

Assessment of Regulatory Reliance in Kenya

Survey Report

Contributors

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Background Information

- **Regulatory Reliance:**

- The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision.
- Supported by WHO, reliance allows relying authorities to make the best use of available resources and expertise, avoid duplication, and concentrate regulatory efforts and resources where they are most needed.

- **Kenya's Adoption:**

- Pharmacy and Poisons Board (PPB) adopted reliance in January 2020.
- Guidance covers marketing authorization, inspections, vigilance, clinical trials, and laboratory testing.

Background Information

Survey Objectives

- Assess industry awareness and understanding of reliance procedures.
- Evaluate the extent of reliance use in regulatory applications.
- Gauge the uptake and perception of reliance since its inception.
- Identify successes, challenges and enablers of reliance in Kenya.

Expected Outcomes

- Highlight benefits and successes of regulatory reliance.
- Promote awareness and adoption of regulatory reliance practices among industry stakeholders.
- Identify gaps and mitigate barriers to effective reliance practices.
- Provide recommendations for improvement in the practice of regulatory reliance.

Survey Design

- **Methodology:**

- Administered via Survey Monkey.
- The survey was sent out to stakeholders within the Pharmaceutical and Medical Technology Industry.
- Total of 68 respondents.

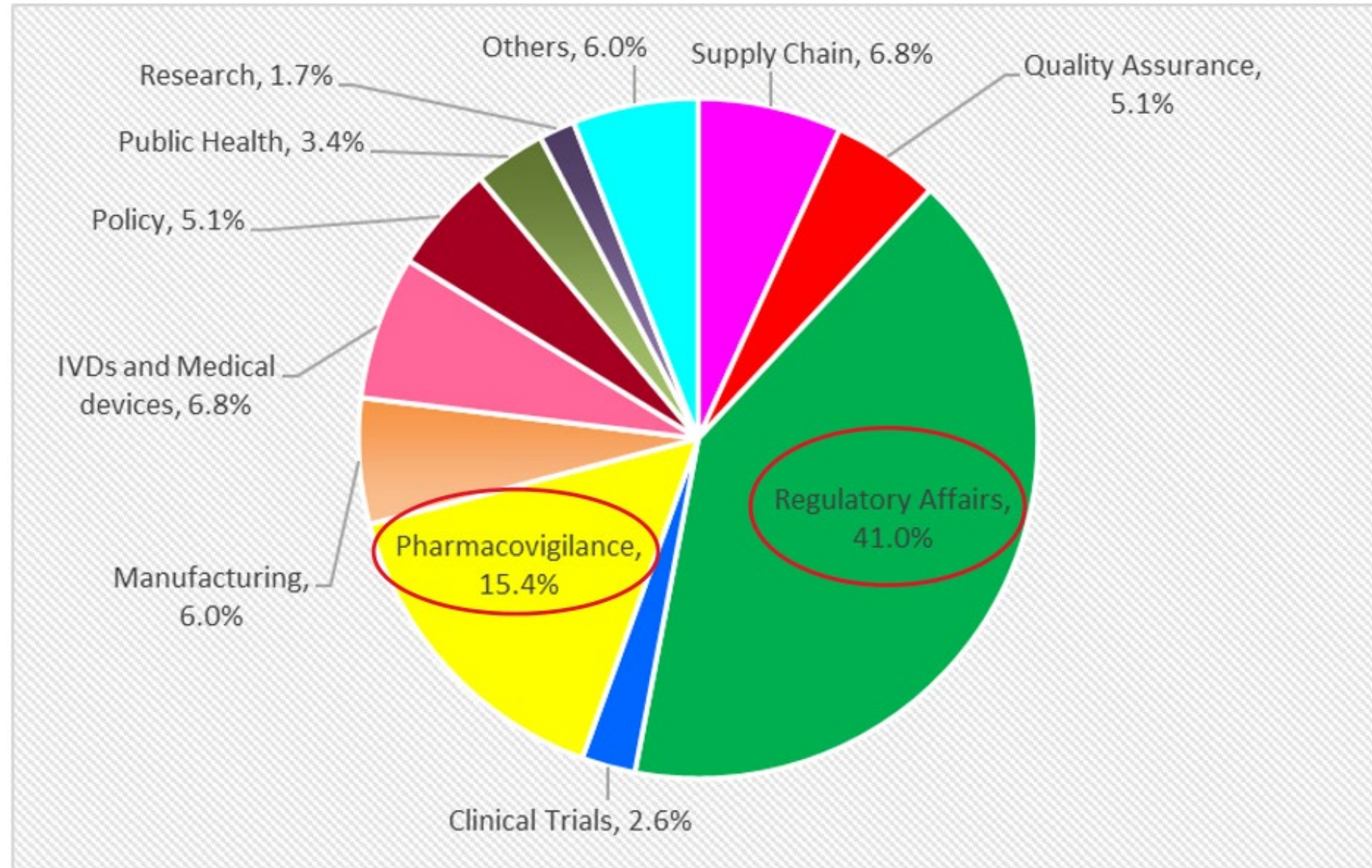
- **Target Participants:**

- Professionals responsible for new product applications, post-approval changes, clinical trials, medical device registrations, GMP certification, pharmacovigilance, and laboratory testing and lot release.

Respondents Profile

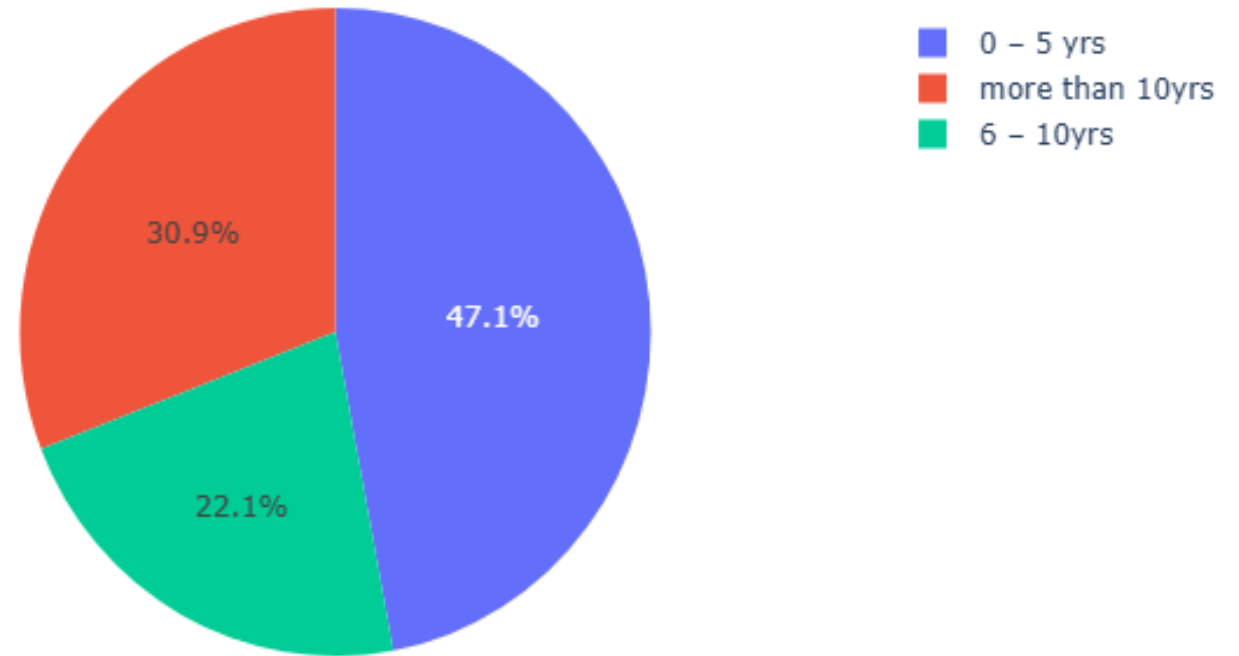


Which area of health products and technologies industry best describes your current field of practice?

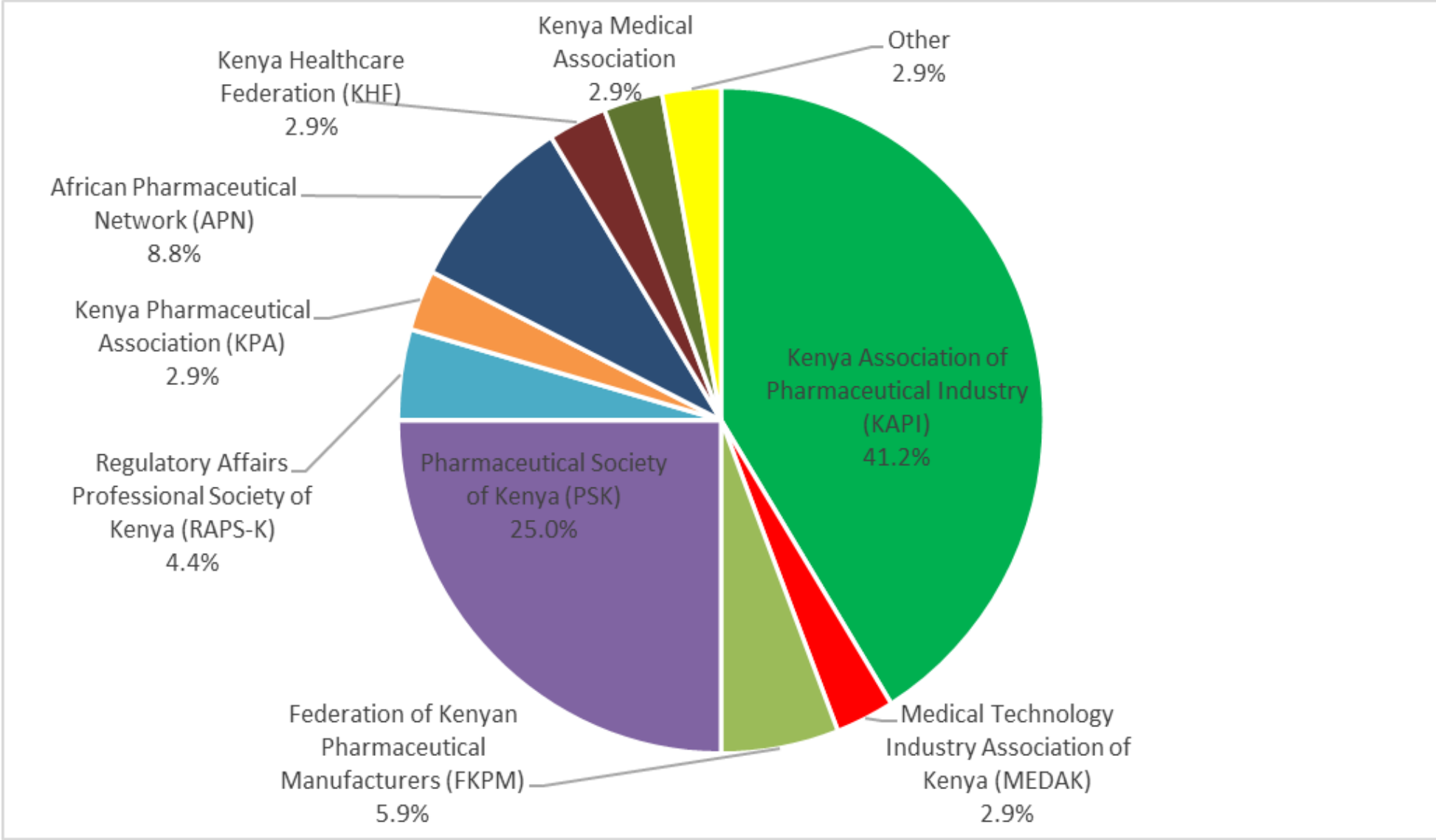


How long have you practiced in the field selected above?

Experience in the Field

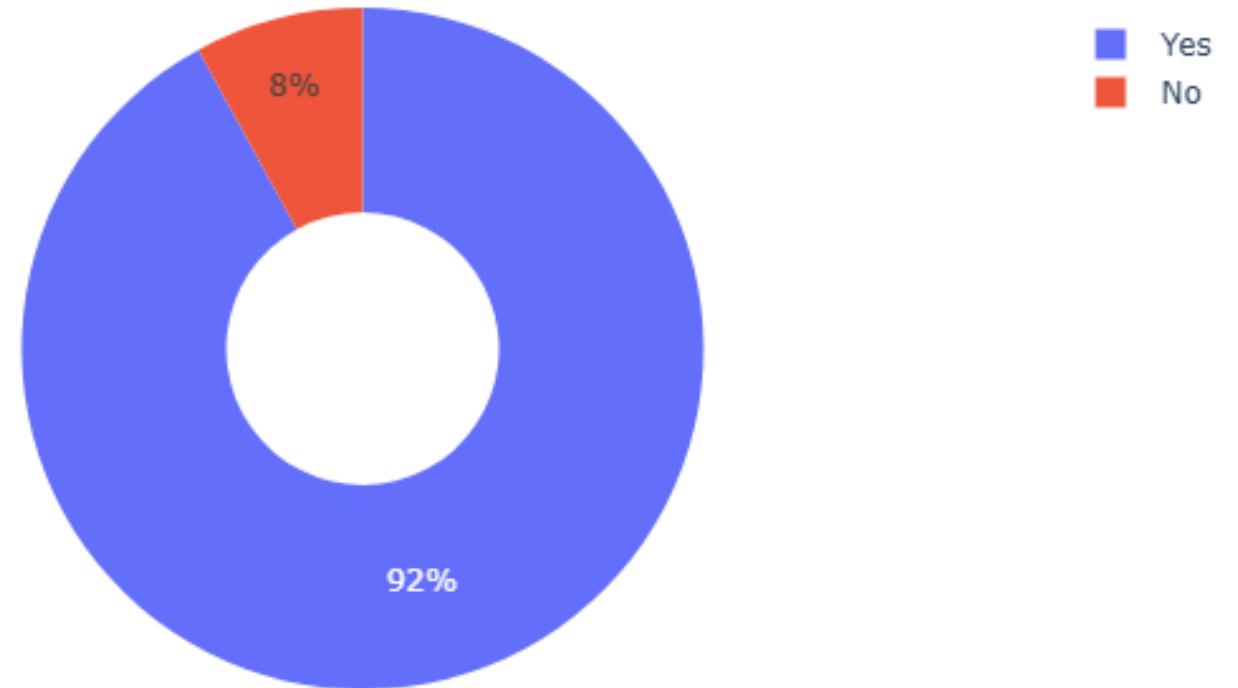


Which association are you affiliated to?

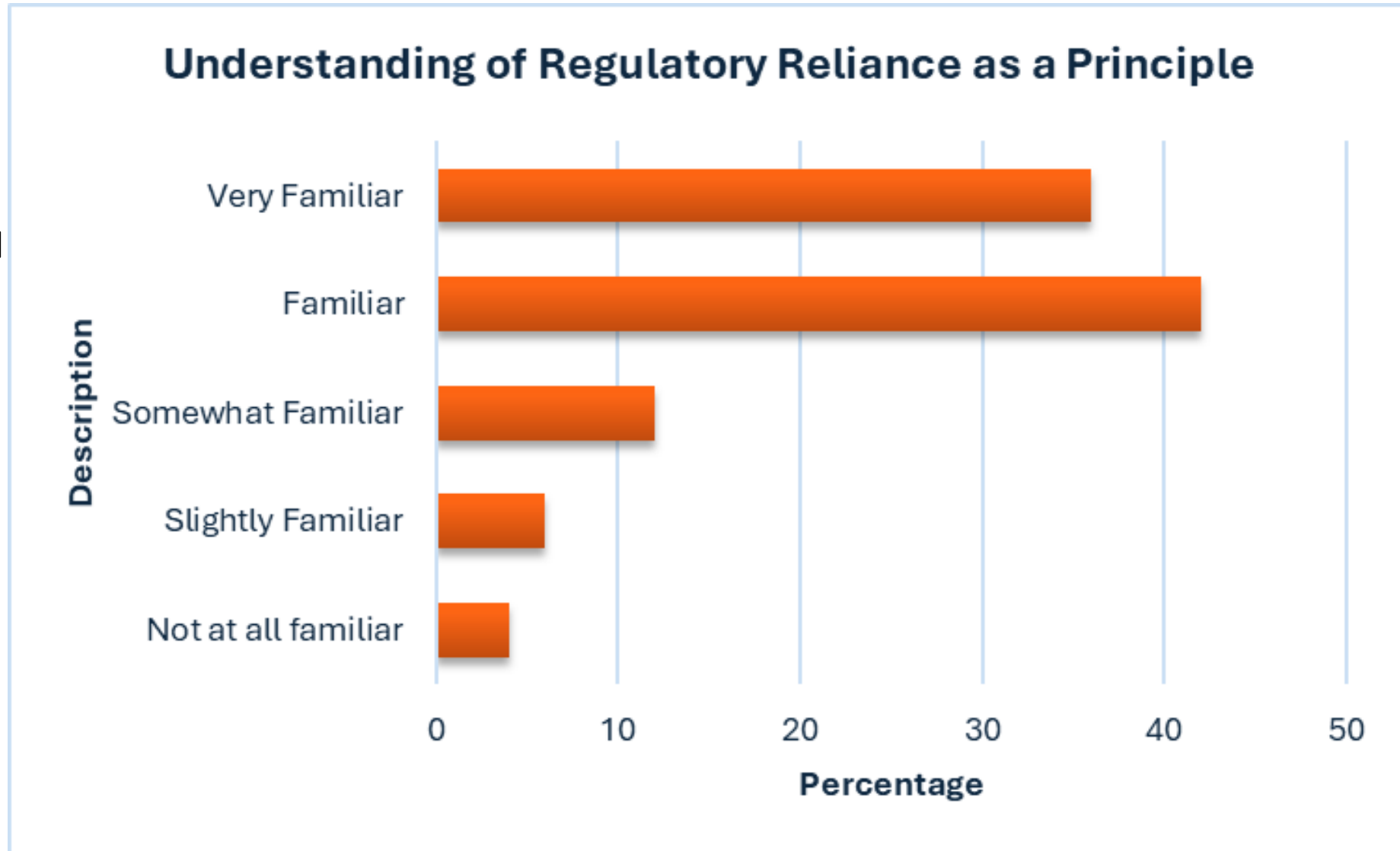


Awareness of Regulatory Reliance

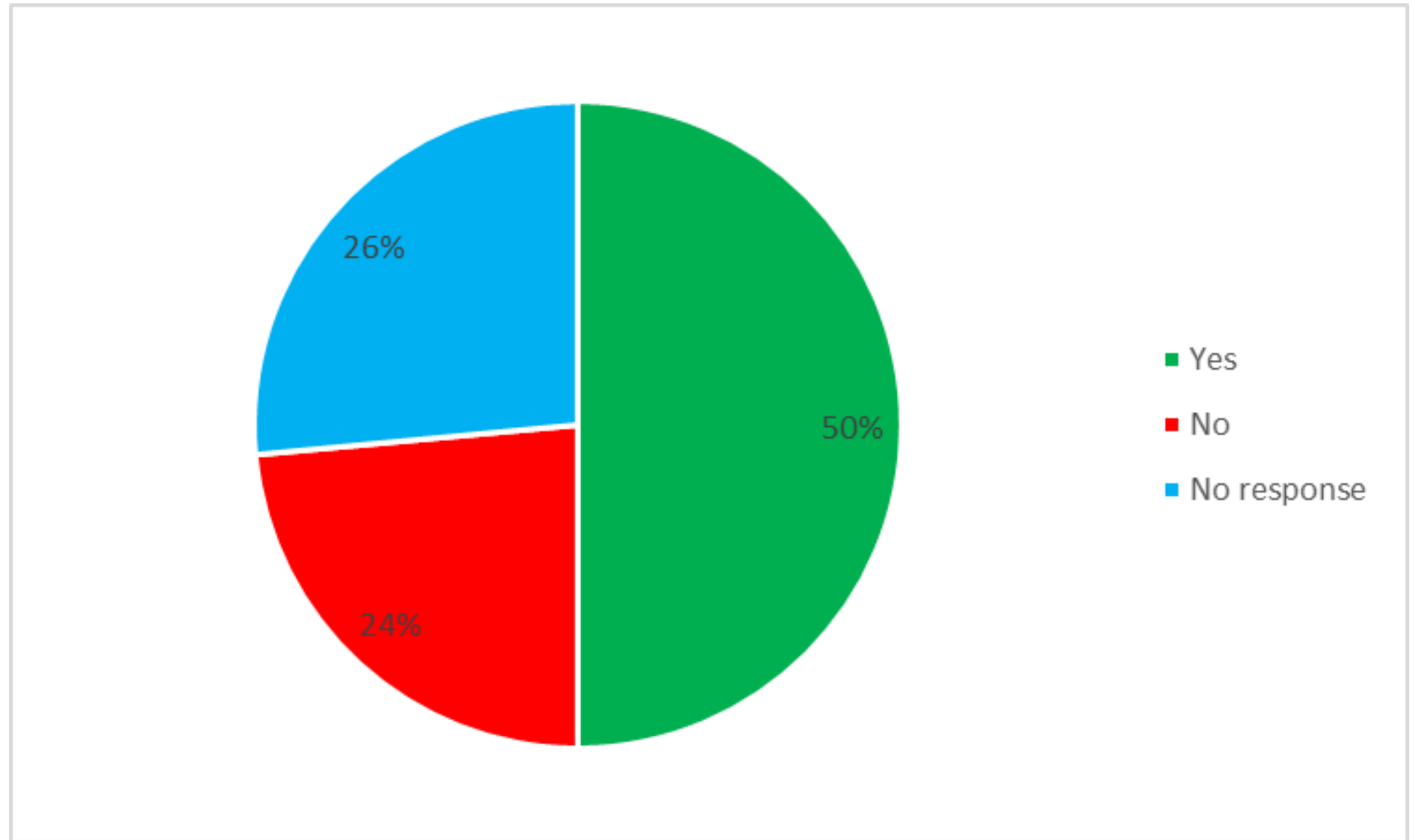
Do you know about the concept of regulatory reliance?



How well would you rate your understanding of regulatory reliance as a principle?



Have you used regulatory reliance in Kenya?



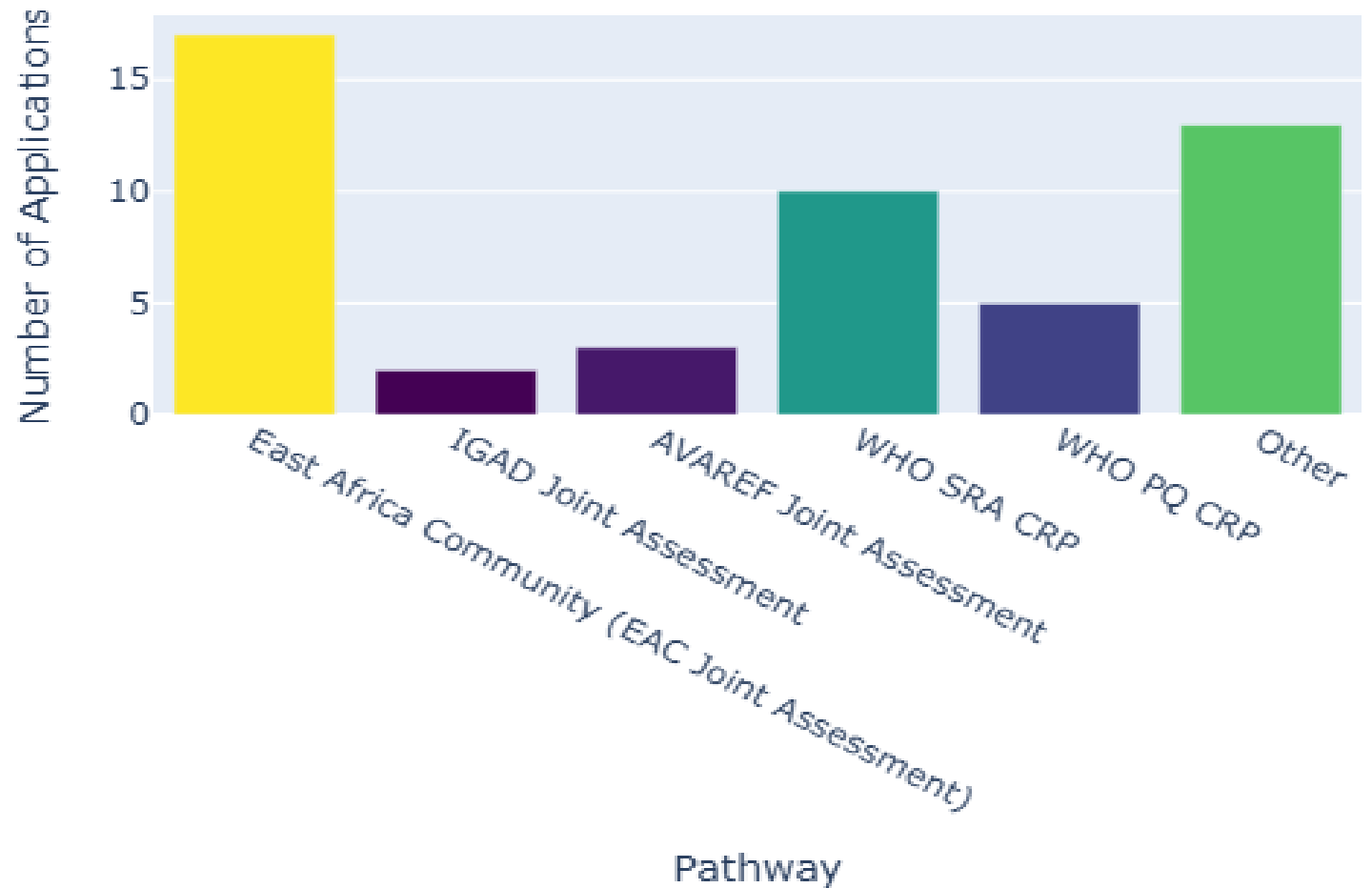
**Which of the following
reliance pathways
have you used?**

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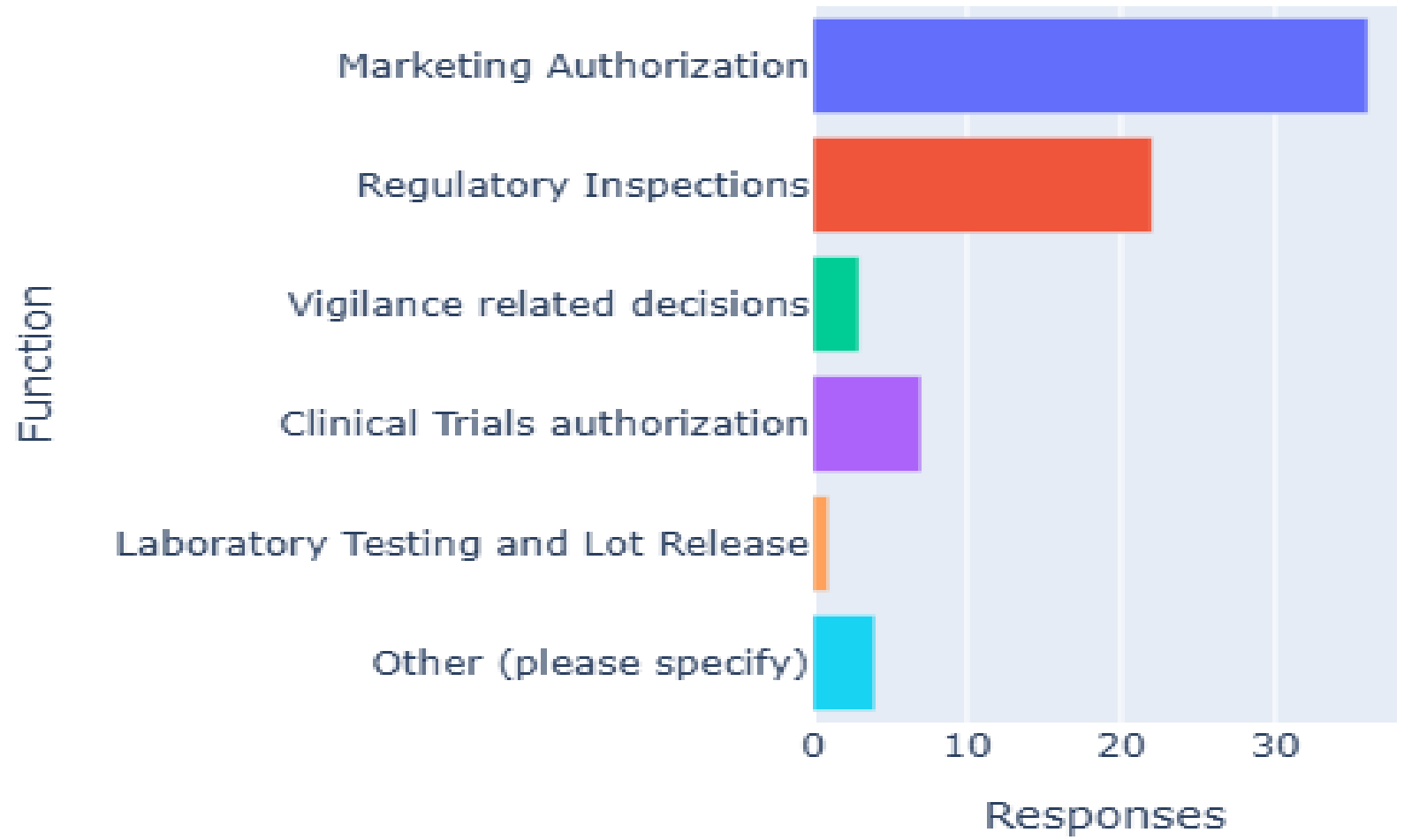


For the pathway selected above, how many applications did you submit?

Number of Applications Submitted by Pathway

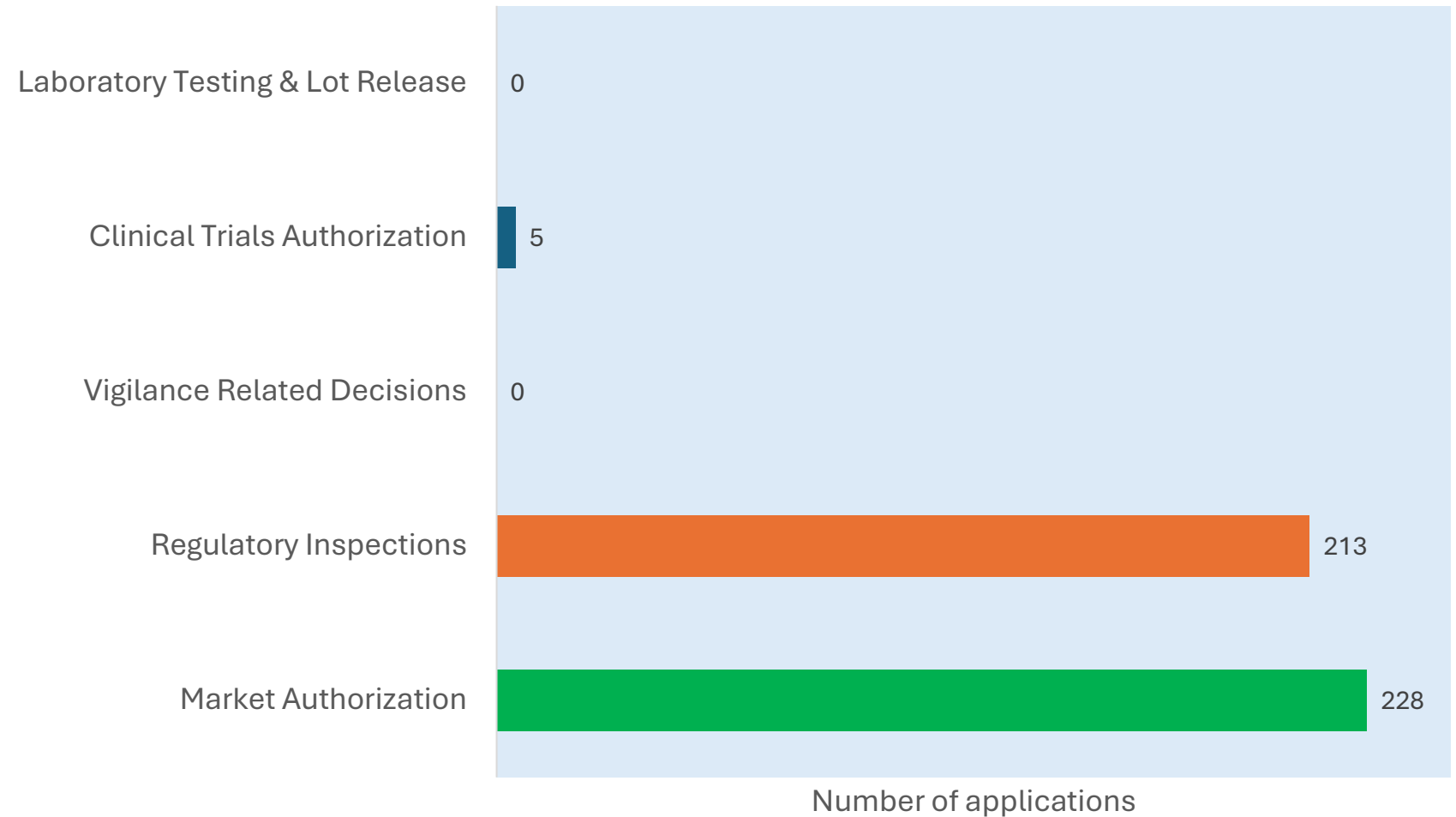


For which of the following functions have you used regulatory reliance?

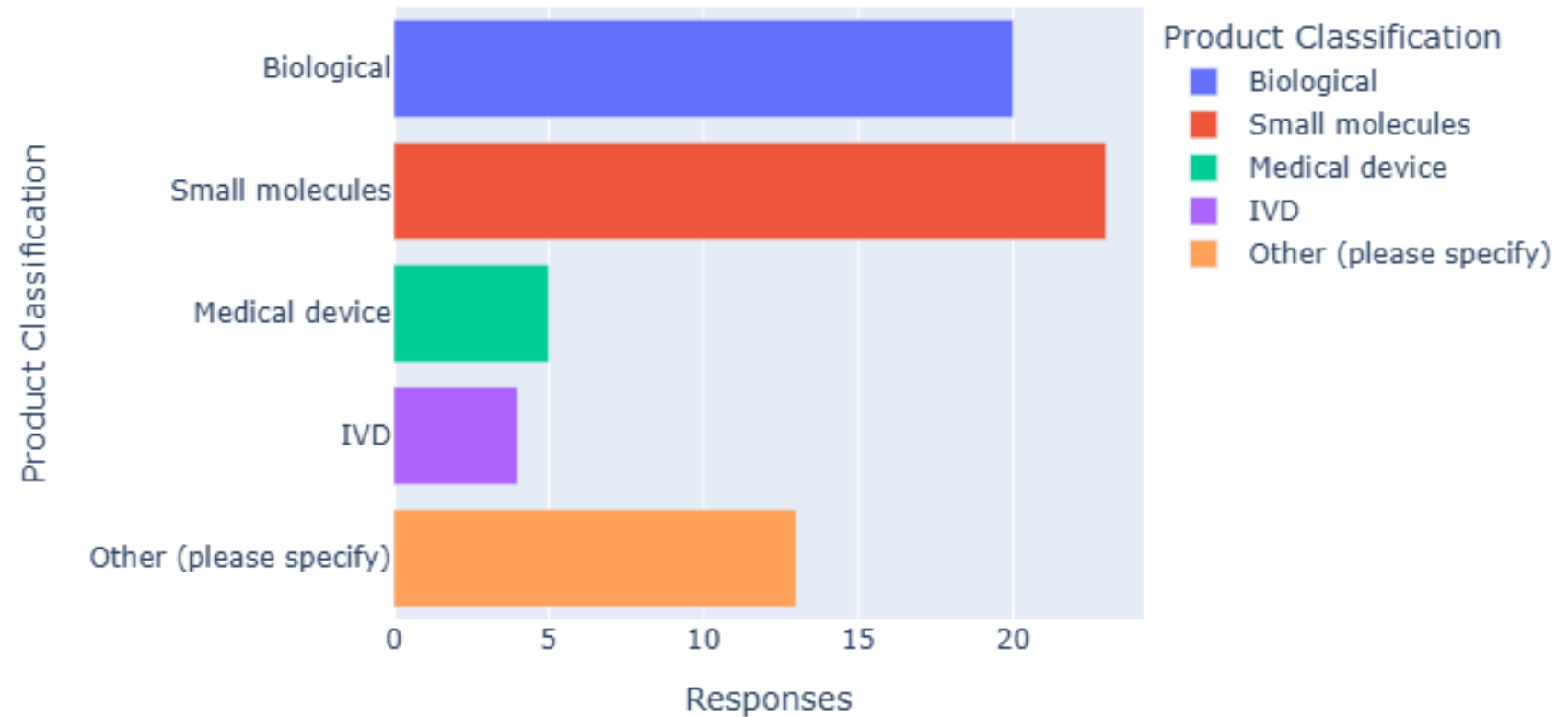


How many regulatory applications have you made using reliance?

Number of Regulatory Applications by Category

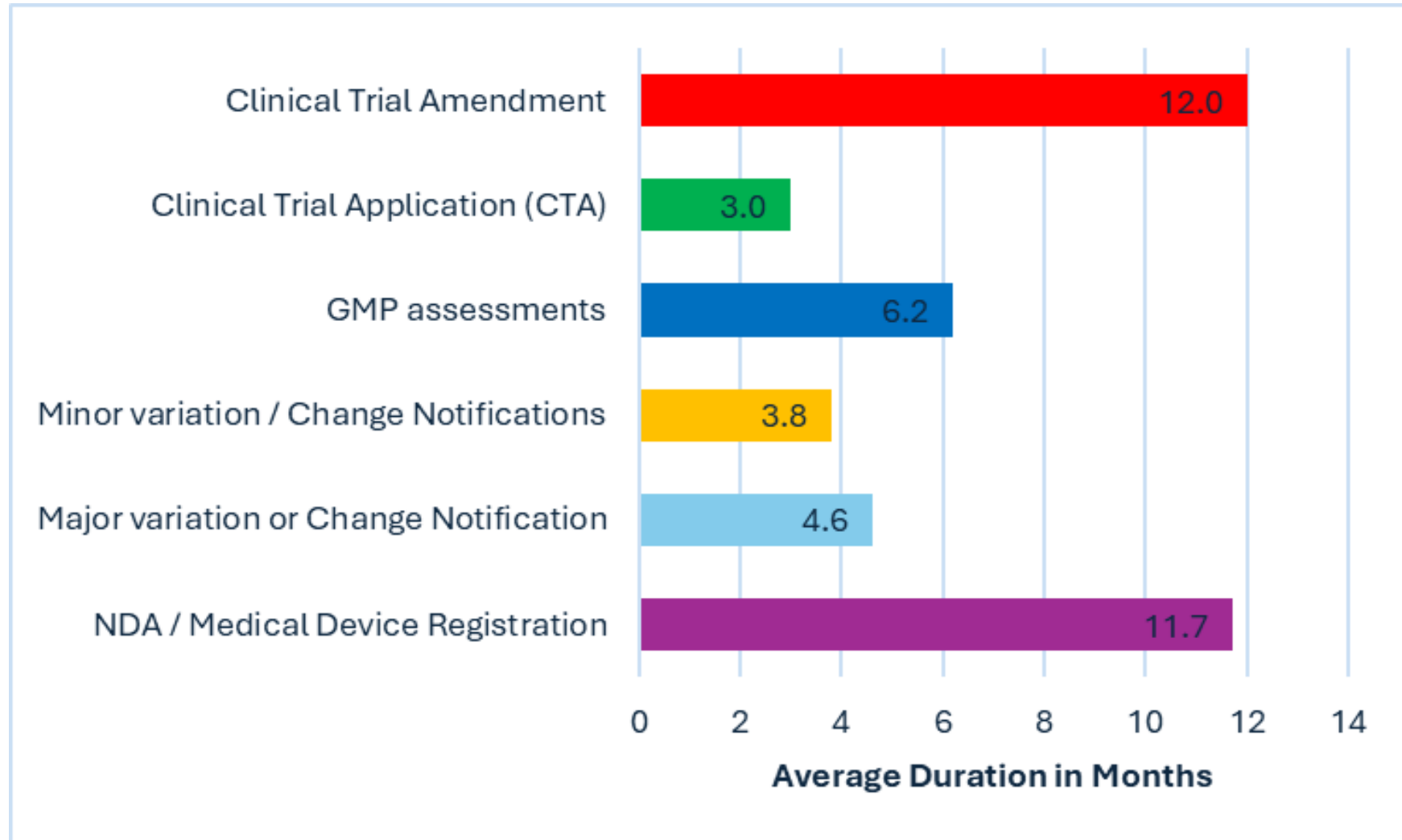


Product Classification for Registered Products using Reliance in Kenya

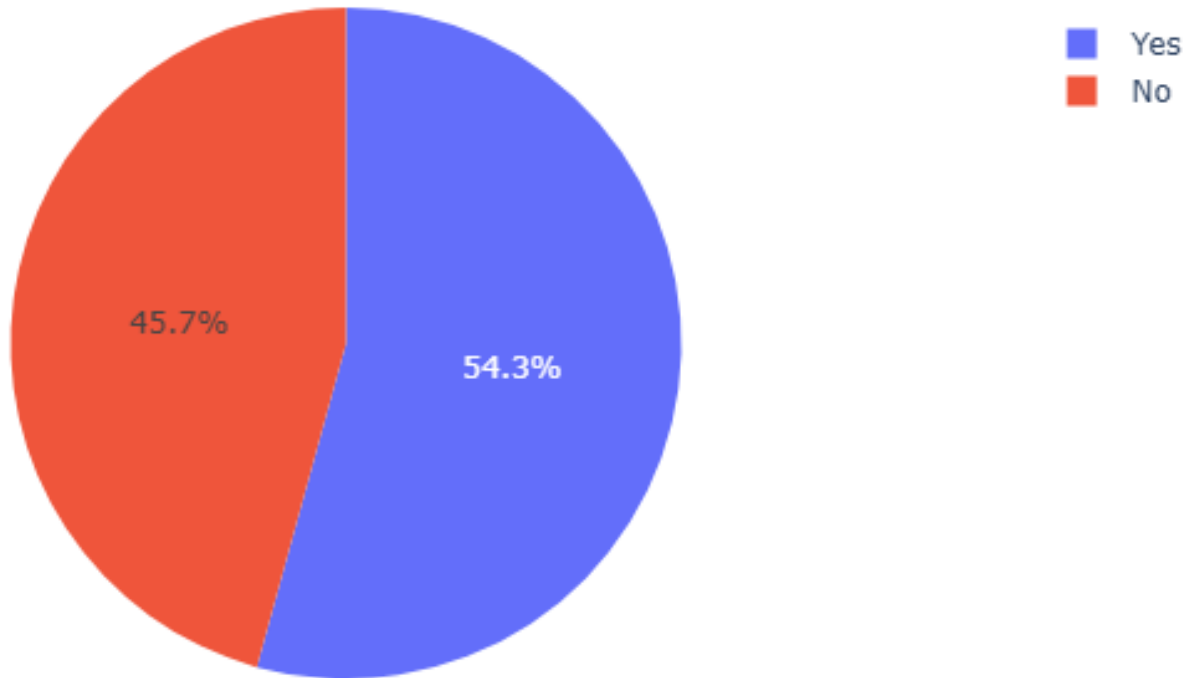


What was the classification of your product being registered for which you used reliance?

In your use of regulatory reliance, please outline the timelines (in months) it took for you to get a regulatory decision?



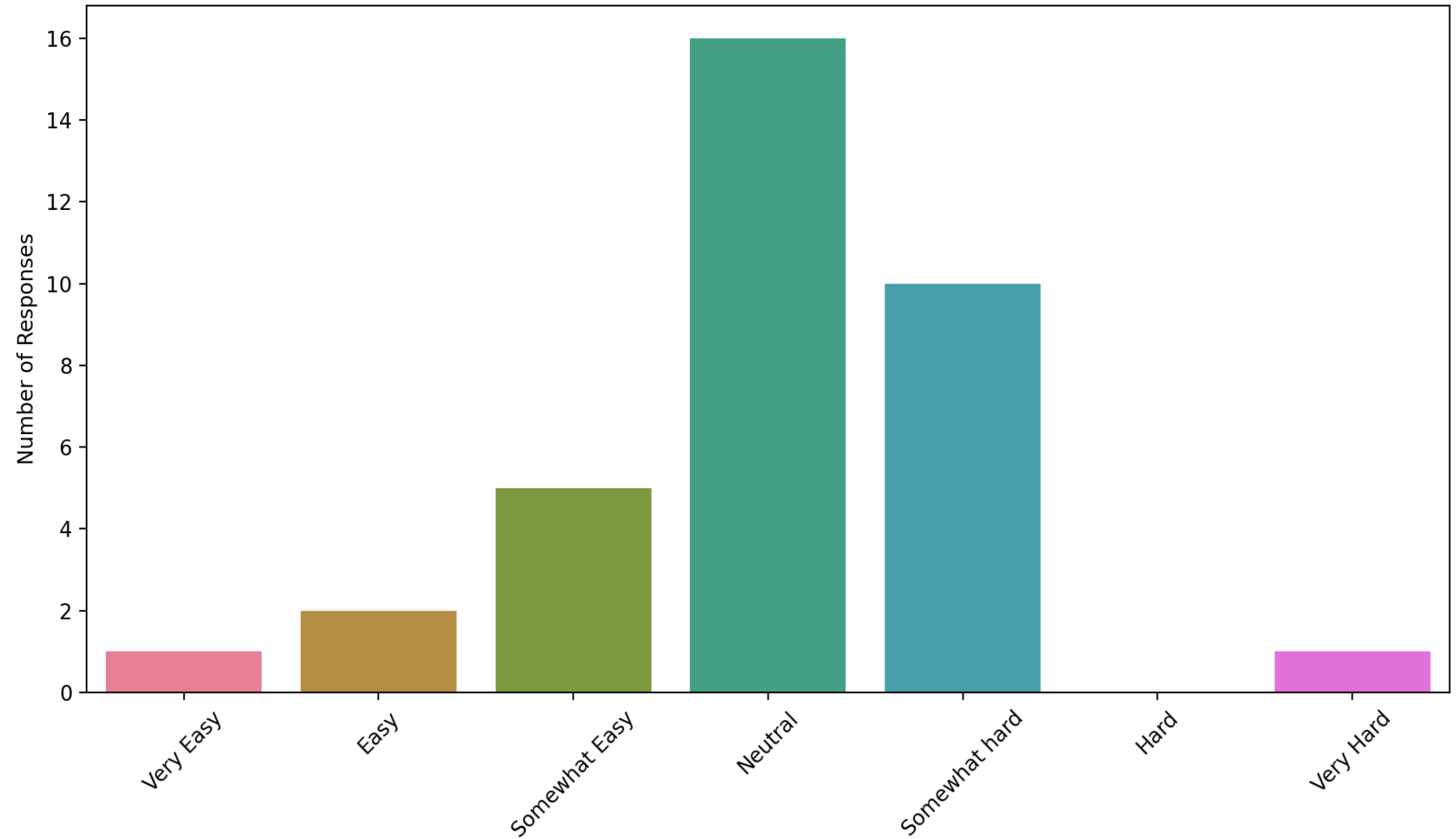
Are there any additional documents other than the standard CTD dossier that were requested from you for this procedure?



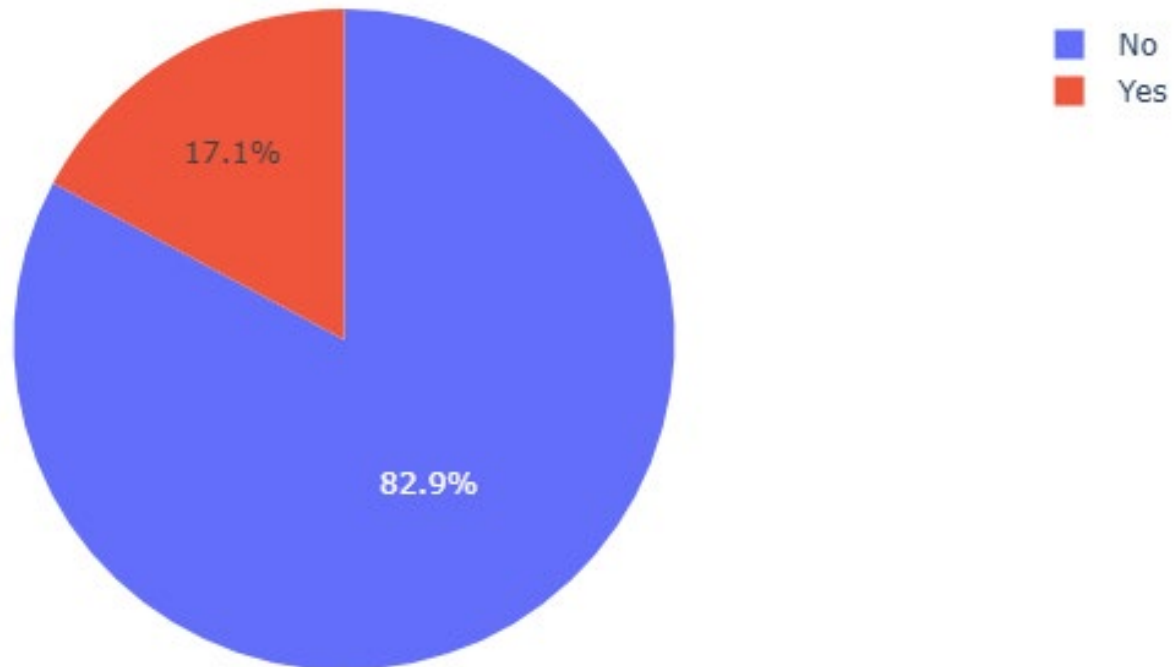
Additional documents requested included:

- Statement of similarity for product submitted with registered reference product,
- Declaration of similarity by qualified person,
- GMP report and certificate from SRA,
- Valid PPB GMP Certificate for the manufacturing site,
- SRA reports for GMP applications from relevant authorities,
- Redacted and unredacted assessment reports,
- Certificate of Analysis from the national recognized laboratory,
- Nitrosamines risk assessment report.

How easy was it for you to get the documents that were requested from you?



Is there any specific document that you were unable to provide out of those requested for?

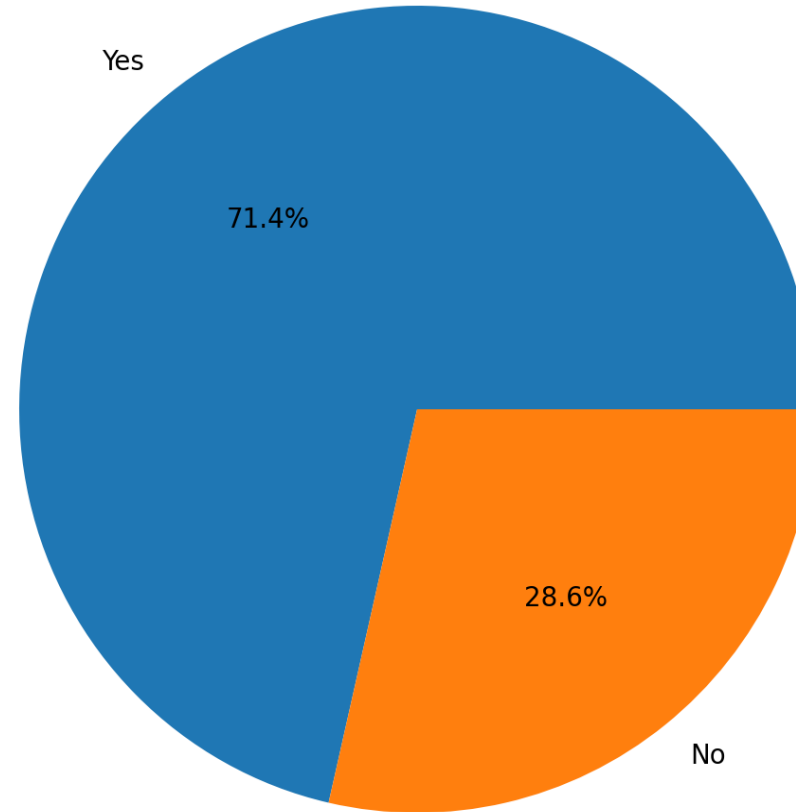


Documents that could not be provided by applicants

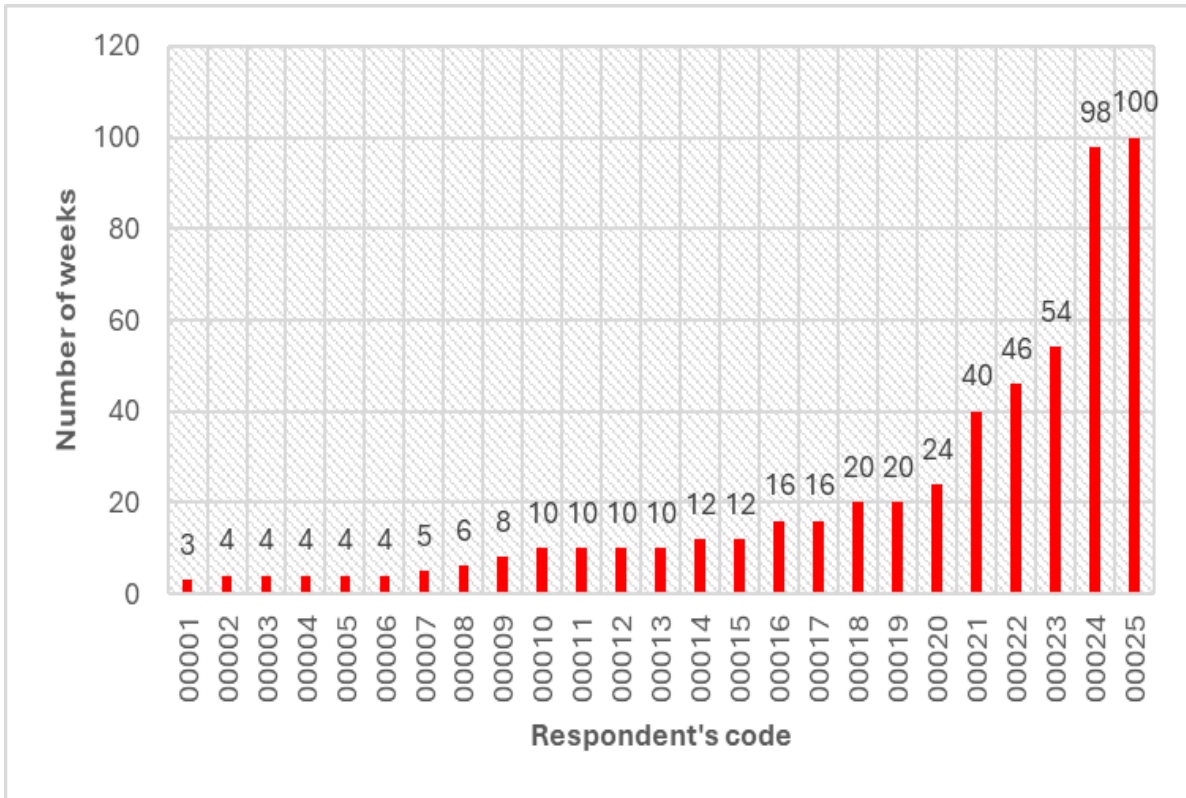
- Full assessment report for the products to be registered.
- Unredacted assessment reports
- Certificate of Analysis from a national recognized laboratory for biological products
- A certificate attesting that the starches used in the formulation are free from aflatoxins

Did you receive a query or deficiency letter in relation to your application?

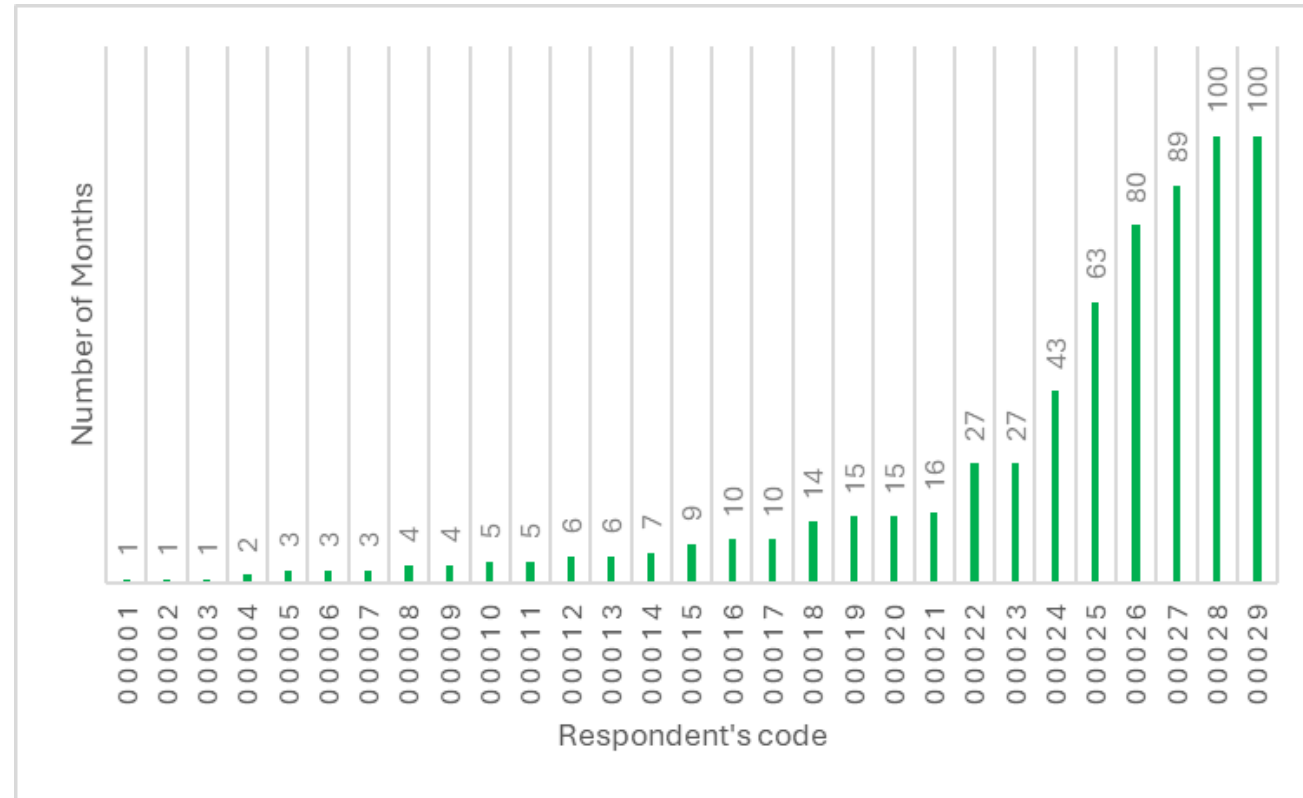
Query/Deficiency Letter Reception Distribution



- How long (in weeks) did it take you to respond to the queries raised under the procedure?

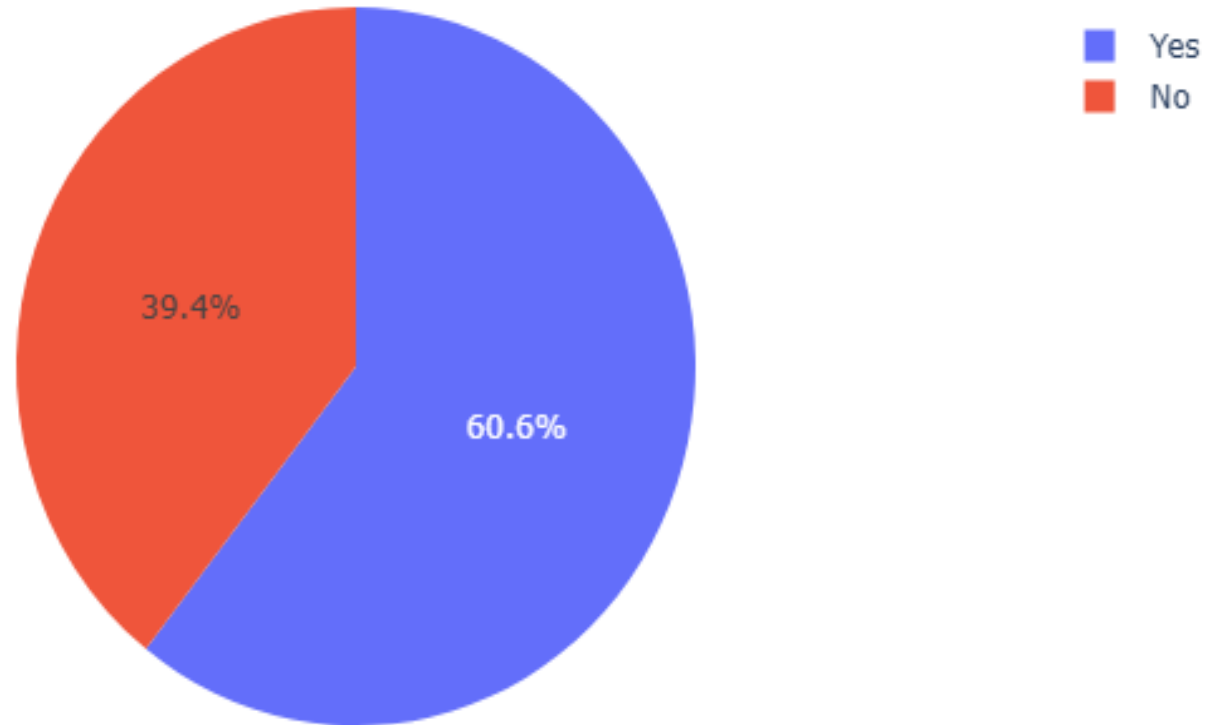


- How long (in months) did it take for you to get feedback on your application after responding to the queries?



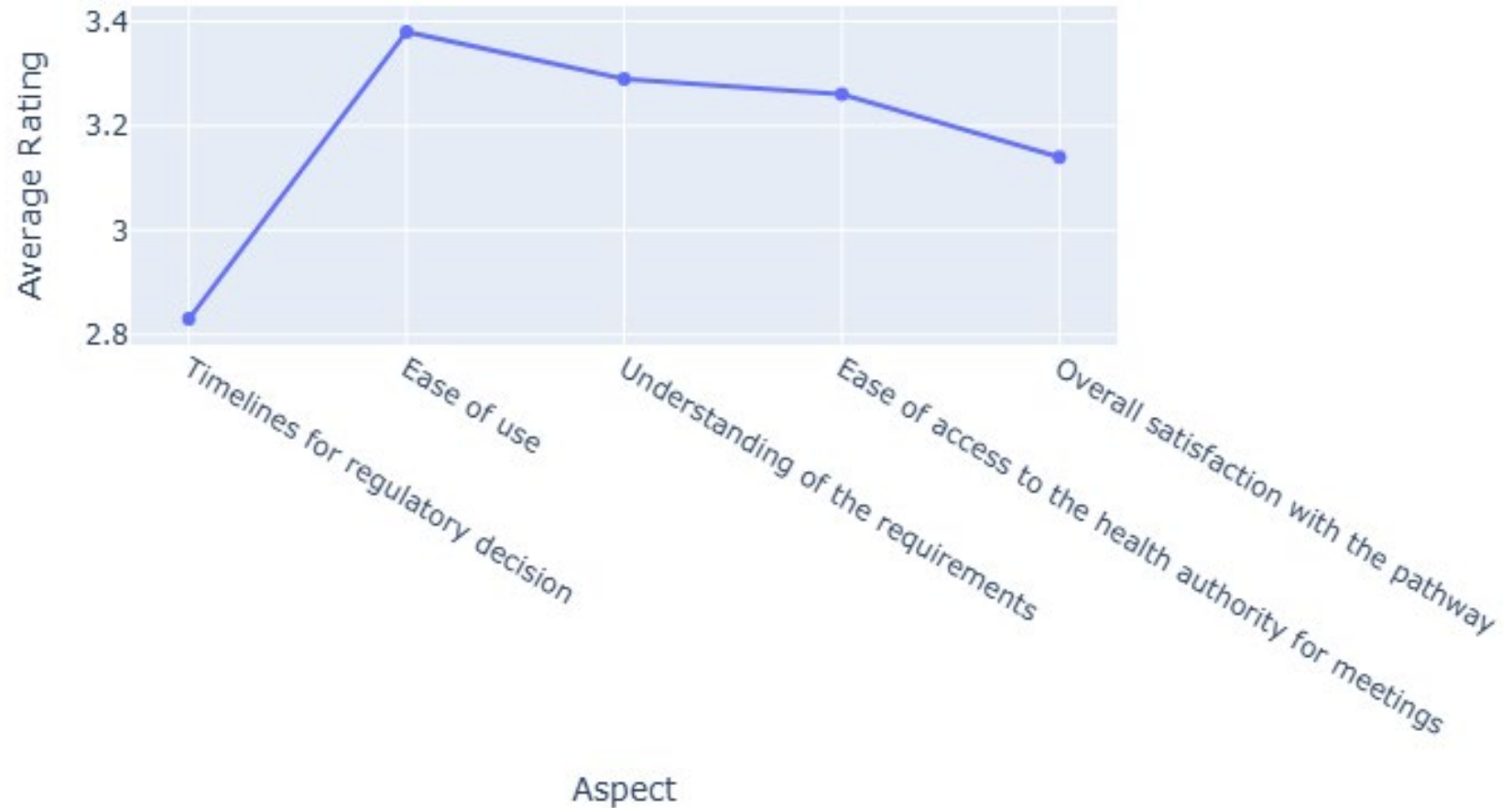
Meeting with Regulatory Authority

Did you need to schedule a meeting with the regulatory authority to address any concerns you had?



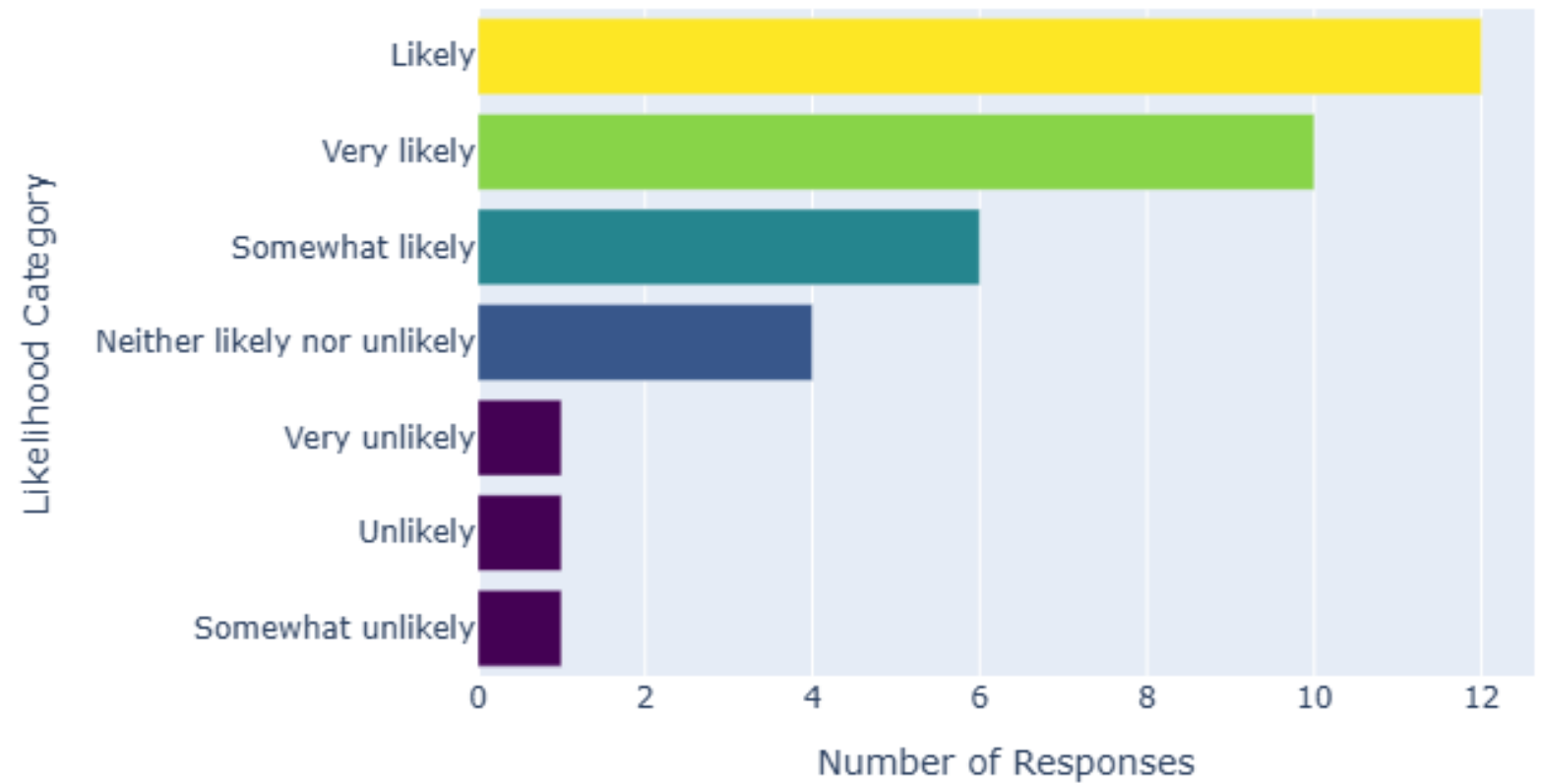
Based on your responses above, how would you rate your experience with using regulatory reliance with respect to the following: (Use the following rates: 1- Very Poor, 2 - Poor, 3 - Acceptable, 4 - Good, 5- Very Good)

Average Ratings for Various Aspects of Regulatory Reliance in Kenya



How likely are you to use this procedure again?

Likelihood of Using the Procedure Again



Recommendations based on identified gaps

- Clarify and streamline guidelines and procedures for reliance
- Support adherence to approval timelines
- Expand reliance options
- Improve inter-agency communication and collaboration
- Train and build capacity at both industry and health authority levels,

Conclusion


- The survey indicates a positive trend in adopting and implementing regulatory reliance in Kenya.
- Benefits such as increased regulatory efficiency and faster product approval timelines were observed.
- To maximize the potential of regulatory reliance, addressing challenges through clear guidelines, improved procedures, and better stakeholder engagement is necessary.
- The recommendations provided offer a roadmap for strengthening the regulatory reliance framework in Kenya, ultimately contributing to improved access to health products and technologies for the Kenyan population.



THANK YOU!

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