Outcomes of the online questionnaire on the quality of veterinary products and pharmacovigilance

6th cycle regional training seminar for OIE focal points for veterinary products (Africa, English)

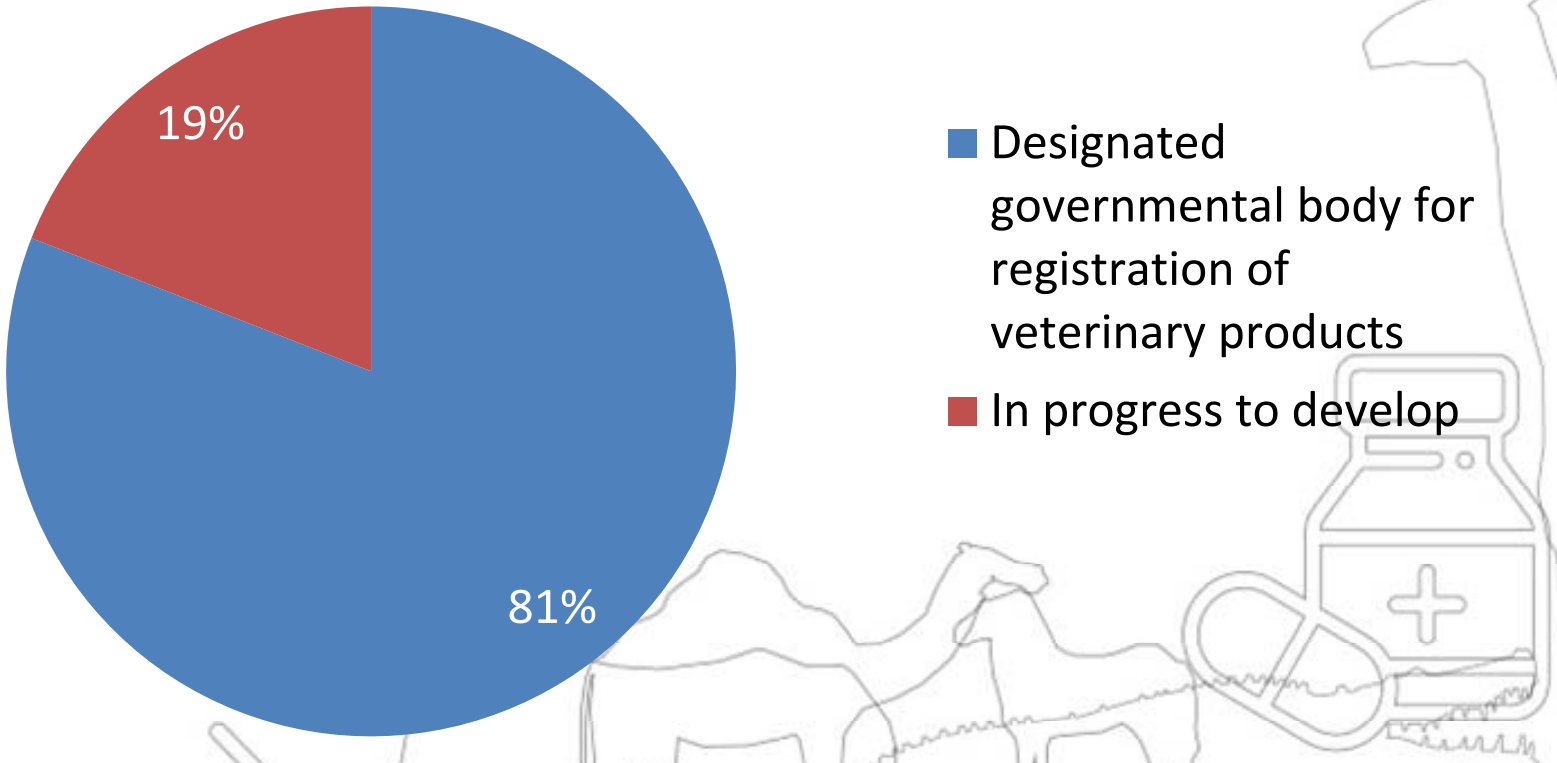
Addis Ababa I Debre-Zeit, Ethiopia
9 - 11 July 2019

Responses from

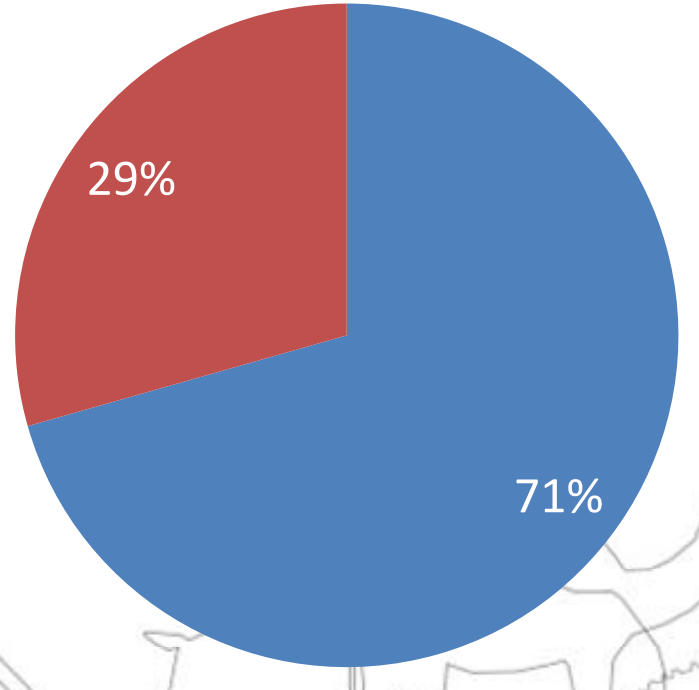
25 respondents in 21 countries

1. Angola
2. Botswana
3. Egypt
4. Eritrea
5. eSwatini
6. Ethiopia
7. Gambia
8. Kenya
9. Libya
10. Malawi
11. Mauritius
12. Mozambique
13. Namibia
14. Nigeria
15. Seychelles
16. Somalia
17. South Africa
18. South Sudan
19. Sudan
20. Tanzania
21. Zimbabwe

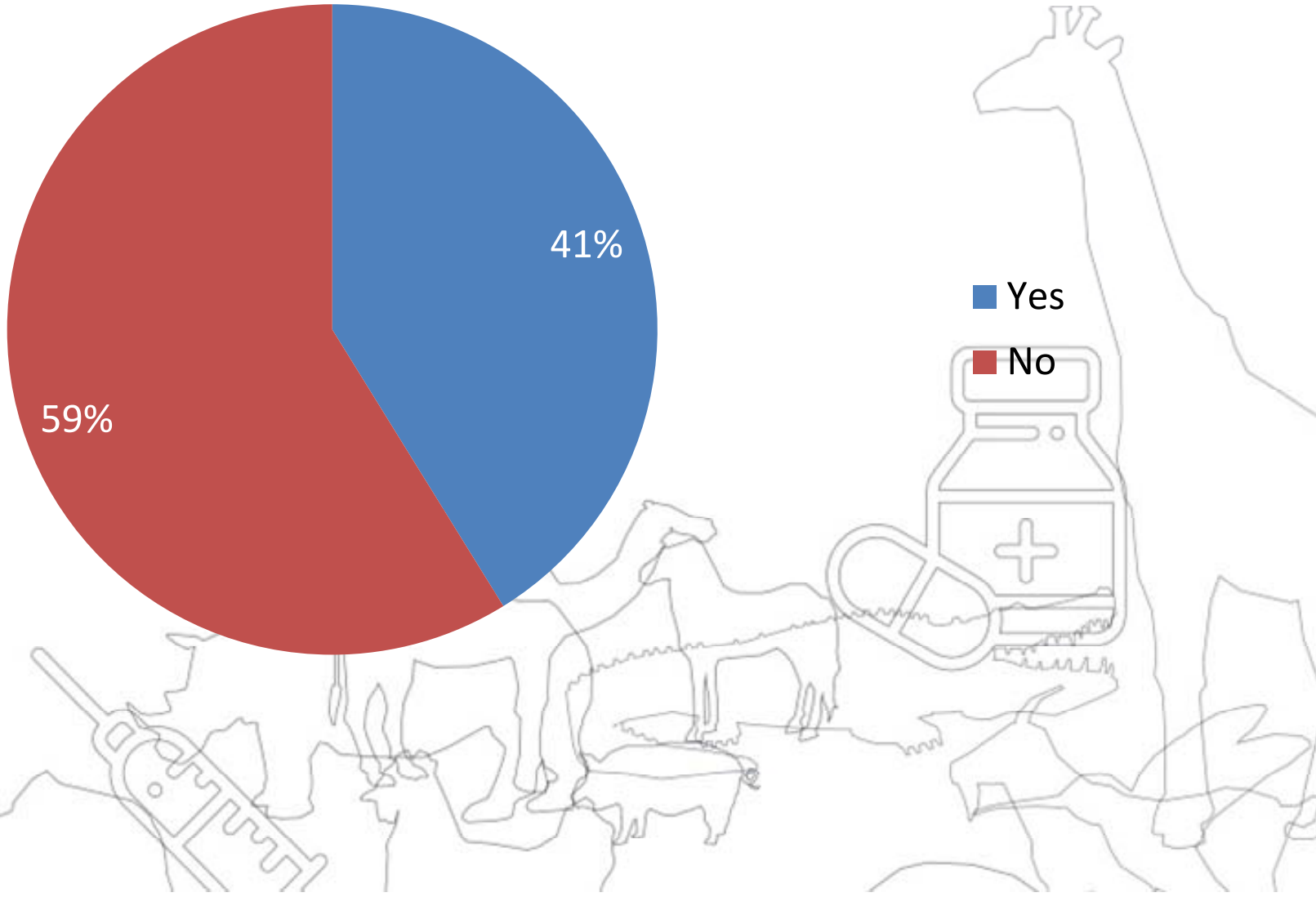
1. Does your country currently have a designated governmental body for registration of veterinary products, or is there work in progress to develop it?



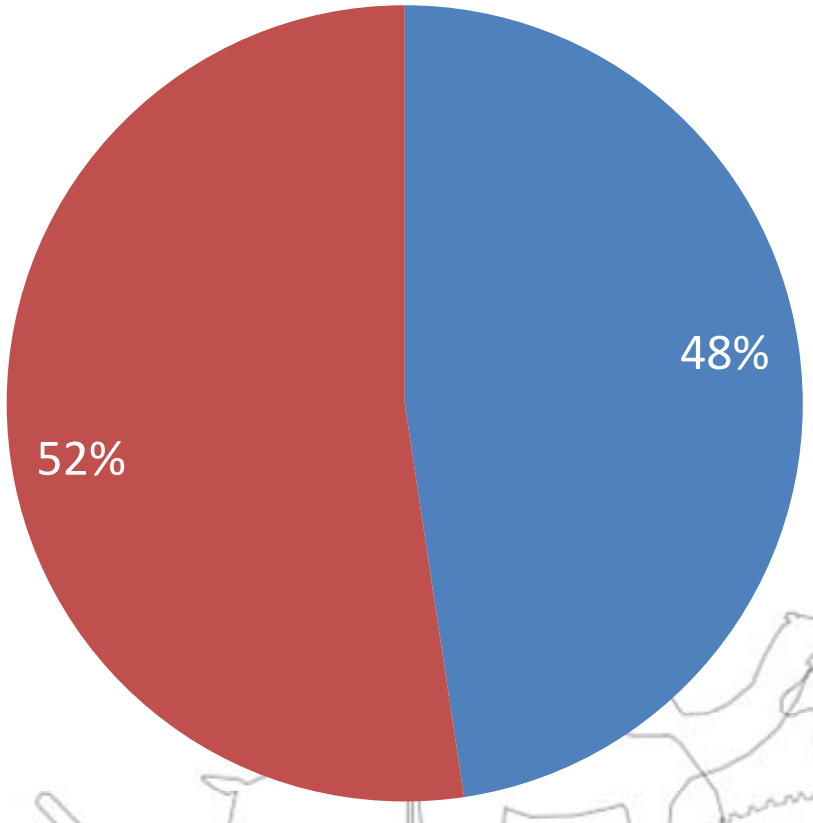
2.a. If you have a designated governmental body for registration of veterinary produts, do you have a database or list for all authorized/registered veterinary medicinal products ?



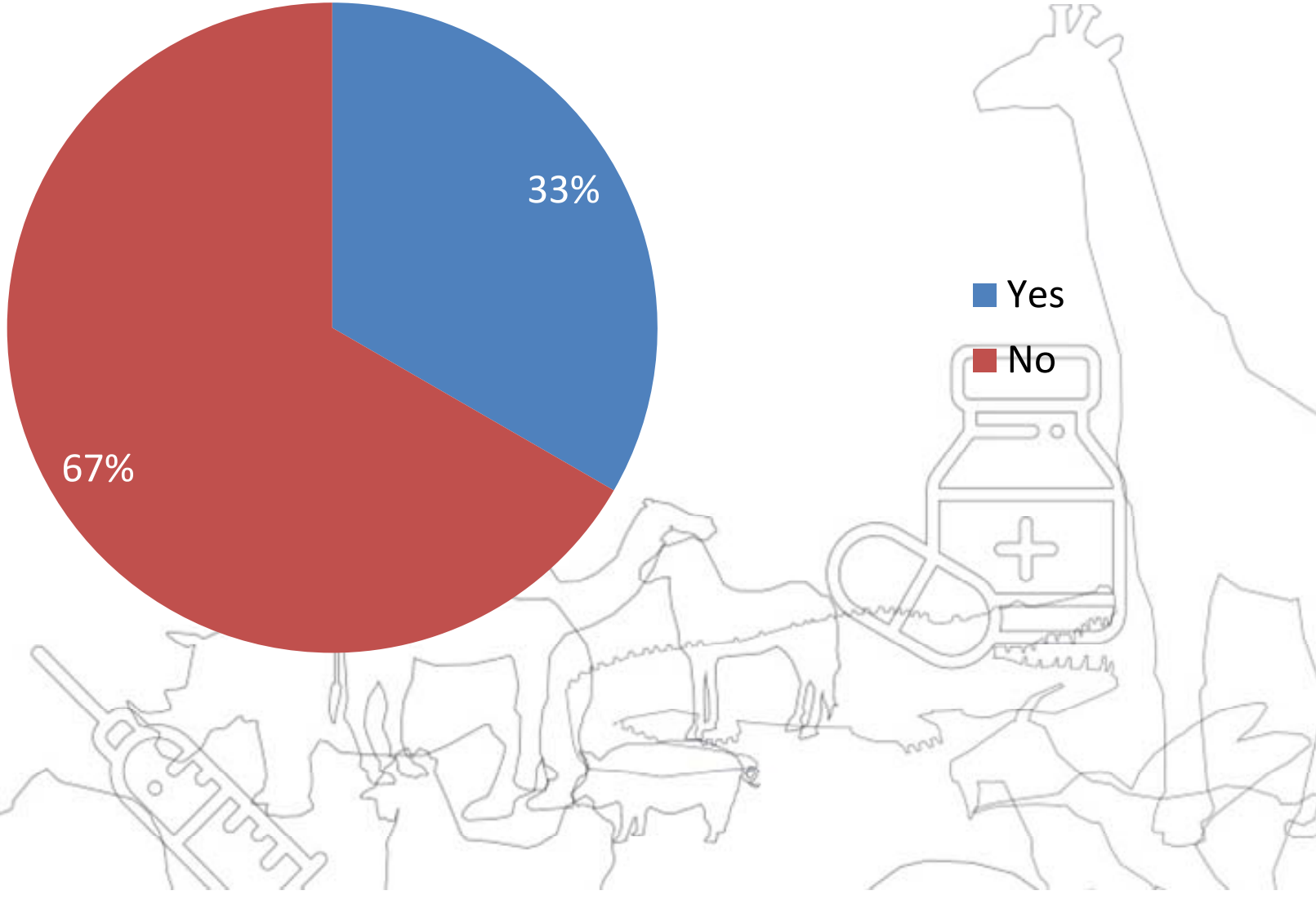
2.b. Is the list of registered products publicly accessible?



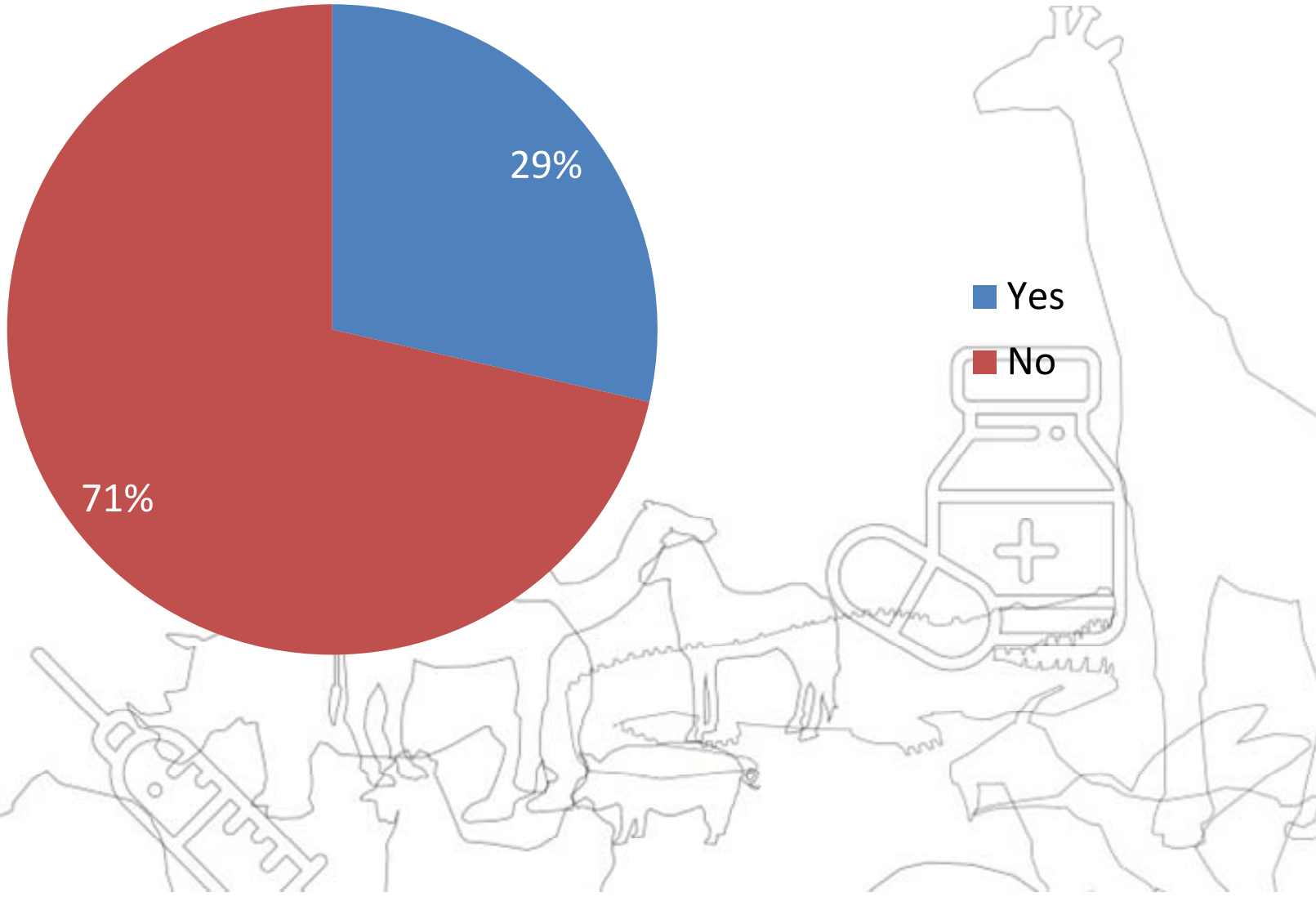
3.a. Do you have pharmacovigilance (PHV) legislation implemented in your country ?



3.b. Do you have a functioning pharmacovigilance system in your country ?



3.c. Do you have (a) PHV guideline(s) that are used in the post-marketing activities?

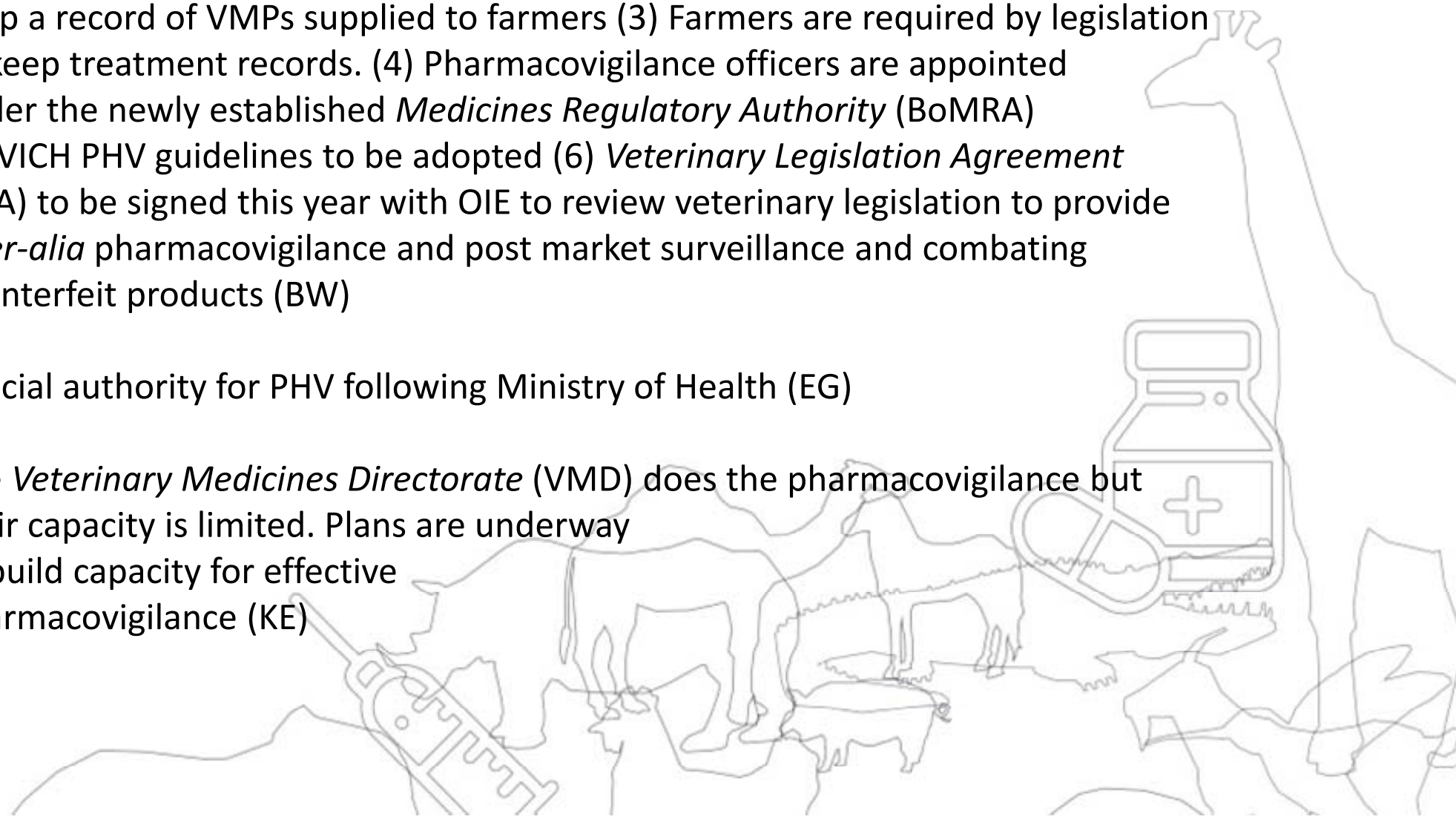


3.d. If you have a pharmacovigilance system, please describe its key elements

- (1) Medicines are supplied to registered suppliers (2) Suppliers are required to keep a record of VMPs supplied to farmers (3) Farmers are required by legislation to keep treatment records. (4) Pharmacovigilance officers are appointed under the newly established *Medicines Regulatory Authority* (BoMRA) (5) VICH PHV guidelines to be adopted (6) *Veterinary Legislation Agreement* (VLA) to be signed this year with OIE to review veterinary legislation to provide *inter-alia* pharmacovigilance and post market surveillance and combating counterfeit products (BW)

- Special authority for PHV following Ministry of Health (EG)

- The *Veterinary Medicines Directorate* (VMD) does the pharmacovigilance but their capacity is limited. Plans are underway to build capacity for effective pharmacovigilance (KE)



3.d. If you have a pharmacovigilance system, please describe its key elements

- (1) There should be guidelines on pharmacovigilance and reporting forms for individual adverse events and periodic adverse reactions following use of VMPs. The reporting forms should capture as a minimum: details of the reporter, details of the animal, details of the VMP and details of the Adverse Event
  (2) The Government or Regulatory Authority should have competency and human resources to: conduct assessments (causality assessments), train or encourage animal keepers, vets, vet paraprofessionals to report adverse events, ensure manufacturers provide periodic adverse reports annually for their VMPs and set specific timelines for reporting and providing feedback. (ZW)

- We have recently adopted some guidelines based on VICH Guidelines. It has been discussed with industry and will be implemented. (ZA)

- We have three cooperating bodies in this respect, all of them belong to the Prime Minister's Office (registration, monitoring, and ongoing to functioning) (LY)

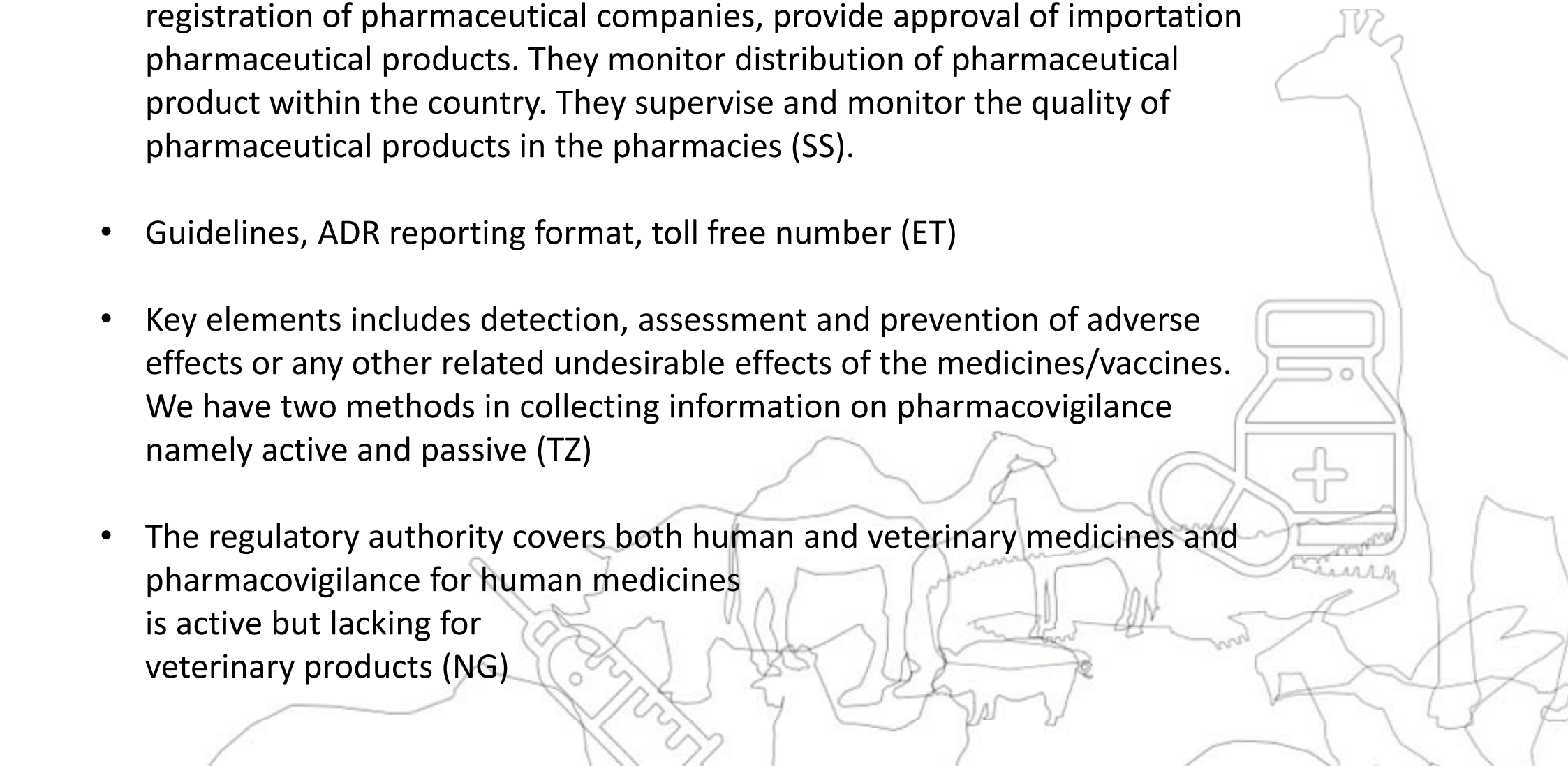
3.d. If you have a pharmacovigilance system, please describe its key elements

- The Food and Drug Authority and the Ministry of Health are responsible for registration of pharmaceutical companies, provide approval of importation pharmaceutical products. They monitor distribution of pharmaceutical product within the country. They supervise and monitor the quality of pharmaceutical products in the pharmacies (SS).

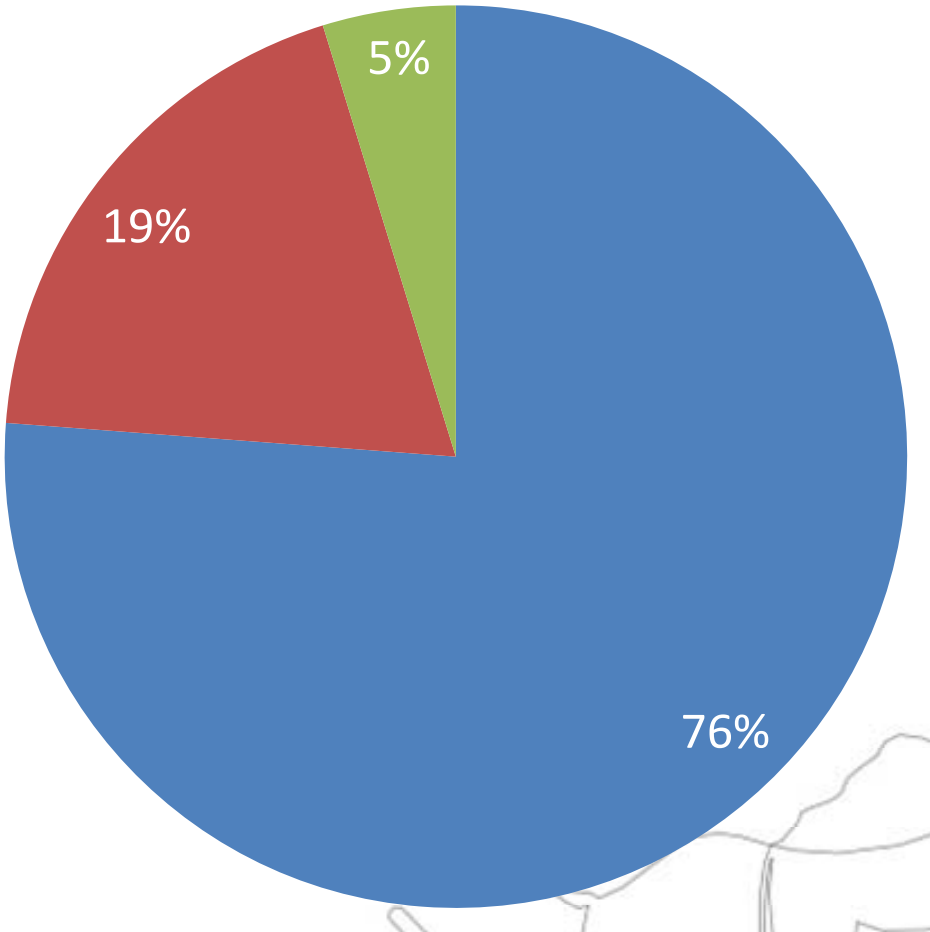
- Guidelines, ADR reporting format, toll free number (ET)

- Key elements includes detection, assessment and prevention of adverse effects or any other related undesirable effects of the medicines/vaccines. We have two methods in collecting information on pharmacovigilance namely active and passive (TZ)

- The regulatory authority covers both human and veterinary medicines and pharmacovigilance for human medicines
  is active but lacking for
  veterinary products (NG)

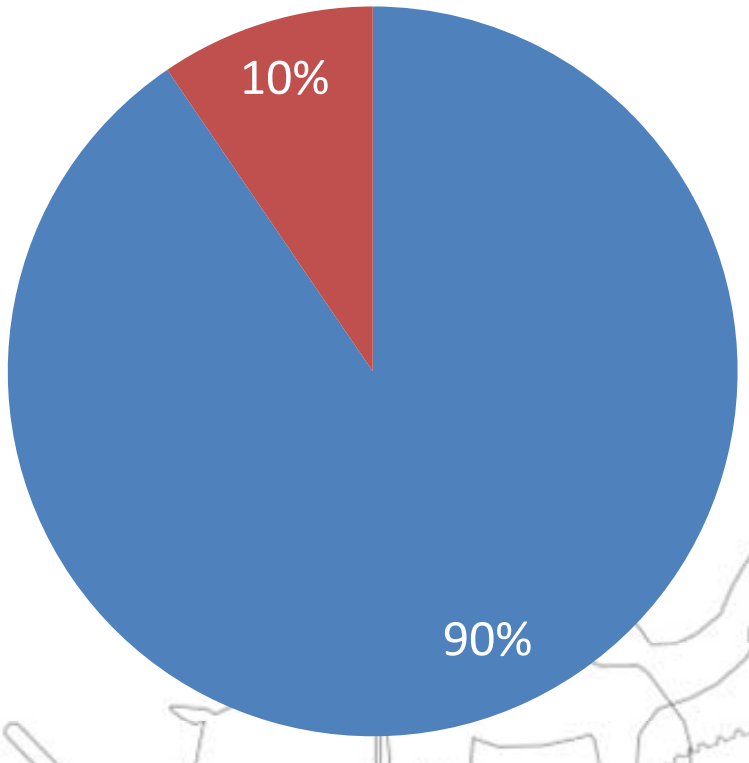


4. What role(s), if any, do you think the OIE should play in defining the minimum requirements for a pharmacovigilance system for veterinary medicinal products?



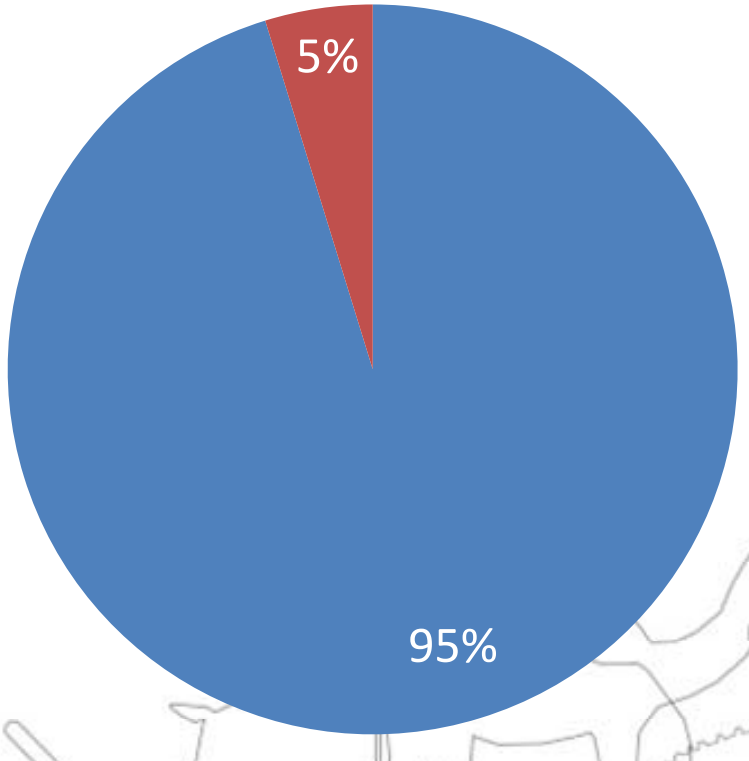
- Prepare a chapter in the OIE Manual or Code on the minimum requirements how to set up a basic pharmacovigilance system to provide standard/guideline(s) for the OIE Member Countries (including non VICH Members)
- Coordination among different stakeholders in order to avoid too many disharmonized systems to be developed worldwide
- Encourage adoption of VICH pharmacovigilance guidelines (GLs) through training of trainer courses thereby developing in harmonised reporting forms for adverse reactions for pharmacovigilence. The emphasis here is not to encourage development of new guidel

5. Do you think that an OIE document describing how to set up a basic pharmacovigilance system would be beneficial for your country?



No = SO, ZW

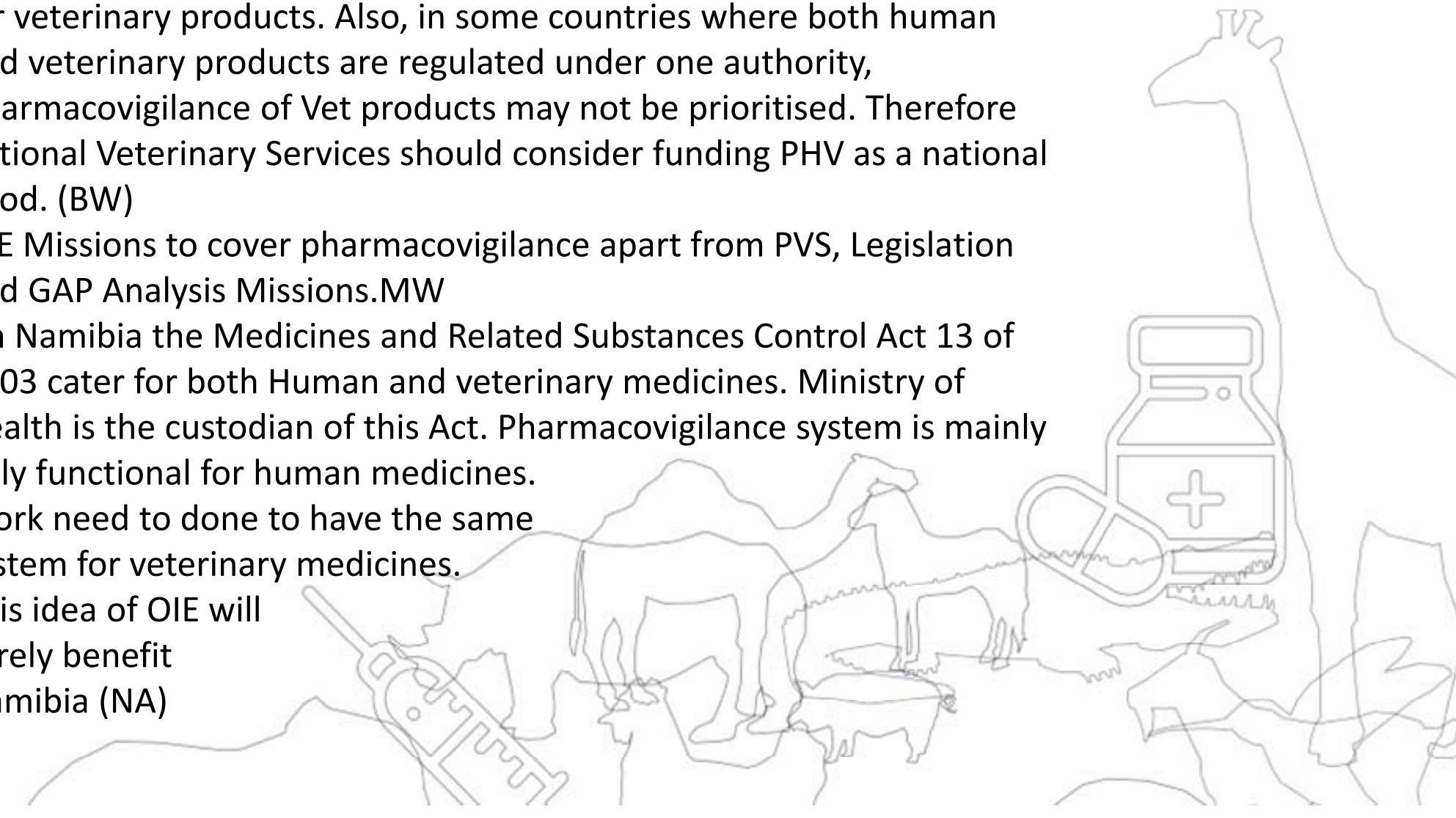
6. Do you consider that a pharmacovigilance system could be set up at a Regional or Sub-Regional level?



No = KE

7. Further thoughts, comments or proposals

- There is a need of training on pharmacovigilance (MZ)
- Medicines Regulatory Authorities (MRAs) may not have adequate budget implement effective PHV systems because of the small market for veterinary products. Also, in some countries where both human and veterinary products are regulated under one authority, pharmacovigilance of Vet products may not be prioritised. Therefore national Veterinary Services should consider funding PHV as a national good. (BW)
- OIE Missions to cover pharmacovigilance apart from PVS, Legislation and GAP Analysis Missions.MW
- "In Namibia the Medicines and Related Substances Control Act 13 of 2003 cater for both Human and veterinary medicines. Ministry of Health is the custodian of this Act. Pharmacovigilance system is mainly only functional for human medicines.
  Work need to done to have the same system for veterinary medicines.
  This idea of OIE will surely benefit Namibia (NA)



7. Further thoughts, comments or proposals

- Inducing more professionality in the veterinary field to enable them to preform pharmacovigilance system instead of none specialists of the veterinary field (pharmacists) (LY)
- Currently the veterinary sector do not play an effective role in the pharmacovigilance system due to lack of legislation. The drug and food authority is dominated by the health sector and the Ministry of Health. There is need to develop a body and legislation in the veterinary sector to manage the pharmacovigilance system (SS)
- The OIE should clearly lay down that it is the role of the National Veterinary Authority of member states to officially shoulder the responsibility for the authorisation, registration, import, distribution and use of veterinary medicinal products (MU)
- This is possible if there is a *Regional* Medicines Regulatory Agency or an agency charged with that at the regional level (NG)
- There is a need to set up systems of veterinary pharmacovigilance to allow the feedback of relevant usage data which includes suspected lack of efficacy of antimicrobial products, in particular, at the recommended dosages (SZ)