



Medicines Control Authority of Zimbabwe

REGULATORY PERFORMANCE INDICATORS BASED ON CIRCULAR 26 OF 2023



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OVERVIEW

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CIRCULAR 26
OF 2023

02

HIGH-LEVEL
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VETERINARY &
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MEDICINES

09

2026 TIMELINES

CIRCULAR 26 OF 2023

MEASURES IMPLEMENTED

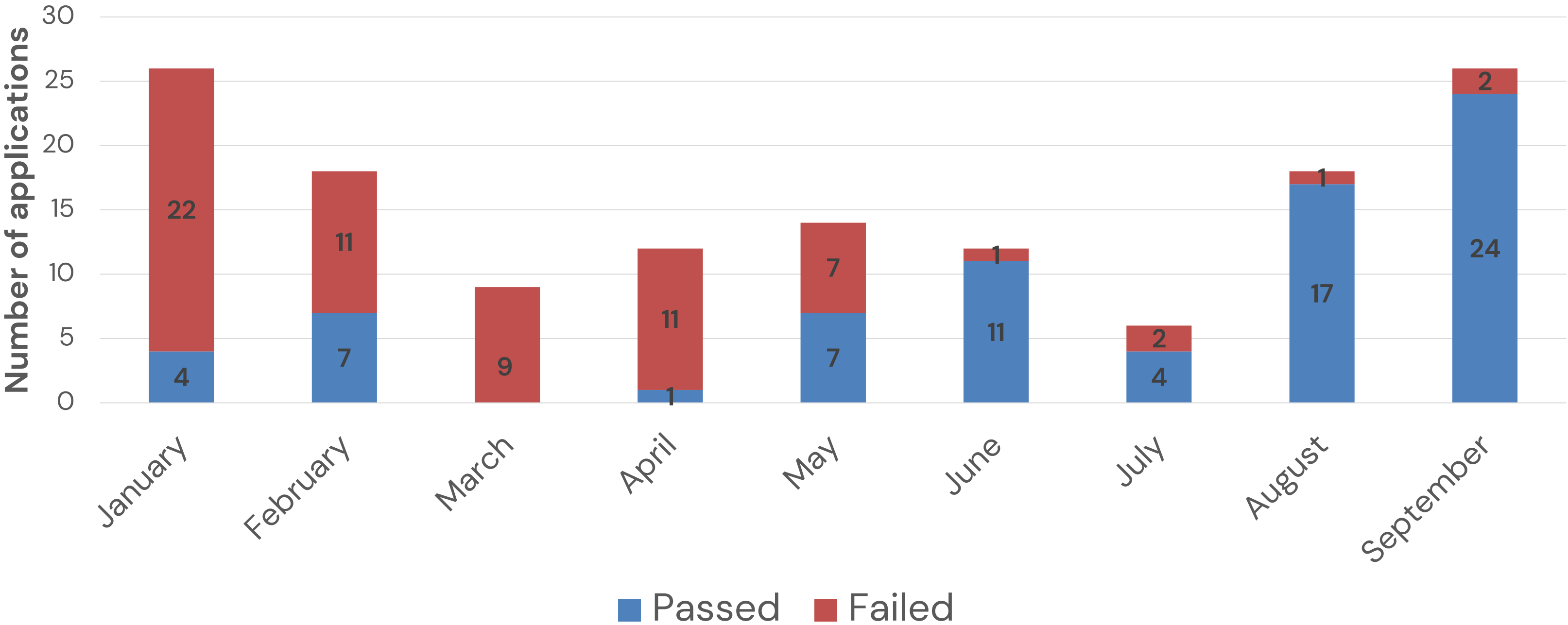
- High-level screening of products received in 2024 with a screening deadline of 10 days.
- High-level screening of products received before 2024.
- Quarantine of products that fail screening with a deadline of 120 days and a resubmission fee
- A maximum of two review cycles after screening of the product
- Revision of the timelines after evaluation as below;

AUTHORITY'S DECISION	APPLICANT'S TIMELINE
INTENT TO REFUSE TO REGISTER	60 CALENDAR DAYS
INTENT TO REGISTER	30 CALENDAR DAYS

2024 HIGH-LEVEL SCREENING

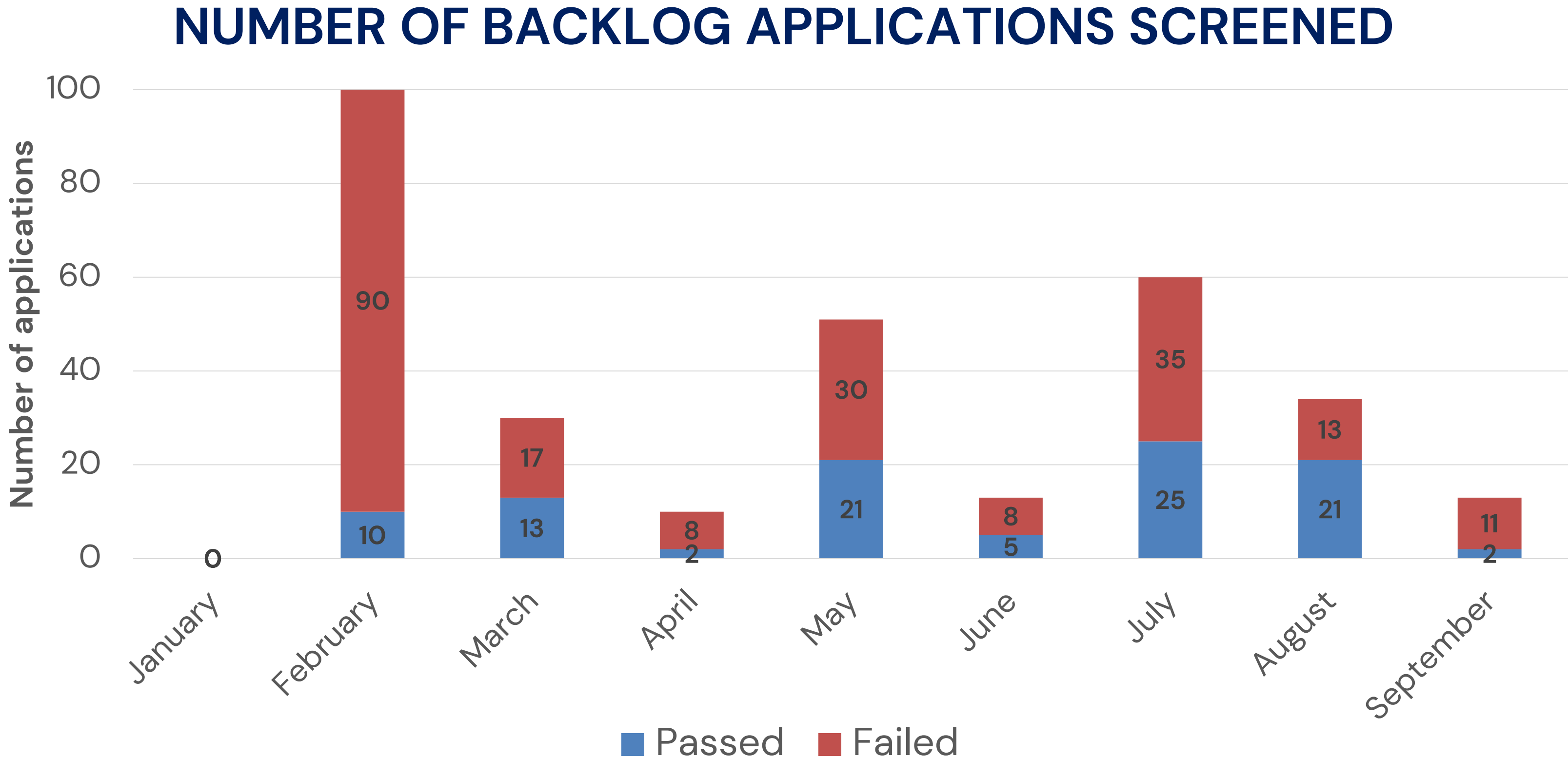
Graph 1.1 The graph shows the applications received in 2024 that passed and failed screening

NUMBER OF APPLICATIONS SCREENED IN 2024

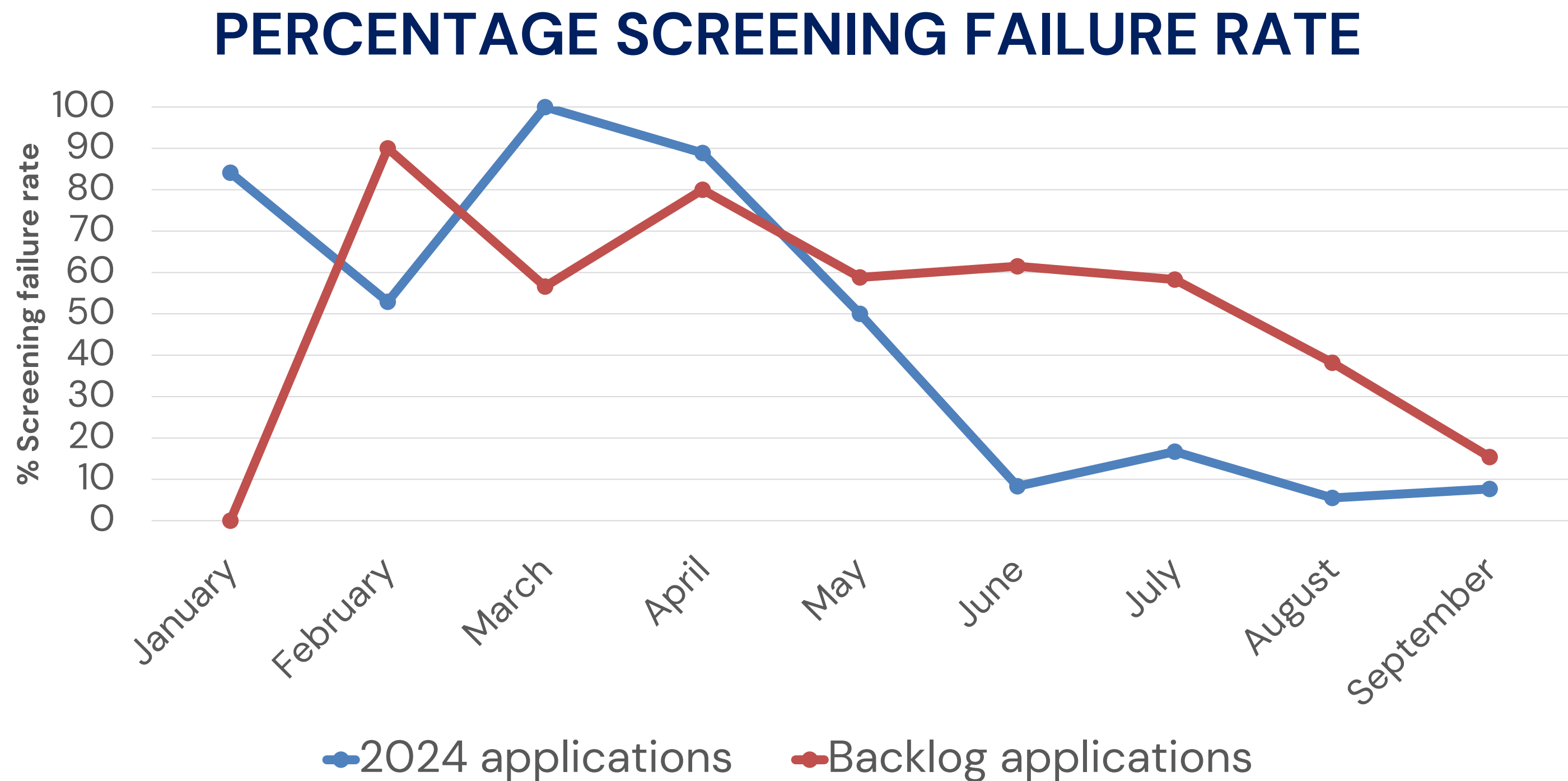


BACKLOG HIGH-LEVEL SCREENING

Graph 1.2 The graph shows the applications from the backlog that passed and failed screening



HIGH-LEVEL SCREENING FAILURE RATE

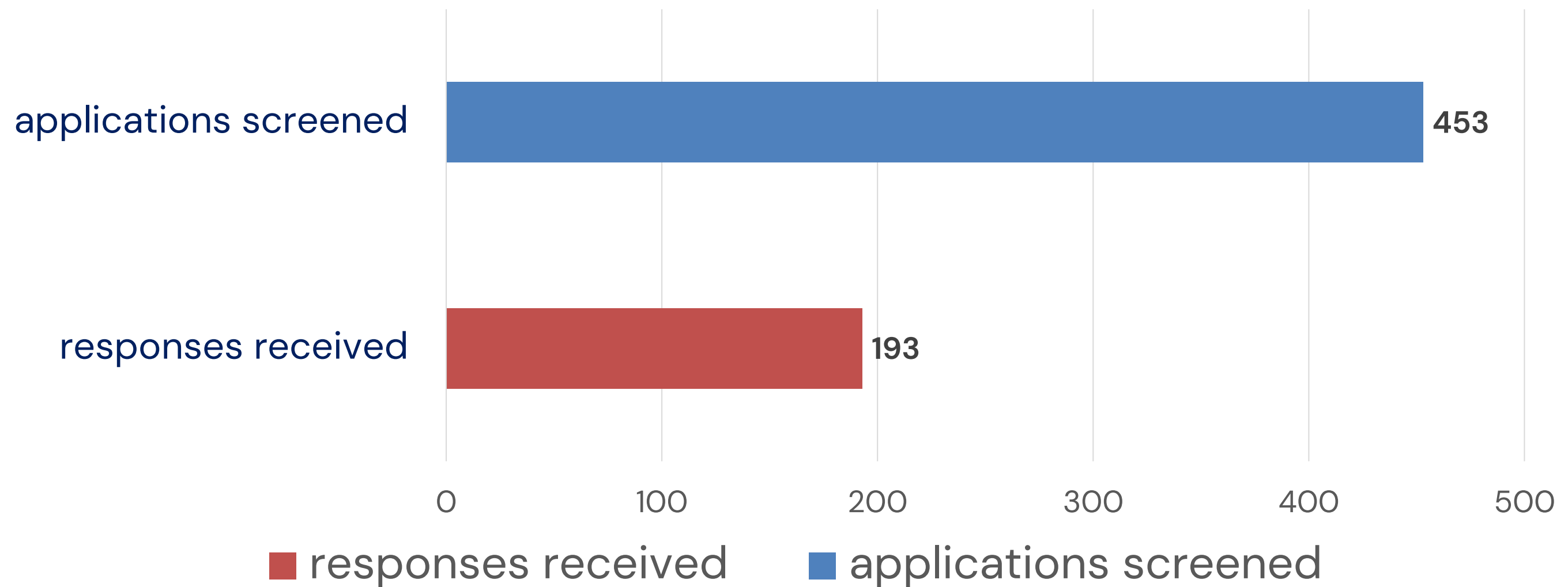


Graph 1.3: The graph shows the screening failure rate of all products screened

RESPONSES TO SCREENING RECEIVED

*Figure 1: Shows the number of
responses to screening received*

NUMBER OF APPLICATIONS SCREENED VS RESPONSES RECEIVED



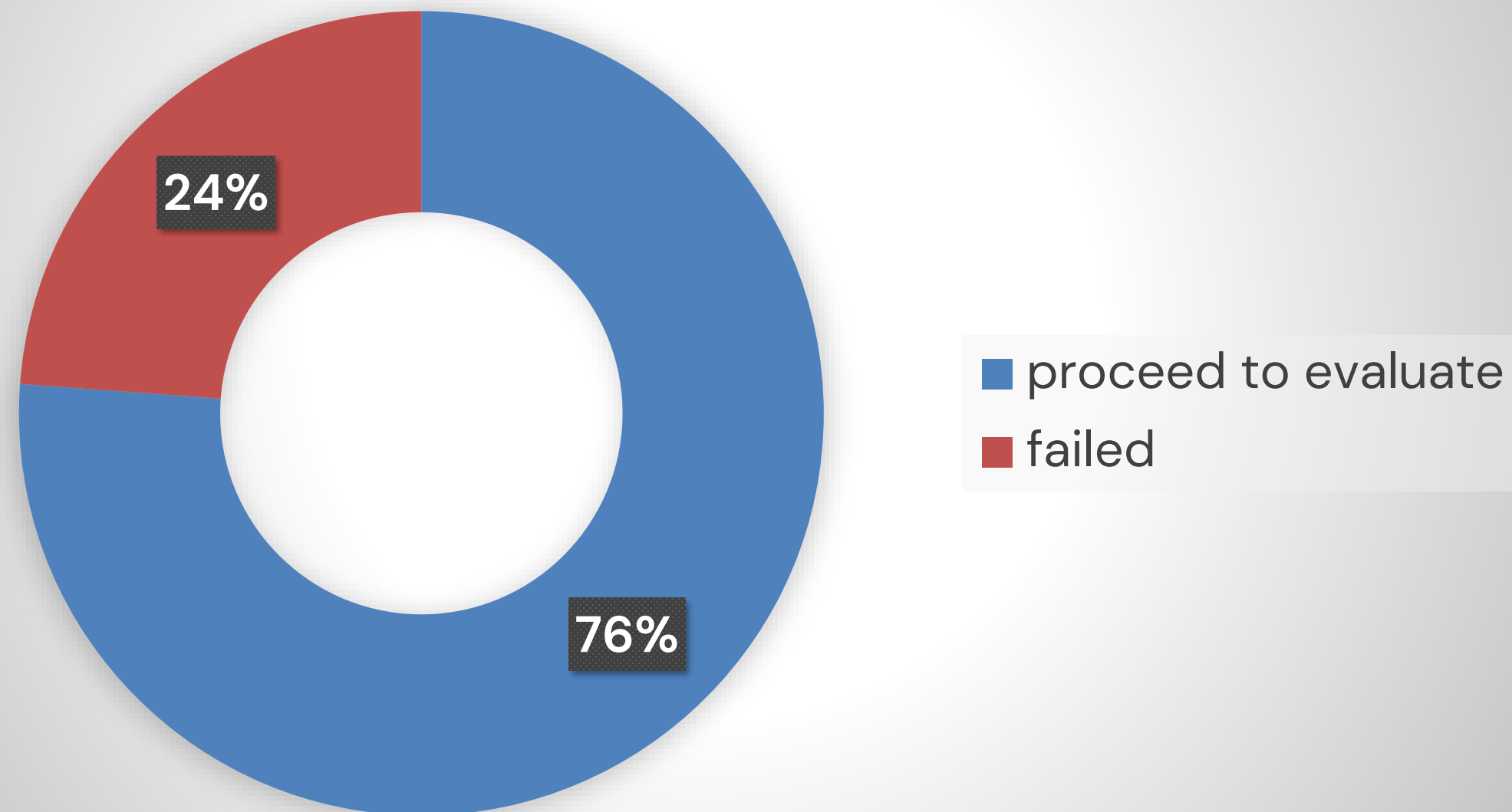
EVALUATION OF RESPONSES TO SCREENING

Period	Responses to screening received	Responses to screening evaluated	Pending responses to screening
January	0	0	0
February	0	0	0
March	1	0	1
April	1	2	0
May	18	1	17
June	35	25	27
July	39	26	40
August	31	7	64
September	68	13	111
Total	193	82	111

Based on September statistics, the median time to evaluate the responses to screening is 2 months with a range of 2 and half months determined by a maximum of 3 months and a minimum of 15 days

EVALUATION OF RESPONSES TO SCREENING

PERCENTAGE OF THE STATUSES OF THE
RESPONSES TO SCREENING RECEIVED



PERFORMANCE

100%

Of all the products eligible for screening received in 2024 were screened

48%

Increase in the number of products registered this year compared to last year



SCREENING DEADLINE

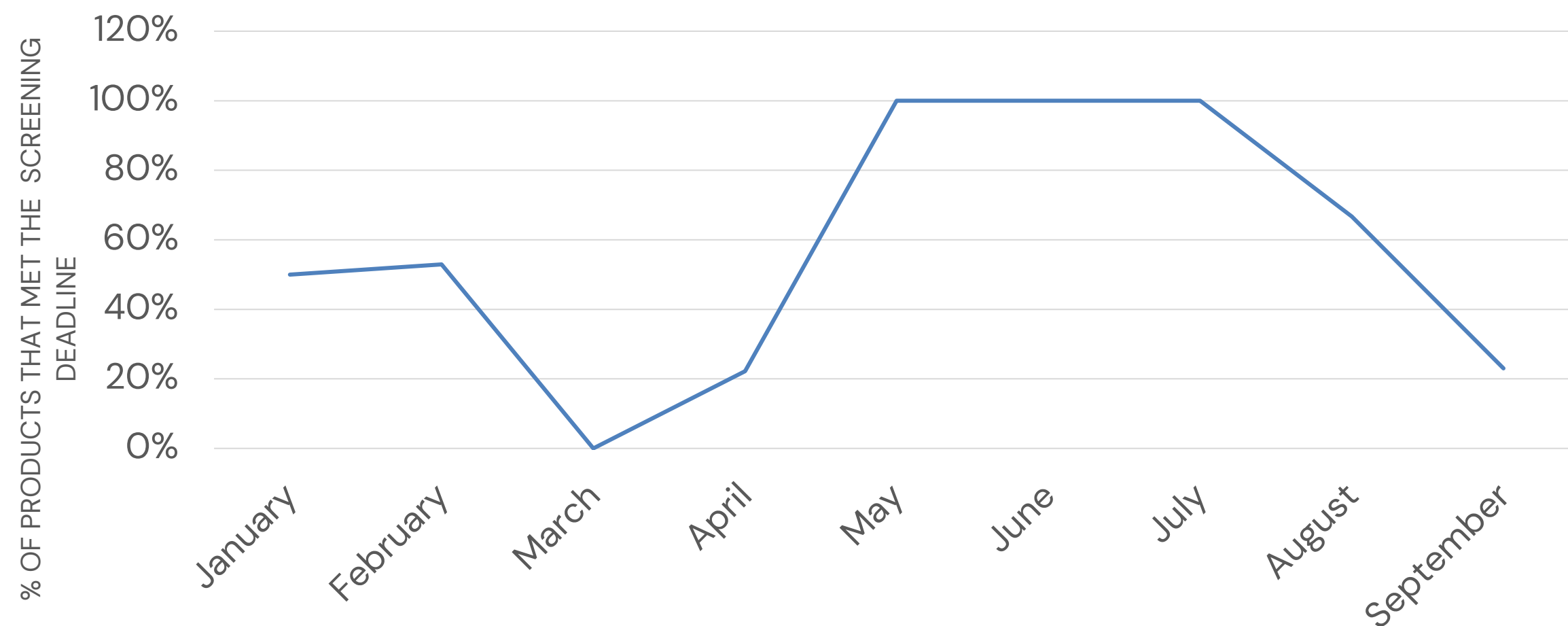
Month	Applications screened	Applications that met the deadline	Percentage of the applications that met the deadline
January	26	13	50%
February	17	9	52.9%
March	12	0	0%
April	9	2	22.2%
May	14	14	100%
June	12	12	100%
July	6	6	100%
August	18	12	67%
September	26	6	23%



SCREENING DEADLINE



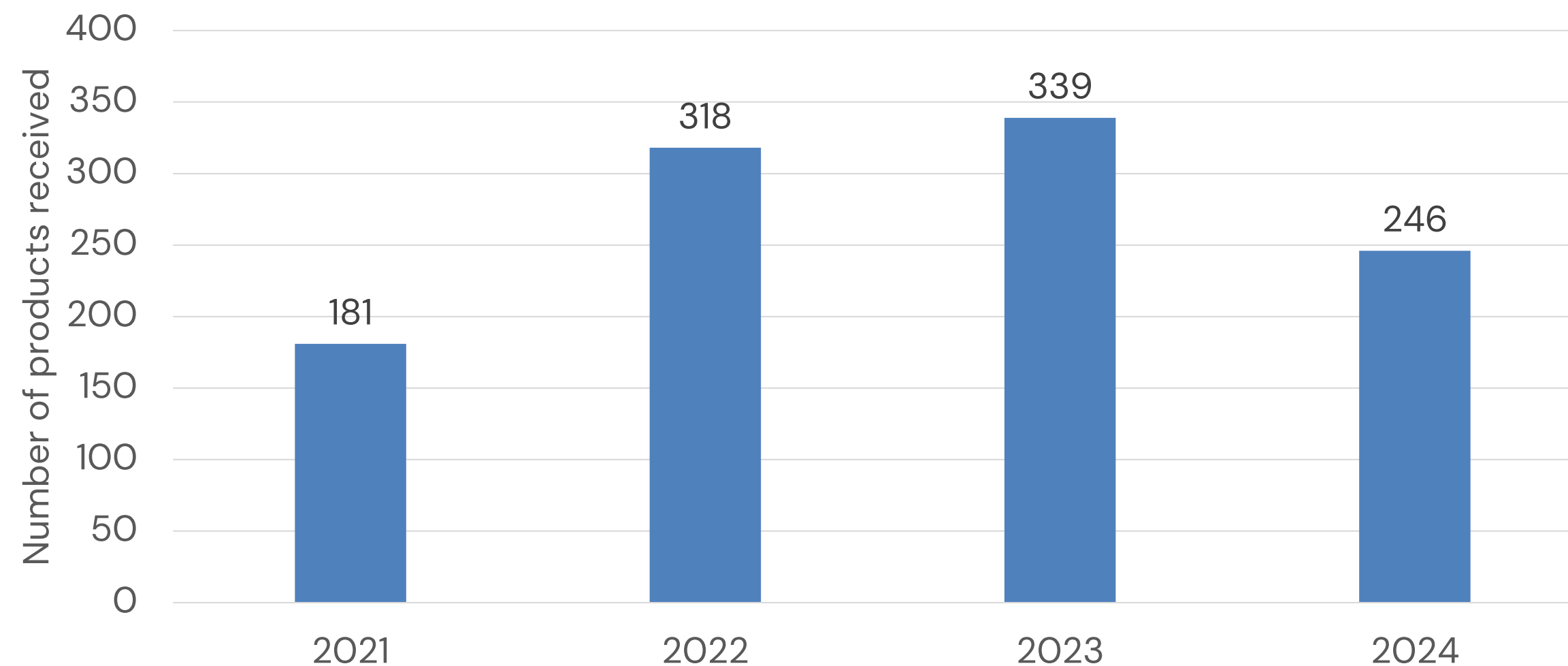
PERCENTAGE OF PRODUCTS THAT MET THE SCREENING DEADLINE



APPLICATIONS RECEIVED

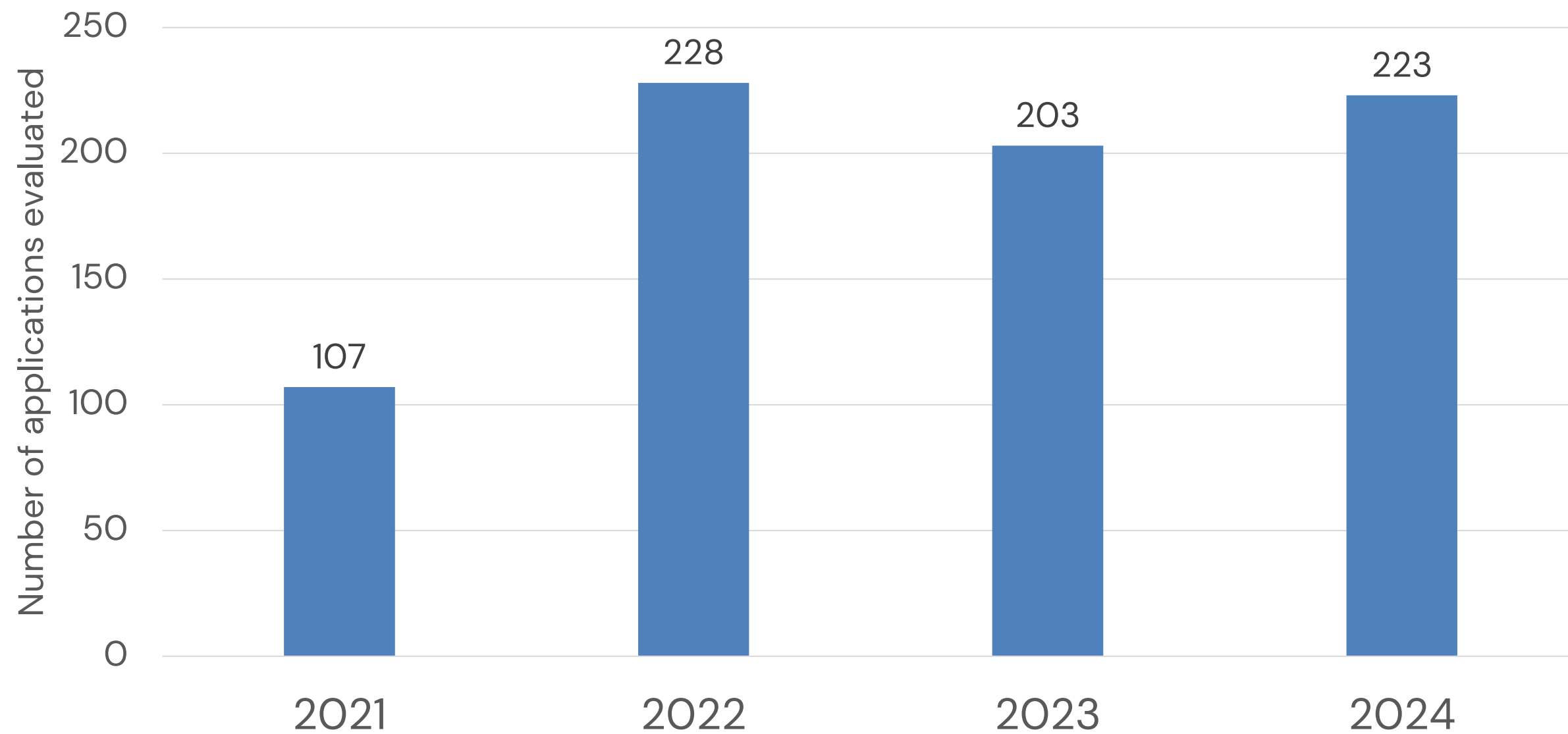


NUMBER OF APPLICATIONS RECEIVED



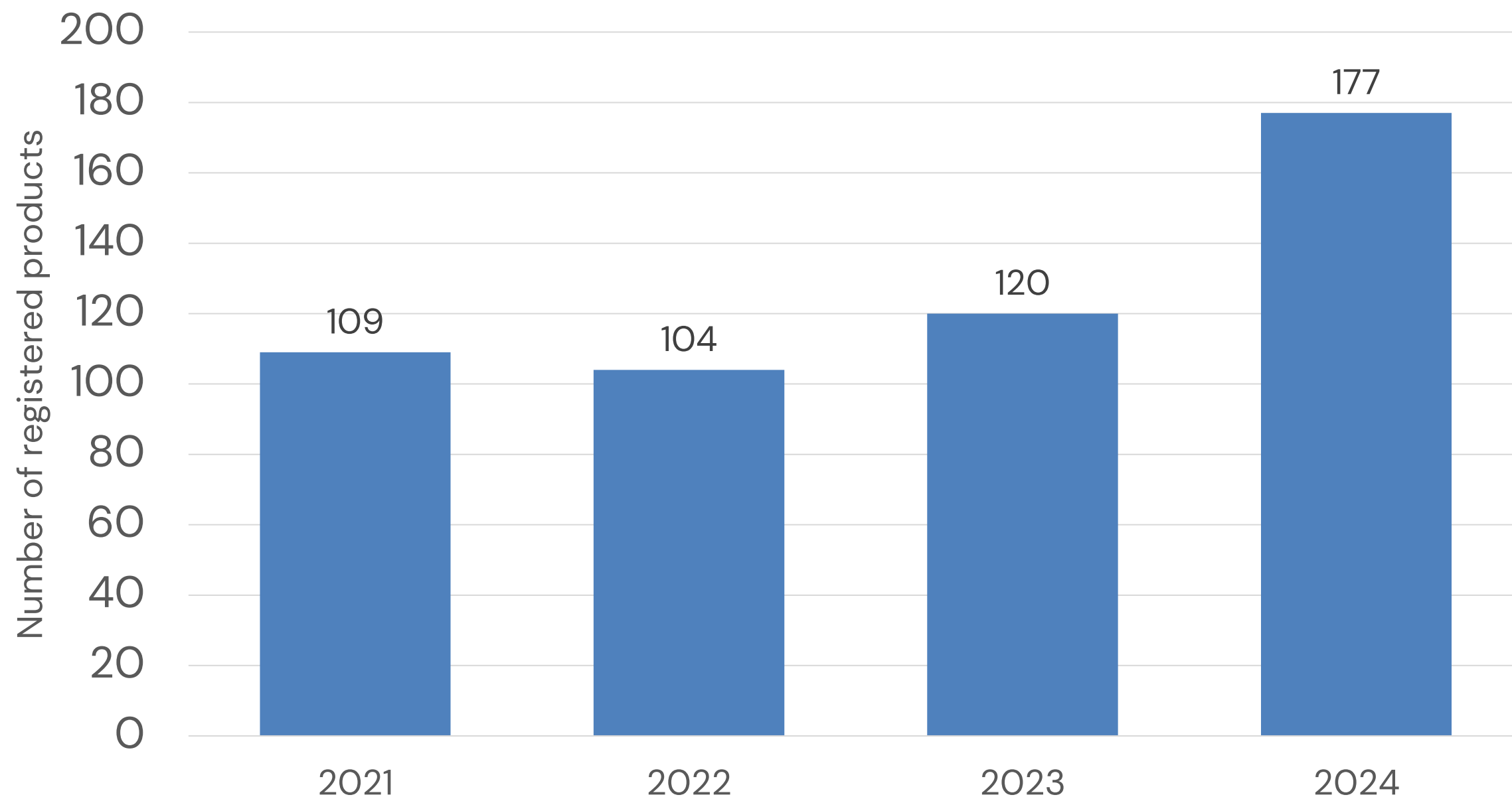
EVALUATION

NUMBER OF APPLICATIONS EVALUATED



REGISTERED PRODUCTS

NUMBER OF REGISTERED PRODUCTS



ANTICIPATED IMPACTS AND THE OUTCOMES

REDUCTION IN THE BACKLOG

- Significant decrease of the backlog from **554** to **209** applications
- Significant increase of registered products from **120** to **177**

SUBMISSION OF COMPLETE DOSSIERS BY APPLICANTS

- Significant decrease of the screening failure rate from **84.1%** to **7.7%**

A MAXIMUM OF TWO REVIEW CYCLES AFTER SCREENING

- Increase in number of evaluated products from **203** to **223**
- A minimum of **2 months** time to registration

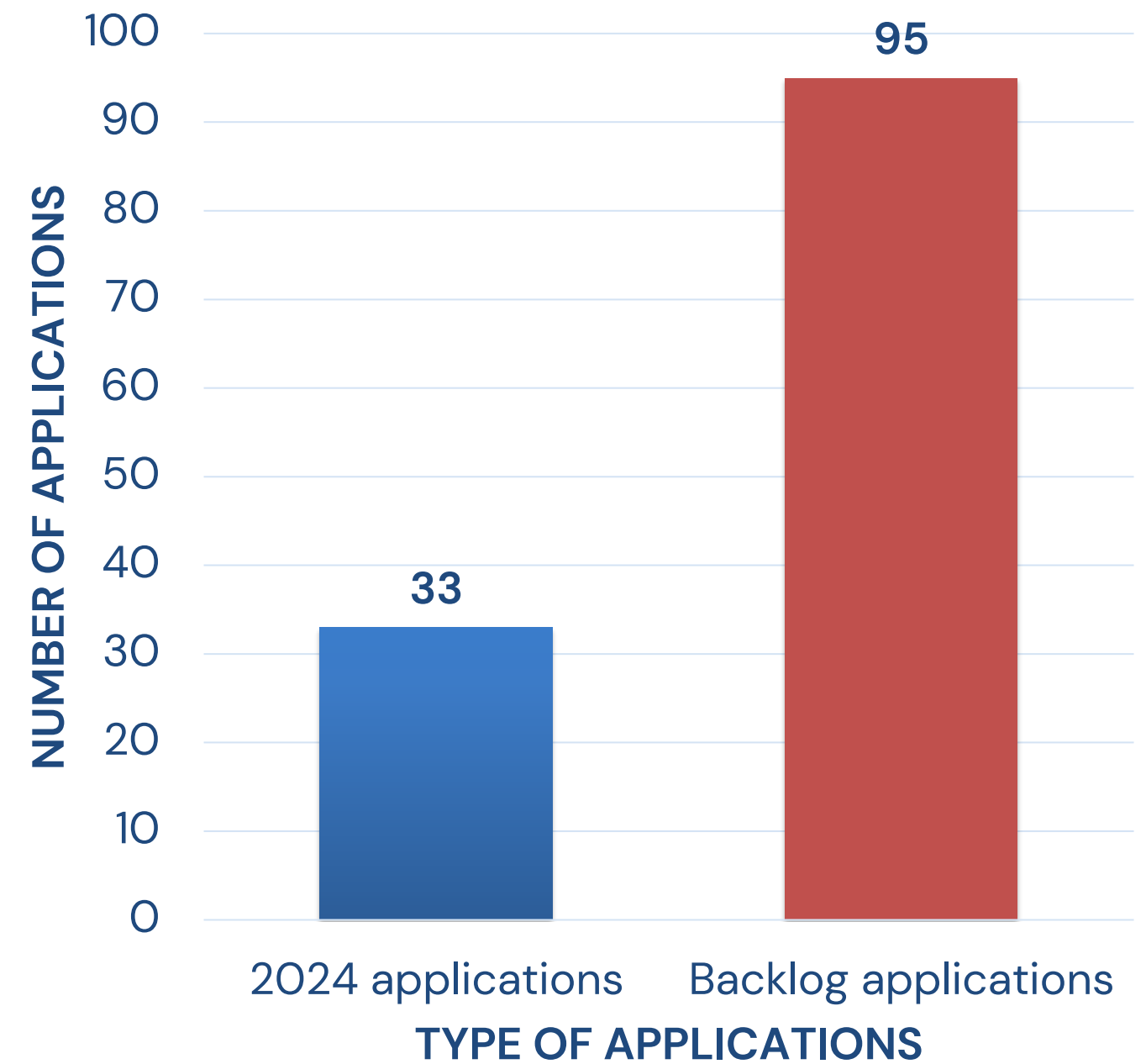
CHALLENGES

01

Applicants missing deadlines



SCREENING RESPONSES PAST DEADLINE



CHALLENGES

- 02 Changes in the local representative that are not communicated to the authority
- 03 Failure to resolve minor issues after an intent to register recommendation
- 04 Applicants requesting reprints of their letters after losing them
- 05 Applicants not confirming the details in their intent to register
- 06 Applicants still requesting deadline extensions



CHALLENGES_(internal)

07

Staff Attrition



Name	Position
FARAI MASEKELA	Head EVR (13 years)
TINASHE MUVIRIMI	Chief Regulatory Officer (13 years)
RUFARO MBANJE	Regulatory Officer (4 years)
PRONALIS TAPFUMANEYI	Regulatory Officer (2 years)
RUMBIDZAI MATSIYA	Regulatory Officer -Data Entry Clerk/ Retriever (6 years)
JONATHAN KATSOKONYA	Regulatory Officer

CHALLENGES_(internal)

08

Delay in automation of our
systems



ZIMDIS

CHALLENGES *(internal)*

- 09 Multitasking of regulatory officers doing both technical and administrative duties
- 10 Low competence levels of new assessors





INTERVENTIONS

NEW ZIMDIS

- **MISSING DEADLINE**
notifications will be sent
 - **RESOLVING QUERIES IN TWO CYCLES**
The system will monitor the review cycles
 - **ISSUANCE OF CERTIFICATES AND LETTERS**
automatically generated by the system
-

REVISED CIRCULAR

- **LOCAL REPRESENTATIVES' VS APPLICANTS**
-



INTERVENTIONS

NEW STAFF

- Training
-

VARIATION

- Amendment of certificates issued with errors because of failure to confirm the details on the intent to register letter will be considered a variation
-

ZIMDIS



Welcome,
Zivanai Makoni

GENERAL

Dashboards

ZIMDIS

ZIMDIS

Submit Application

Drug Application

View Applications

Certificates

Sign Cover Letter

Letters

Allocations

House keeping

Tracking

0



Zivanai Makoni

ZIMDIS DASHBOARD

38

Drug Applications
(Capturing)

[More info](#)

0

Drug Applications
(Verification)

[More info](#)

163

Drug Applications
(Screening
Allocation)

[More info](#)

38

Drug Applications
(Screening R1)

[More info](#)

1

Drug Applications
(Screening R2)

[More info](#)

0

Drug Applications
(Drug Capturing)

[More info](#)

10

Drug Applications
(Initial Evaluation
Allocation)

[More info](#)

1

Drug Applications
(Q1R1)

[More info](#)

0

Drug Applications
(Q1R2)

[More info](#)

0

Drug Applications
(Responses
Allocation)

[More info](#)

0

Drug Applications
(Q2R1)

[More info](#)

0

Drug Applications
(Q2R2)

[More info](#)

User Tracking

[View More](#)

ApplicationNo	QuarantineNo	Submission Date	Current Stage	Current User	Days Taken	Duration	
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VETERINARY MEDICINES

DESCRIPTION	NUMBER
Total applications that were screened	26
Total applications that failed screening	16
Total applications that passed screening	10
Total responses resubmitted	10
Total pending responses	16
Deadline extensions requested	9



COMPLIMENTARY MEDICINE

DESCRIPTION	NUMBER
Total applications that were screened	101
Total applications that failed screening	22
Total applications that passed screening	79
Total responses resubmitted	22
Total pending responses	79
Approved products	30





2025 TIMELINES

	TIMELINES
Screening deadline	20 days
Proceed to evaluate after screening	45 days
Intent to refuse after screening	120 days
Intent to register after evaluation	45 days
Intent to refuse after evaluation	60 days

[illegible]