter**

NNHPD NC-DIS REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
SAFETY 90	0	0	0	0	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	0	0	0	0	0
Non Backlog	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

NC – Disinfectant Drugs: Screening Workload/Backlog at End of Quarter

NNHPD NC-DIS SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2018-03-31	2018-06-30	2018-09-30	2018-12-31	2019-03-31
SAFETY 90	0	0	0	0	0
<i>Backlog</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
Total	0	0	0	0	0
Non Backlog	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

PERFORMANCE

NC – Disinfectant Drugs: Review Performance

REVIEW Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Jan-Mar 2018	0	0	1	100%	1
Apr-Jun 2018	0	0	0	-	0
Jul-Sep 2018	0	0	0	-	0
Oct-Dec 2018	0	0	0	-	0
Jan-Mar 2019	0	0	0	-	0

NC – Disinfectant Drugs: Screening Performance

SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Jan-Mar 2018	0	0	0	-	0
Apr-Jun 2018	0	0	0	-	0
Jul-Sep 2018	0	0	0	-	0
Oct-Dec 2018	0	0	0	-	0
Jan-Mar 2019	0	0	0	-	0

DECISION DOCUMENTS

NC – Disinfectant Drugs: Decision Documents

User Fee Category	Decision	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
SAFETY 90	NO OBJECTION LETTER	1	0	0	0	0
	CANCELLATION LETTER	0	0	0	0	0

MPNDS: PRE-NDS MEETING**MPNDS – Disinfectant Drugs: Received by Fee Category**

PRE - NDS MEETING (MPNDS)	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	0	0	0

MPSNDS: PRE-SNDS MEETING**MPSNDS – Disinfectant Drugs: Received by Fee Category**

PRE - SNDS MEETING (MPSNDS)	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA	0	1	0	0	1