

Natural and Non-Prescription Health Products Directorate

Drug Submission Performance Quarterly Report July – September 2018





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.

Également disponible en français sous le titre : Direction des produits de santé naturels et sans ordonnance – Rapport trimestriel du rendement des présentations de drogue – juillet – septembre 2018

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Table of Contents

OVERVIEW	9
ACRONYMS	12
Submission Types	12
Documents	
FEE CATEGORIES	13
PART 1: NON-PRESCRIPTION DRUGS	14
NON PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1	14
DINA: DRUG IDENTIFICATION NUMBER APPLICATIONS	15
SUBMISSIONS RECEIVED	15
DINA: Received by Fee Category	15
WORKLOAD	16
DINA: Review Workload Showing Percentage in Backlog	16
DINA: Review Workload by Fee Category	16
DINA: Screening Workload Showing Percentage in Backlog	17
DINA: Screening Workload by Fee Category	17
DINA: Administrative-Screening Workload Showing Percentage in Backlog	18
DINA: Administrative-Screening Workload by Fee Category	18
DECISION DOCUMENTS	19
DINA: Decision Documents by Fee Category	19
PERFORMANCE	20
DINA: Review Cycle Completions Showing Percentage within Target	20
DINA: Screening Cycle Completions Showing Percentage within Target	20
DINA: Administrative-Screening Cycle Completions Showing Percentage within Target	21

DINF: CATEGORY FOUR DIN APPLICATIONS	22
SUBMISSIONS RECEIVED	22
DINF: Received by Fee Category	
WORKLOAD	23
DINF: Screening Workload Showing Percentage in Backlog	
DINF: Screening Workload by Fee Category	
DECISION DOCUMENTS	24
DINF: Decision Documents by Fee Category	
PERFORMANCE	25
DINF: Screening Cycle Completions	
DINF: Admin-Screening Cycle Completions	
PDC: POST AUTHORIZATION DIVISION 1 CHANGES	26
SUBMISSIONS RECEIVED	26
PDC: Received by Fee Category	
WORKLOAD	27
PDC: Screening Workload Showing Percentage in Backlog	
PDC: Screening Workload by Fee Category	
DECISION DOCUMENTS	
PDC: Decision Documents by Fee Category	
PERFORMANCE	28
PDC: Screening Cycle Completions	
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 8	29
NDS: NEW DRUG SUBMISSIONS	30
SUBMISSIONS RECEIVED	
NDS: Received by Fee Category	30
WORKLOAD	31
NDS: Review Workload Showing Percentage in Backlog	
NDS: Review Workload by Fee Category	

39 39 39 40 40 40 41 41 41 41 42 42 42 43
39 39 40 40 40 41 41 41 42 42
39 39 40 40 40 41 41 41 42
39 39 40 40 40 41 41
39 39 40 40 40 41
39 39 40 40 40
39 39 40 40
39 39 40 4 0
39 39 40
39 39
39
39
38
38
37
37
36
36
36
35
35
35
34
34
34
33
32 33 33

PERFORMANCE	44
NC: Review Cycle Completions Showing Percentage within Target	
NC: Screening Cycle Completions Showing Percentage within Target	
MPDIN: PRE-DIN MEETING	45
MPDIN – Pre-DIN Meeting Received by Fee Category	
MPNDS: PRE-NDS MEETING	45
MPNDS – Pre-NDS Meeting Received by Fee Category	
MPSNDS: PRE-SNDS MEETING	45
MPSNDS – Pre-SNDS Meeting Received by Fee Category	
PART 2: DISINFECTANT DRUGS	46
DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1.	46
DIND: DIN APPLICATION – DISINFECTANT DRUGS	47
SUBMISSIONS RECEIVED	47
DIND: Received by Fee Category	
WORKLOAD	
DIND: Review Workload Showing Percentage in Backlog	
DIND: Screening Workload Showing Percentage in Backlog	
DIND: Administrative-Screening Workload Showing Percentage in Backlog	
PERFORMANCE	
DIND: Review Performance Showing Percentage within Target	
DIND: Screening Performance Showing Percentage within Target	
DIND: Administrative-Screening Performance Showing Percentage within Targe	
DECISION DOCUMENTS	52
DIND: Decisions Documents by Fee Category	
PDC: POST AUTHORIZATION DIVISION 1 CHANGES	53
SUBMISSIONS RECEIVED	53
NNHPD Quarterly Drug Submission Performance Report:	July – September 2018

PDC: Received by Fee Category	53
WORKLOAD	54
PDC: Screening Workload Showing Percentage in Backlog	54
PERFORMANCE	54
PDC: Screening Performance Showing Percentage within Target	54
DECISION DOCUMENTS	55
PDC: Decision Documents by Fee Category	55
DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 8	
NDS-D: NEW DRUG SUBMISSIONS-DISINFECTANT DRUGS	57
SUBMISSIONS RECEIVED	57
NDS-D: Received by Fee Category	57
WORKLOAD	57
NDS-D: Review Workload/Backlog at End of Quarter	57
NDS-D: Screening Workload/Backlog at End of Quarter	57
NDS-D: Administrative-Screening Workload/Backlog at End of Quarter	57
PERFORMANCE	58
NDS-D: Review Performance	
NDS-D: Screening Performance	
NDS-D: Administrative-Screening Performance	58
DECISION DOCUMENTS	58
NDS-D: Decision Documents by Fee Category	58
NC: NOTIFIABLE CHANGES	
SUBMISSIONS RECEIVED	59
NC – Disinfectant Drugs: Received by Fee Category	59
WORKLOAD	59
NC – Disinfectant Drugs: Review Workload/Backlog at End of Quarter	59
NC – Disinfectant Drugs: Screening Workload/Backlog at End of Quarter	59
PERFORMANCE	60

Natural and Non-Prescription Health Products Directorate – November 14, 2018

NC – Disinfectant Drugs: Review Performance	60
NC – Disinfectant Drugs: Screening Performance	60
DECISION DOCUMENTS	60
NC – Disinfectant Drugs: Decision Documents	60
MPNDS: PRE-NDS MEETING	61
MPNDS – Disinfectant Drugs: Received by Fee Category	61
MPSNDS: PRE-SNDS MEETING	61
MPSNDS – Disinfectant Drugs: Received by Fee Category	61

OVERVIEW

The NNHPD Quarterly Drug Submission Performance Report reflects Non-Prescription and Disinfectant Drug submission review activity over five consecutive quarters from July – September 2017 to July – September 2018. 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 July – September 2018 report are:

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

• There was a decrease (25%) in the number of DINA submissions received: from 28 in April-June 2018 to 21 during this quarter (July-September 2018).

• The number of PDC submissions received decreased (39%): from 72 in April-June 2018 to 44 this quarter (July-September 2018).

• There was a slight decrease (6%) in the number of DINF submissions received: from 35 in April-June 2018 to 33 during this quarter (July-September 2018).

• There was a significant (233%) increase in the number of SNDS received this quarter as compared to the previous 4 quarters (i.e., 3-3-3-7), while the number of NDS received remained the same as the previous quarter (i.e., with 0 received).

• The number of NCs received during this past quarter has stabilized to previous levels as compared to the previous 4 quarters (i.e., 3-5-5-13-6), however the number received this quarter represents a 216% reduction as compared to the previous quarter (i.e., April-June 2018).

• Overall, total non-prescription drug submissions received decreased by 25% during this past quarter (114) compared to last quarter (153).

Disinfectant Drugs:

• The number of DIND submissions received this quarter has remained stable as compared to the previous quarter (i.e., 34 in July-September 2018 compared to 35 in April-June 2018).

• There was a significant (42%) decrease in the number of PDC submissions received in this quarter (i.e., 7 in July-September 2018 compared to 12 in April-June 2018).

• Overall, total disinfectant drug submissions received decreased by 13% during this past quarter (42) compared to last quarter (48).

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 <u>Guidance for Industry: Management of Drug Submissions</u>.

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 <u>performance standard</u>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 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

NNHPD Quarterly Drug Submission Performance Report:

² Performance continues to be measured against performance standards for Submission Type/Submission Class/ Status combinations as set out in Appendix 3 of the <u>Guidance for Industry: Management of Drug Submissions</u>. 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 <u>Prescription Drug List</u> . This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
Labelling Only ³	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission ⁴	Submissions in support of a manufacturer or product name change.
Disinfectants⁵	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 <u>Guidance Document - Fees for the Review of Drug</u> <u>Submissions and Applications</u>

NNHPD Quarterly Drug Submission Performance Report:

³ For more information, please consult the <u>Guidance Document: Question and Answers about Plain Language Labelling</u>

⁴ For additional information, please consult the <u>"Changes in Manufacturer and/or Product Name Policy"</u> (2015)

⁵ 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

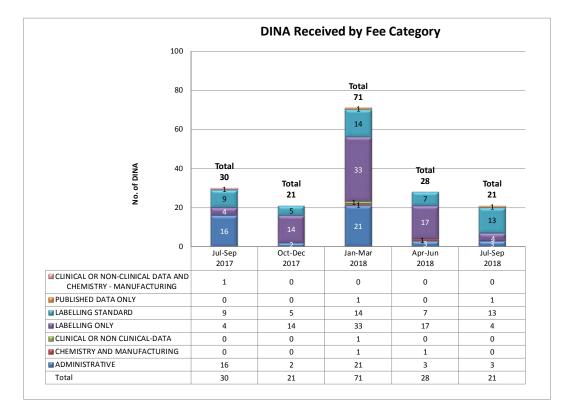
NON PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 1

in Part C of the Food and Drug Regulations

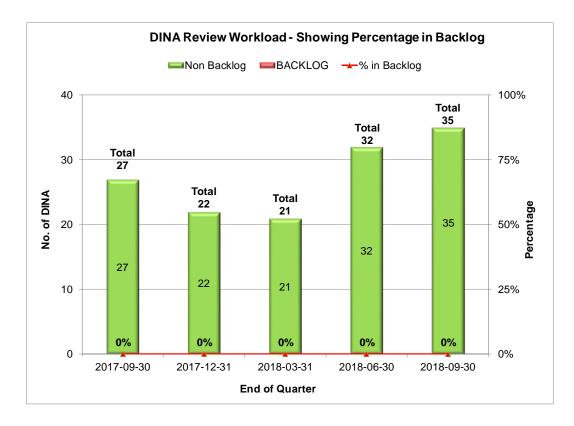
DINA: DRUG IDENTIFICATION NUMBER APPLICATIONS

SUBMISSIONS RECEIVED

DINA: Received by Fee Category



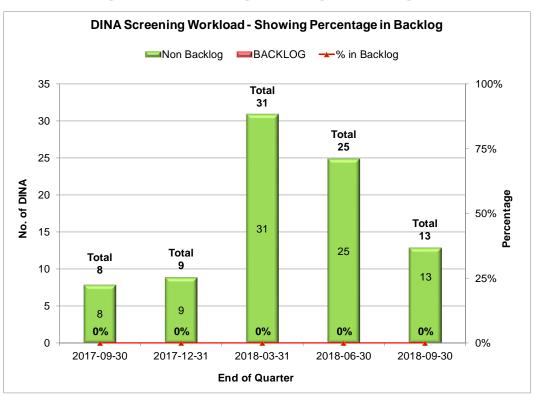
DINA: Review Workload Showing Percentage in Backlog



DINA: Review Workload by Fee Category

NNHPD DINA REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
Chemistry and Manufacturing	3	0	1	1	1
Backlog	0	0	0	0	0
Clinical or Non-Clinical Data	3	1	0	1	1
Backlog	0	0	0	0	0
Clinical or Non-Clinical Data and Chemistry - Manufacturing	0	1	1	0	1
Backlog	0	0	0	0	0
Labelling Only	20	19	19	30	31
Backlog	0	0	0	0	0
Published Data	1	1	0	0	1
Backlog	0	0	0	0	0
Total	27	22	21	32	35
Non Backlog	27	22	21	32	35
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%



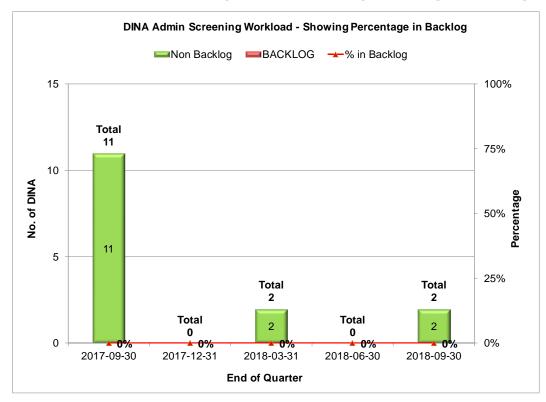


DINA: Screening Workload Showing Percentage in Backlog

DINA: Screening Workload by Fee Category

NNHPD DINA SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
Chemistry and Manufacturing	0	0	0	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clinical	0	0	0	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clinical Data and Chemistry - Manufacturing	1	0	0	0	0
Backlog	0	0	0	0	0
Labelling Only	4	5	21	13	8
Backlog	0	0	0	0	0
Labelling Standard	3	4	10	12	5
Backlog	0	0	0	0	0
Published Data	0	0	0	0	0
Backlog	0	0	0	0	0
Total	8	9	31	25	13
Non Backlog	8	9	31	25	13
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DINA: Administrative-Screening Workload Showing Percentage in Backlog



DINA: Administrative-Screening Workload by Fee Category

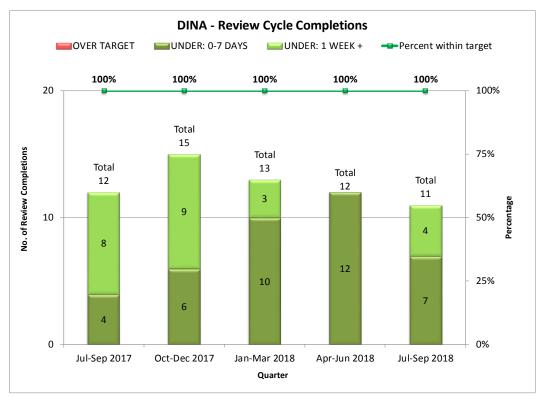
NNHPD DINA ADMIN SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
Administrative	11	0	2	0	2
Backlog	0	0	0	0	0
Total	11	0	2	0	2
Non Backlog	11	0	2	0	2
BACKLOG	0	0	0	0	0
% in Backlog	0%	0%	0%	0%	0%

DECISION DOCUMENTS

DINA: Decision Documents by Fee Category

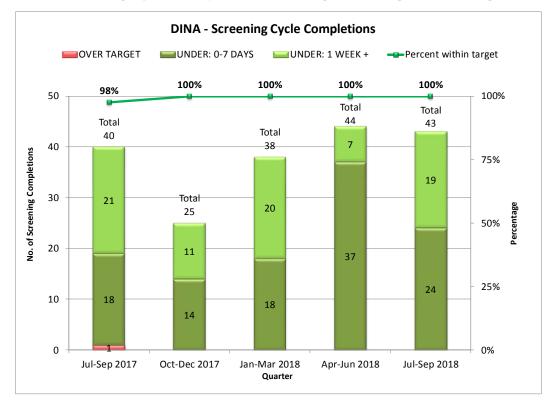
User Fee Category	Decision	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
ADMINISTRATIVE	CANCELLATION LETTER	3	15	18	5	1
	NOTIFICATION FORM DIN SUB	11	0	0	0	0
	REJECTION LETTER (SCR)	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	1	0	0	0	0
	NO OBJECTION LETTER	0	0	0	0	0
CHEMISTRY AND	NOTICE OF DEFICIENCY	0	0	0	0	0
MANUFACTURING	NOTICE OF NON-COMPLIANCE	1	3	0	0	0
	NOTIFICATION FORM DIN SUB	0	0	0	0	0
	NO OBJECTION LETTER	0	0	0	0	1
	CANCELLATION LETTER	0	2	2	0	0
		-				
	SCREENING DEFICIENCY NOTICE WITHDRAWAL NO RESP TO NON	0	0	0	0	0
CLINICAL OR NON-CLINICAL DATA	NOTIFICATION FORM DIN SUB	0	1	0	0	0
	NOTICE OF NON-COMPLIANCE	0	1	0	0	0
	NO OBJECTION LETTER	0	0	1	0	0
	SCREENING DEFICIENCY NOTICE	0	0	1	0	0
	CANCELLATION LETTER	0	0	0	1	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	SCREENING DEFICIENCY NOTICE	1	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	1	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTIFICATION FORM DIN SUB	0	0	0	0	0
LABELLING ONLY	CANCELLATION LETTER	5	0	8	4	0
	NO OBJECTION LETTER	1	0	0	0	1
	NOTICE OF NON-COMPLIANCE	0	0	0	3	2
		-		-		
	NOTICE OF DEFICIENCY	0	1	0	1	1
		8	9	11	7	7
	REJECTION LETTER (SCR)	0	0	1	0	2
	SCREENING DEFICIENCY NOTICE	5	7	5	5	6
	WITHDRAWAL NO RESP TO NOD	0	0	0	0	1
		-	-			
LABELLING STANDARD	CANCELLATION LETTER	0	0	0	1	3
	NO OBJECTION LETTER	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	5	6	10	4	13
	REJECTION LETTER (SCR)	0	0	0	0	1
	SCREENING DEFICIENCY NOTICE	10	2	1	9	6
		0	0	1		
PUBLISHED DATA	SCREENING DEFICIENCY NOTICE	0	0	1	0	0
	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	CANCELLATION LETTER	0	0	0	1	0
	NON WITTERAWAL LETTER	U	0	U	U	0

PERFORMANCE



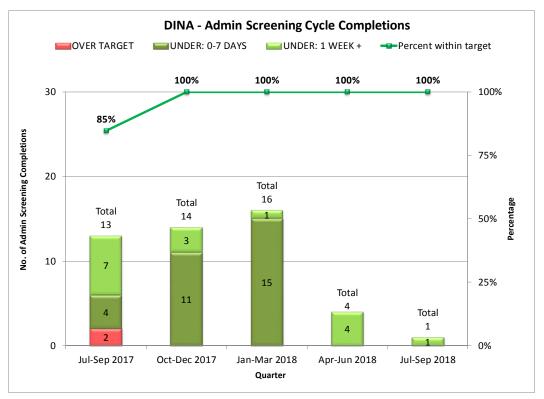
DINA: Review Cycle Completions Showing Percentage within Target

DINA: Screening Cycle Completions Showing Percentage within Target



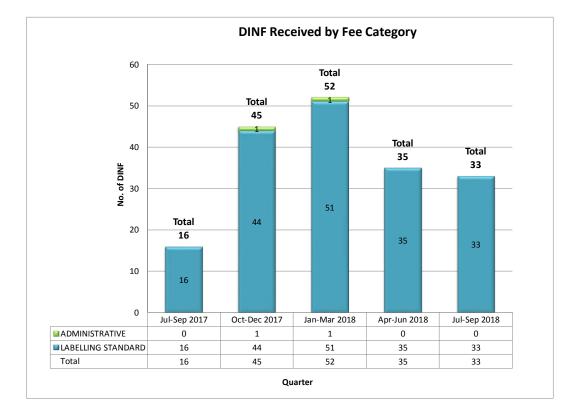
PERFORMANCE



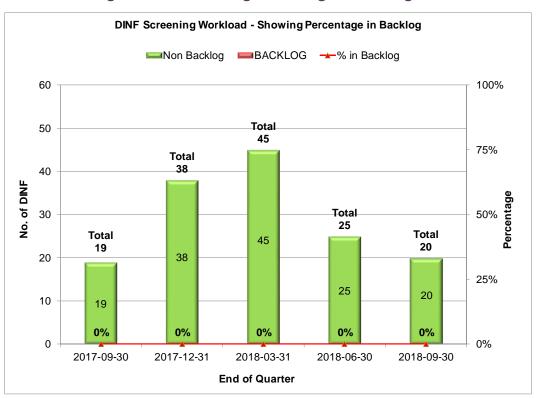


DINF: CATEGORY FOUR DIN APPLICATIONS

SUBMISSIONS RECEIVED



DINF: Received by Fee Category



DINF: Screening Workload Showing Percentage in Backlog

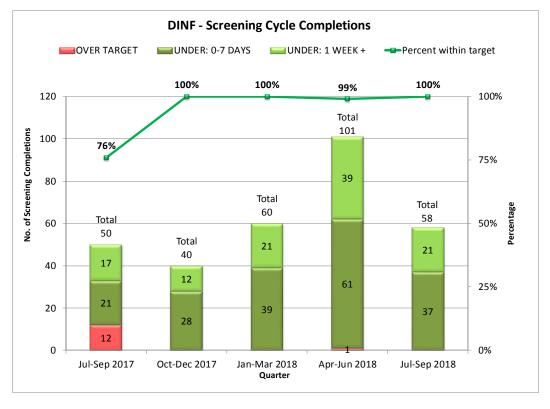
DINF: Screening Workload by Fee Category

NNHPD DINF SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER								
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30			
Labelling Standard	19	38	45	25	20			
Backlog	0	0	0	0	0			
Administrative	0	0	0	0	0			
Backlog	0	0	0	0	0			
Total	19	38	45	25	20			
Non Backlog	19	38	45	25	20			
BACKLOG	0	0	0	0	0			
% in Backlog	0%	0%	0%	0%	0%			

DECISION DOCUMENTS

User Fee Category	Decision	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
LABELLING STANDARD	CANCELLATION LETTER	0	1	1	5	2
	NO OBJECTION LETTER	1	0	0	0	2
	NEW DRUG LETTER SCREEN	1	0	0	0	0
	NOTIFICATION FORM DIN SUB	36	15	29	53	39
	REJECTION LETTER (SCR)	1	1	0	6	1
	SCREENING DEFICIENCY NOTICE	12	25	31	43	18
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	0	1	1	0	0

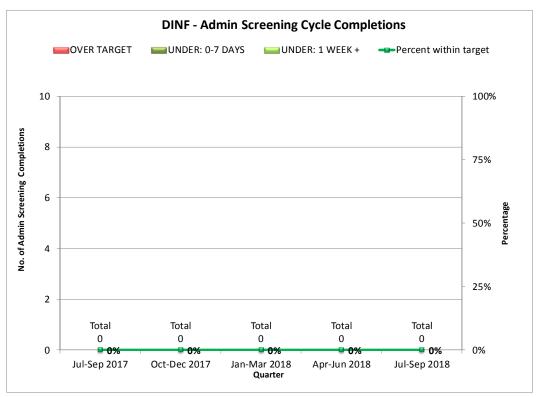
DINF: Decision Documents by Fee Category



PERFORMANCE

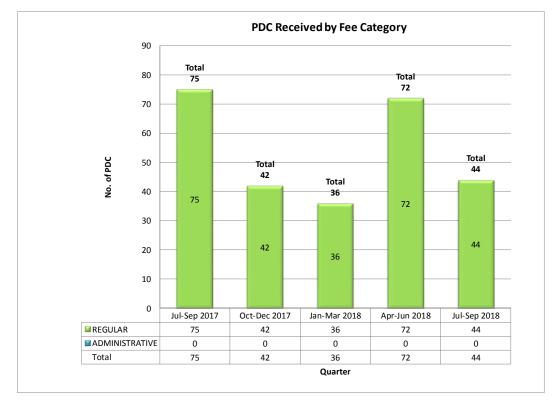
DINF: Screening Cycle Completions

DINF: Admin-Screening Cycle Completions

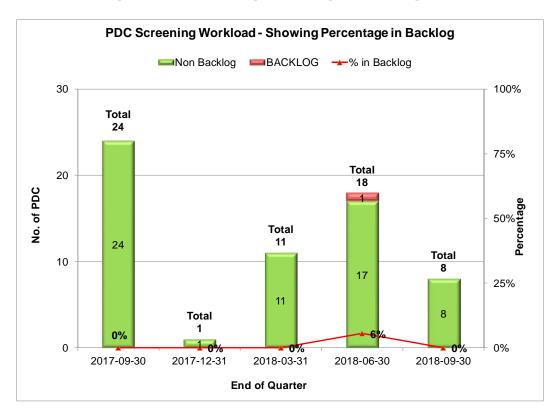


PDC: POST AUTHORIZATION DIVISION 1 CHANGES

SUBMISSIONS RECEIVED



PDC: Received by Fee Category



PDC: Screening Workload Showing Percentage in Backlog

PDC: Screening Workload by Fee Category

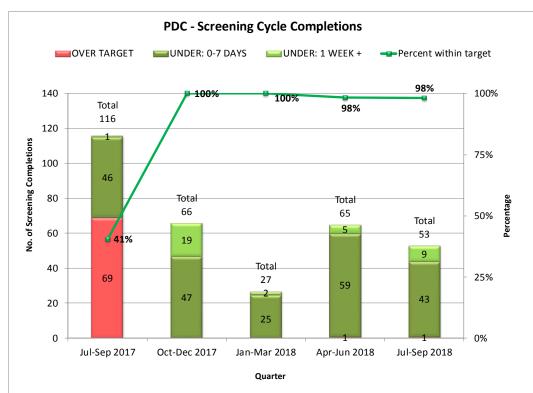
NNHPD PDC SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER								
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30			
Regular	24	1	11	18	8			
Backlog	0	0	0	1	0			
Total	24	1	11	18	8			
Non Backlog	24	1	11	17	8			
BACKLOG	0	0	0	1	0			
% in Backlog	0%	0%	0%	6%	0%			

DECISION DOCUMENTS

User Fee Category	Decision	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
REGULAR	CANCELLATION LETTER	1	1	0	3	6
	NO OBJECTION LETTER	114	60	24	57	40
	NOT SATISFACTORY NOTICE	2	4	3	7	6
	SCREENING DEFICIENCY NOTICE	0	0	0	0	1

PDC: Decision Documents by Fee Category

PERFORMANCE



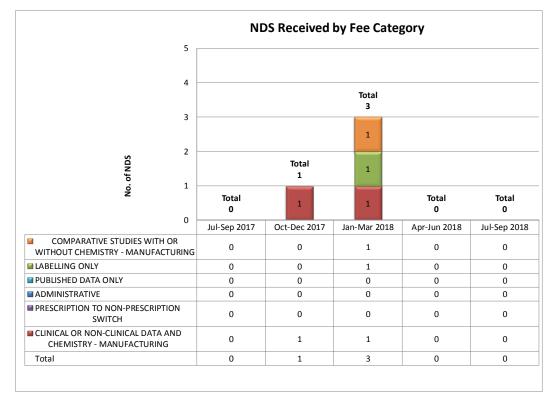
PDC: Screening Cycle Completions

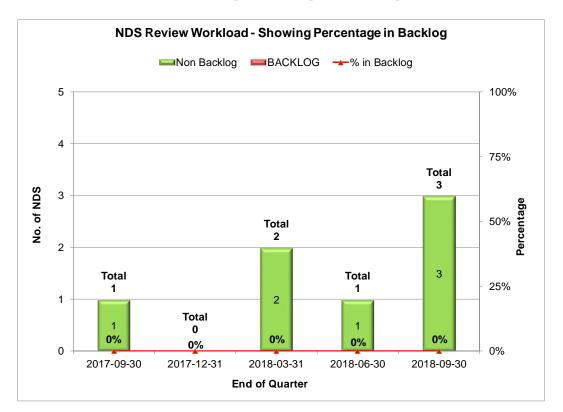
NON-PRESCRIPTION DRUGS FILED PURSUANT TO DIVISION 8 in Part C of the Food and Drug Regulations

NDS: NEW DRUG SUBMISSIONS

SUBMISSIONS RECEIVED

NDS: Received by Fee Category

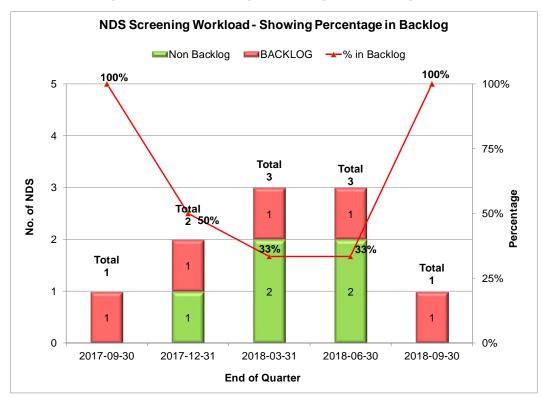




NDS: Review Workload Showing Percentage in Backlog

NDS: Review Workload by Fee Category

NNHPD NDS REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER								
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30			
Clinical or Non-Clinical Data and Chemistry - Manufacturing	0	0	1	1	2			
Backlog	0	0	0	0	0			
Comparative Studies with or								
without Chemistry -	0	0	0	0	1			
Manufacturing								
Backlog	0	0	0	0	0			
Labelling Only	1	0	1	0	0			
Backlog	0	0	0	0	0			
Total	1	0	2	1	3			
Non Backlog	1	0	2	1	3			
BACKLOG	0	0	0	0	0			
% in Backlog	0%	0%	0%	0%	0%			



NDS: Screening Workload Showing Percentage in Backlog

NDS: Screening Workload by Fee Category

NNHPD NDS SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER							
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30		
Prescription to Non- Prescription Switch	0	0	0	0	0		
Backlog	0	0	0	0	0		
Published Data	0	0	0	0	0		
Backlog	0	0	0	0	0		
Clinical or Non-Clinical Data and Chemistry - Manufacturing	0	0	1	1	0		
Backlog	0	0	0	0	0		
Labelling Only	1	1	1	1	1		
Backlog	1	1	1	1	1		
Comparative Studies with or without Chemistry - Manufacturing	о	1	1	1	0		
Backlog	0	0	0	0	0		
Total	1	2	3	3	1		
Non Backlog	0	1	2	2	0		
BACKLOG	1	1	1	1	1		
% in Backlog	100%	50%	33%	33%	100%		

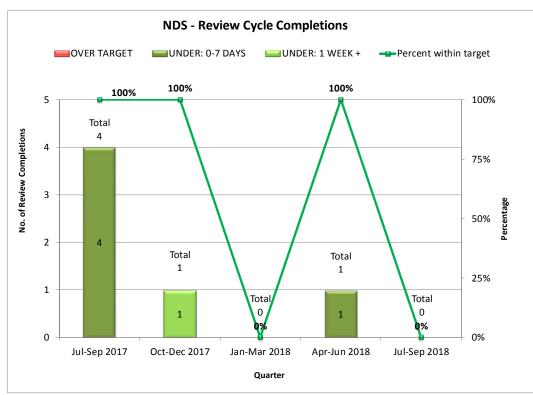
DECISION DOCUMENTS

User Fee Category	Decision	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
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	1	0
	NOD WITHDRAWAL LETTER	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	0	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
	SCREENING DEFICIENCY NOTICE	0	0	0	1	0
LABELLING ONLY	NOTICE OF COMPLIANCE*	4	0	0	1	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
	CANCELLATION LETTER	0	1	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

NDS: Decision Documents by Fee Category

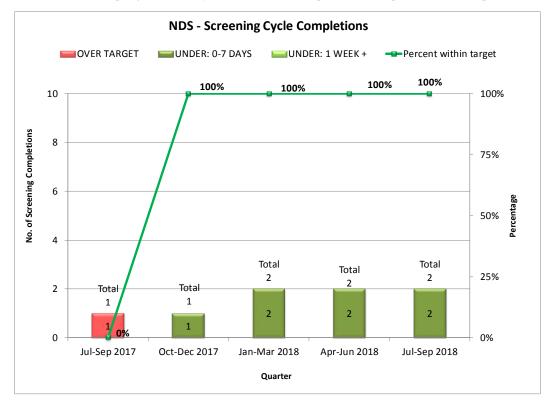
*Approvals are the NOCs Issued or Issuable at the conclusion of review (not NOCs issued at the end of a switch or patent hold).

PERFORMANCE



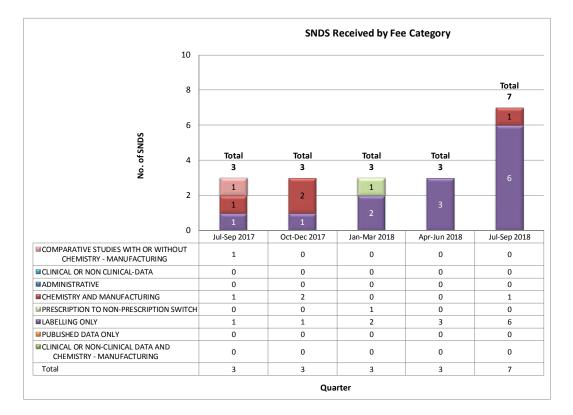
NDS: Review Cycle Completions Showing Percentage within Target

NDS: Screening Cycle Completions Showing Percentage within Target

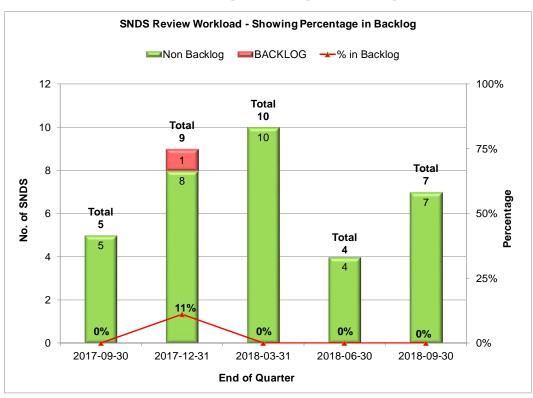


SNDS: SUPPLEMENTAL NEW DRUG SUBMISSIONS

SUBMISSIONS RECEIVED



SNDS: Received by Fee Category

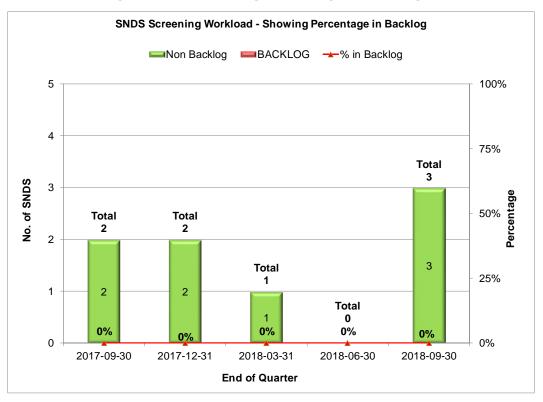


SNDS: Review Workload Showing Percentage in Backlog

SNDS: Review Workload by Fee Category

	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30
Clinical or Non-Clinical Data	1	1	1	0	0
Backlog	0	0	0	0	0
Clinical or Non-Clinical Data and Chemistry - Manufacturing	0	0	0	0	0
Backlog	0	0	0	0	0
Labelling Only	1	1	2	1	5
Backlog	0	0	0	0	0
Published Data	0	0	0	0	0
Backlog	0	0	0	0	0
Prescription to Non- Prescription Switch	0	0	1	1	0
Backlog	0	0	0	0	0
Comparative Studies with or without Chemistry - Manufacturing	1	1	2	1	1
Backlog	0	0	0	0	0
Chemistry and Manufacturing	2	6	4	1	1
Backlog	0	1	0	0	0
Total	5	9	10	4	7
Non Backlog	5	8	10	4	7
BACKLOG	0	1	0	0	0
% in Backlog	0%	11%	0%	0%	0%





SNDS: Screening Workload by Fee Category

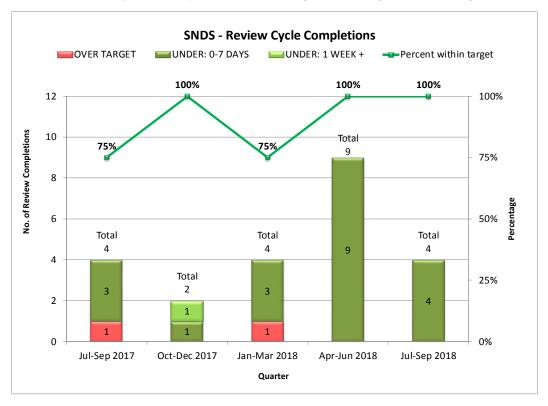
NNHPD SNDS SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER									
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30				
Chemistry and Manufacturing	1	1	1	0	2				
Backlog	0	0	0	0	0				
Clinical or Non-Clinical Data	0	0	0	0	0				
Backlog	0	0	0	0	0				
Comparative Studies with or									
without Chemistry -	1	1	0	0	0				
Manufacturing									
Backlog	0	0	0	0	0				
Labelling Only	0	0	0	0	1				
Backlog	0	0	0	0	0				
Published Data	0	0	0	0	0				
Backlog	0	0	0	0	0				
Total	2	2	1	0	3				
Non Backlog	2	2	1	0	3				
BACKLOG	0	0	0	0	0				
% in Backlog	0%	0%	0%	0%	0%				

DECISION DOCUMENTS

SNDS: Decision Documents by Fee Category

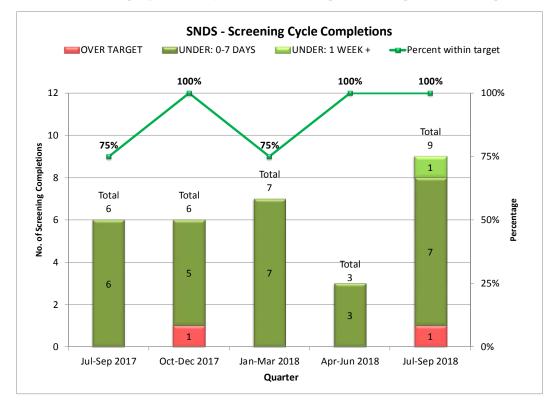
User Fee Category	Decision	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
CLINICAL OR NON-CLINICAL DATA	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOTICE OF COMPLIANCE*	0	0	0	1	0
CLINICAL OR NON CLINICAL DATA AND CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	0	0	0	0
COMPARATIVE STUDIES WITH OR WITHOUT CHEMISTRY - MANUFACTURING	NOTICE OF COMPLIANCE*	0	0	0	0	1
	NOTICE OF NON-COMPLIANCE	0	0	0	1	0
	NOTICE OF DEFICIENCY	0	1	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	0
LABELLING ONLY	NOC ON HOLD (SWITCH)*	0	0	0	0	0
	NOTICE OF COMPLIANCE*	2	0	2	2	1
	SCREENING DEFICIENCY NOTICE	0	0	1	0	2
	CANCELLATION LETTER	0	0	0	0	0
	NOTICE OF DEFICIENCY	0	0	0	0	0
	NOTICE OF NON-COMPLIANCE	0	1	0	1	1
PRESCRIPTION TO NON- PRESCRIPTION SWITCH	NOC ON HOLD (SWITCH) *	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*	1	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	0	0	1	0
	NOTICE OF COMPLIANCE*	1	0	2	3	0
	SCREENING DEFICIENCY NOTICE	3	0	1	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).



SNDS: Review Cycle Completions Showing Percentage within Target

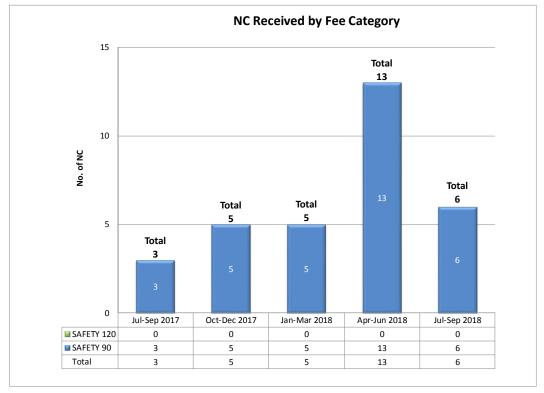
SNDS: Screening Cycle Completions Showing Percentage within Target

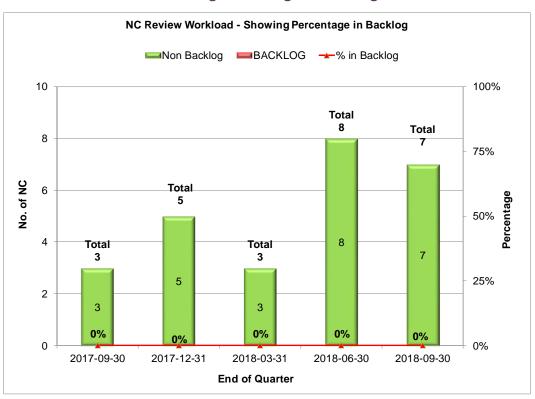


NC: NOTIFIABLE CHANGES

SUBMISSIONS RECEIVED





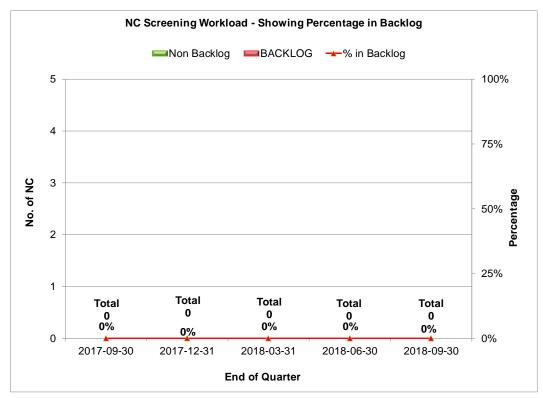


NC: Review Workload Showing Percentage in Backlog

NC: Review Workload by Fee Category

NNHPD NC REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER									
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30				
Safety 90	3	5	3	8	7				
Backlog	0	0	0	0	0				
Safety 120	0	0	0	0	0				
Backlog	0	0	0	0	0				
Total	3	5	3	8	7				
Non Backlog	3	5	3	8	7				
BACKLOG	0	0	0	0	0				
% in Backlog	0%	0%	0%	0%	0%				





NC: Screening Workload by Fee Category

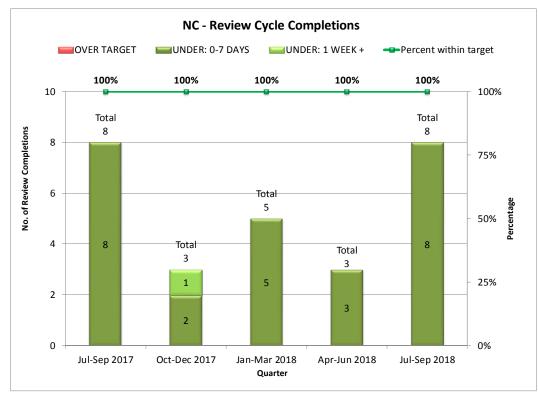
NNHPD NC SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER									
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30				
Safety 90	0	0	0	0	0				
Backlog	0	0	0	0	0				
Total	0	0	0	0	0				
Non Backlog	0	0	0	0	0				
BACKLOG	0	0	0	0	0				
% in Backlog	0%	0%	0%	0%	0%				

DECISION DOCUMENTS

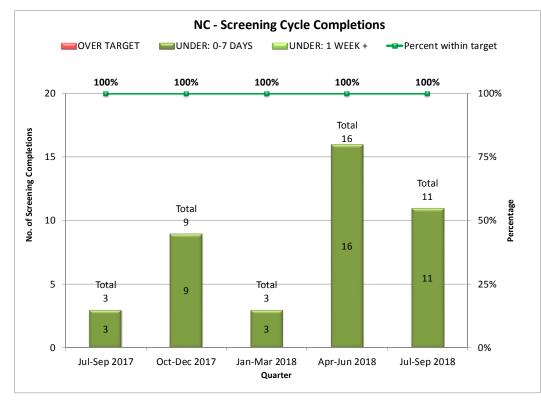
User Fee Category	Decision	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
SAFETY 90	NO OBJECTION LETTER	7	3	5	3	8
	NC-HOLD (SWITCH)	0	0	0	0	0
	NOT SATISFACTORY NOTICE	0	0	0	0	0
	REJECTION LETTER (SCR)	0	0	0	1	0
	CANCELLATION LETTER	1	1	0	1	4
	SCREENING DEFICIENCY NOTICE	0	4	0	7	4
SAFETY 120	CANCELLATION LETTER	0	0	0	0	0

NC: Decision Documents by Fee Category

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)	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA	0	0	0	0	1

MPNDS: PRE-NDS MEETING

MPNDS – Pre-NDS Meeting Received by Fee Category

PRE - NDS MEETING (MPNDS)	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA AND CHEMISTRY - MANUFACTURING	0	0	0	0	2

MPSNDS: PRE-SNDS MEETING

MPSNDS – Pre-SNDS Meeting Received by Fee Category

PRE - NDS MEETING (MPSNDS)	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA	0	0	0	1	0

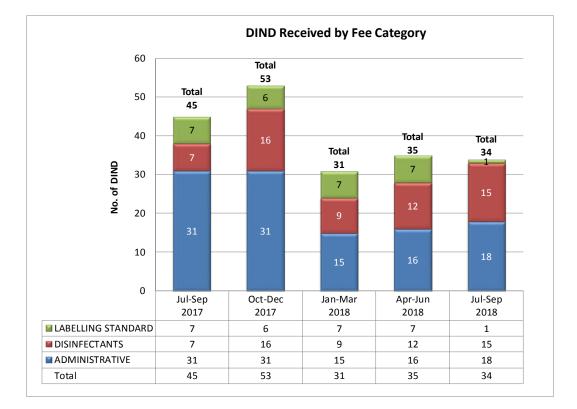
PART 2: DISINFECTANT DRUGS

DISINFECTANT DRUGS FILED PURSUANT TO DIVISION 1

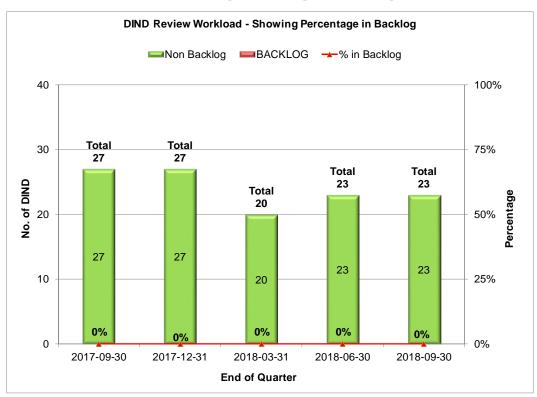
in Part C of the Food and Drug Regulations

DIND: DIN APPLICATION – DISINFECTANT DRUGS

SUBMISSIONS RECEIVED

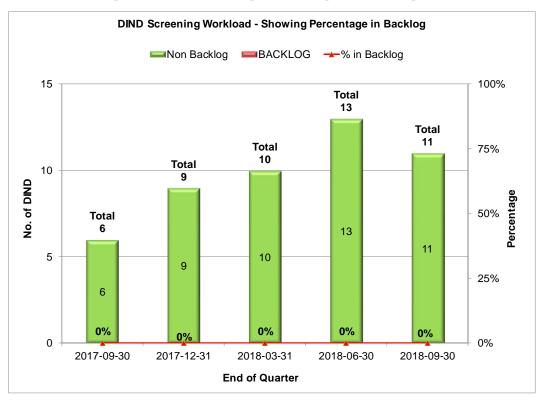


DIND: Received by Fee Category

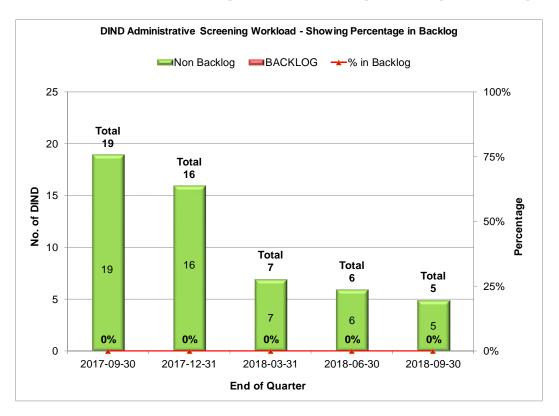


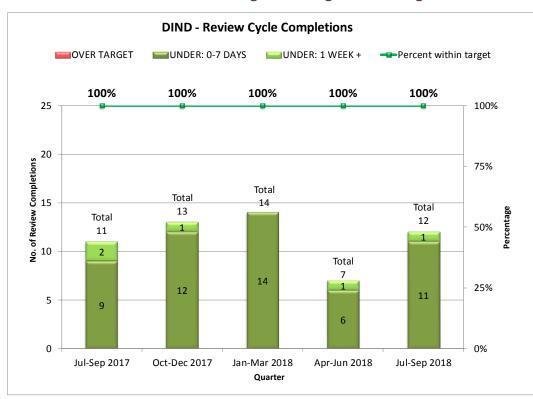
DIND: Review Workload Showing Percentage in Backlog

DIND: Screening Workload Showing Percentage in Backlog



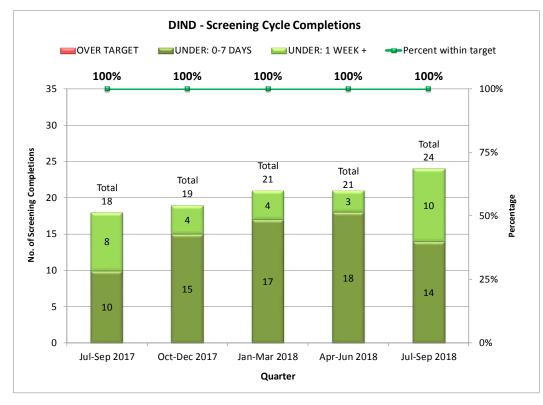
DIND: Administrative-Screening Workload Showing Percentage in Backlog



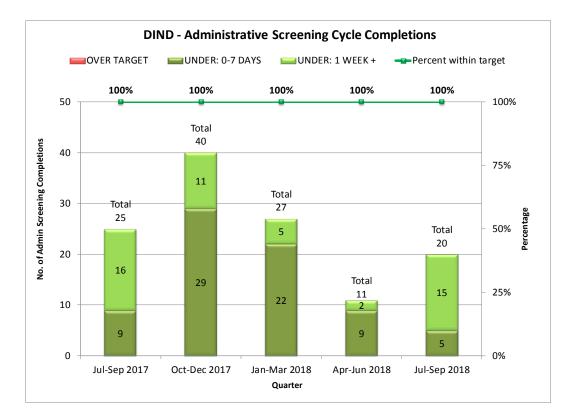


DIND: Review Performance Showing Percentage within Target

DIND: Screening Performance Showing Percentage within Target



DIND: Administrative-Screening Performance Showing Percentage within Target



DECISION DOCUMENTS

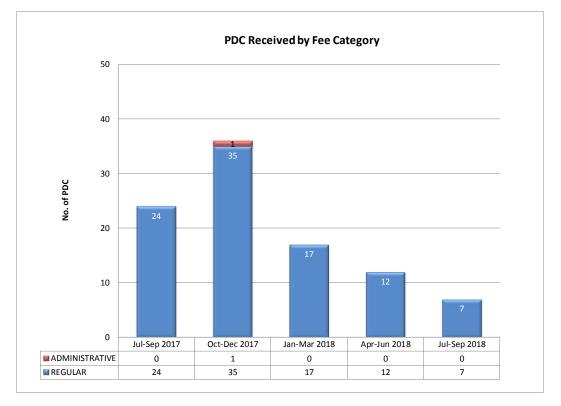
DIND: Decisions Documents by Fee Category

User Fee Category	Decision	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
ADMINISTRATIVE	CANCELLATION LETTER	1	0	0	2	0
	NO OBJECTION LETTER	0	0	0	0	1
	DIN INCORR SUBTYPE-CLASS	0	0	0	0	0
	NOTIFICATION FORM DIN SUB	16	30	27	10	12
	REJECTION LETTER (SCR)	7	3	0	0	0
	SCREENING DEFICIENCY NOTICE	3	8	1	0	7
DISINFECTANTS	DIN INCORR SUBTYPE-CLASS	0	0	0	0	0
	NO OBJECTION LETTER	1	2	7	0	0
	CANCELLATION LETTER	1	2	0	0	1
	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	1	0	0	0
	NOTIFICATION FORM DIN SUB	9	10	7	7	12
	SCREENING DEFICIENCY NOTICE	2	1	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	3	3	6	5	5
	NO OBJECTION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	1	2	5	1	3
	REJECTION LETTER (SCR)	3	0	0	3	1

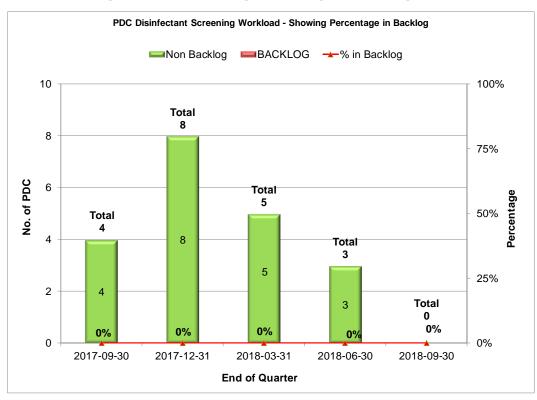
PDC: POST AUTHORIZATION DIVISION 1 CHANGES

SUBMISSIONS RECEIVED

PDC: Received by Fee Category

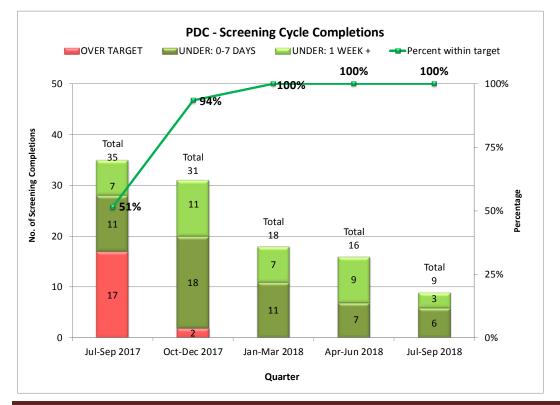






PERFORMANCE

PDC: Screening Performance Showing Percentage within Target



NNHPD Quarterly Drug Submission Performance Report: **PDC: Post Authorization Division 1 Changes**

DECISION DOCUMENTS

PDC: Decision Documents by Fee Category

User Fee Category	Decision	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
ADMINISTRATIVE	CANCELLATION LETTER	0	0	1	0	0
REGULAR	CANCELLATION LETTER	0	0	0	0	0
	NO OBJECTION LETTER	17	21	15	15	4
	NOT SATISFACTORY NOTICE	17	9	0	1	5
	NOTIFICATION FORM DIN SUB	0	0	3	0	0
	REJECTION LETTER (SCR)	1	2	0	0	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	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep
	2017	2017	2018	2018	2018
Submission Type - User Fee Category					
ADMINISTRATIVE	0	0	0	0	1
DISINFECTANTS	1	1	0	0	0
Total	1	1	0	0	1

WORKLOAD

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

NNHPD NDS-D REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER									
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30				
Disinfectants	3	1	2	1	1				
Backlog	0	0	0	0	0				
Total	3	1	2	1	1				
Non Backlog	3	1	2	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										
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30					
Disinfectants	1	2	0	0	0					
Backlog	0	0	0	0	0					
Total	1	2	0	0	0					
Non Backlog	1	2	0	0	0					
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										
	2017-09-30	2017-12-31	2018-03-31	2018-06-30	2018-09-30					
Administrative	0	0	0	0	1					
Backlog	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: Review Performance

REVIEW Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Jul-Sep 2017	0	1	0	100%	1
Oct-Dec 2017	0	2	0	100%	2
Jan-Mar 2018	0	0	0	-	0
Apr-Jun 2018	0	1	0	100%	1
Jul-Sep 2018	0	0	0	-	0

NDS-D: Screening Performance

SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent with Target	Total
Jul-Sep 2017	0	0	0	-	0
Oct-Dec 2017	0	1	0	100%	1
Jan-Mar 2018	0	5	0	100%	5
Apr-Jun 2018	0	0	0	-	0
Jul-Sep 2018	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
Jul-Sep 2017	0	0	0	-	0
Oct-Dec 2017	0	0	0	-	0
Jan-Mar 2018	0	0	0	-	0
Apr-Jun 2018	0	0	0	-	0
Jul-Sep 2018	0	1	0	100%	1

DECISION DOCUMENTS

NDS-D: Decision Documents by Fee Category

User Fee Category	Decision	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
ADMINISTRATIVE	CANCELLATION LETTER	0	0	0	0	0
	SCREENING DEFICIENCY NOTICE	0	0	0	0	1
DISINFECTANTS	NOTICE OF NON-COMPLIANCE	0	0	0	0	0
	NOTICE OF DEFICIENCY	1	1	1	0	0
	NOD WITHDRAWAL LETTER	0	0	1	0	0
	NOTICE OF COMPLIANCE*	0	1	0	1	0
	CANCELLATION LETTER	0	0	0	0	0
	REJECTION LETTER (SCR)	0	0	1	0	0
	SCREENING DEFICIENCY NOTICE	0	1	1	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)	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Submission Type - User Fee Category					
SAFETY 90	0	1	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										
2017-09-30 2017-12-31 2018-03-31 2018-06-30 2018-09-										
SAFETY 90	0	1	0	0	0					
Backlog	0	0	0	0	0					
Total	0	1	0	0	0					
Non Backlog	0	1	0	0	0					
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										
2017-09-30 2017-12-31 2018-03-31 2018-06-30 2018-09-										
SAFETY 90	0	0	0	0	0					
Backlog	0	0	0	0	0					
Total	0	0	0	0	0					
Non Backlog	0	0	0	0	0					
BACKLOG	0	0	0	0	0					
% in Backlog	0%	0%	0%	0%	0%					

REVIEW Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Jul-Sep 2017	0	0	0	-	0
Oct-Dec 2017	0	0	0	-	0
Jan-Mar 2018	0	0	1	100%	1
Apr-Jun 2018	0	0	0	-	0
Jul-Sep 2018	0	0	0	-	0

NC – Disinfectant Drugs: Review Performance

NC – Disinfectant Drugs: Screening Performance

SCREENING Quarter	OVER TARGET	UNDER: 0-7 DAYS	UNDER: 1 WEEK +	Percent within Target	Total
Jul-Sep 2017	0	0	0	-	0
Oct-Dec 2017	0	1	0	100%	1
Jan-Mar 2018	0	0	0	-	0
Apr-Jun 2018	0	0	0	-	0
Jul-Sep 2018	0	0	0	-	0

DECISION DOCUMENTS

NC – Disinfectant Drugs: Decision Documents

User Fee Category	Decision	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
SAFETY 90	NO OBJECTION LETTER	0	0	1	0	0
	CANCELLATION LETTER	0	0	0	0	0

MPNDS: PRE-NDS MEETING

MPNDS – Disinfectant Drugs: Received by Fee Category

PRE - NDS MEETING (MPNDS)	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
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)	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018	Jul-Sep 2018
Submission Type - User Fee Category					
CLINICAL OR NON-CLINICAL DATA	0	0	0	1	0