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

14-16 January 2020

Kuala Lumpur,

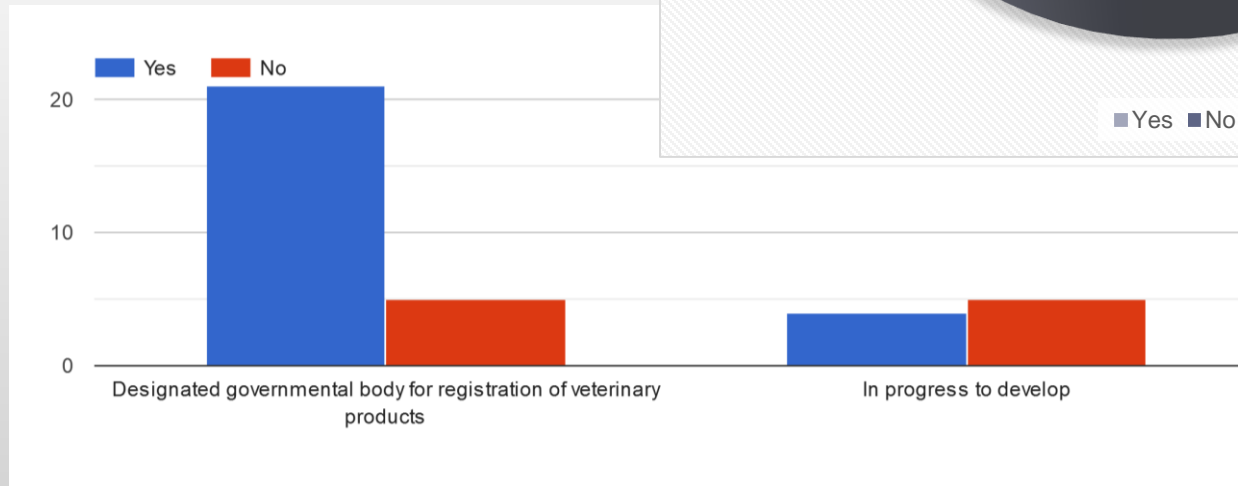
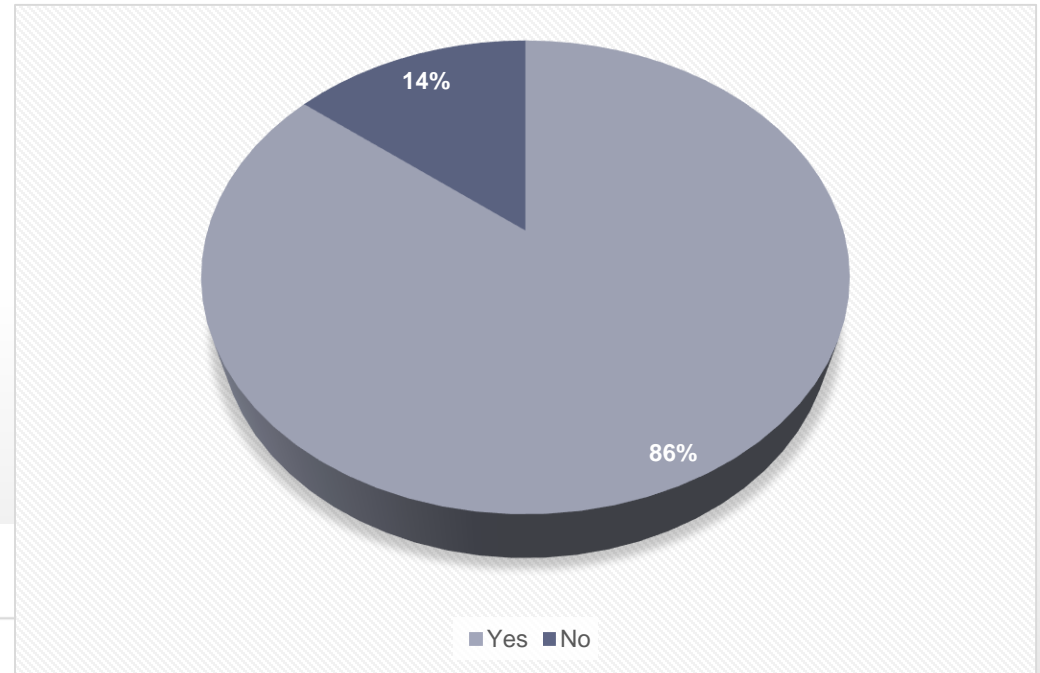
Malaysia.



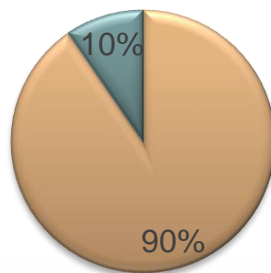
Countries reported

1. Nepal
2. Thailand
3. New Caledonia
4. New Zealand
5. Micronesia
6. Papua New Guinea
7. VIET NAM
8. Myanmar
9. Chinese Taipei
10. Fiji
11. Mongolia
12. IRAN
13. Philippines
14. Singapore
15. Bhutan
16. Pakistan
17. INDIA
18. Bangladesh
19. Japan
20. Laos
21. Sri Lanka

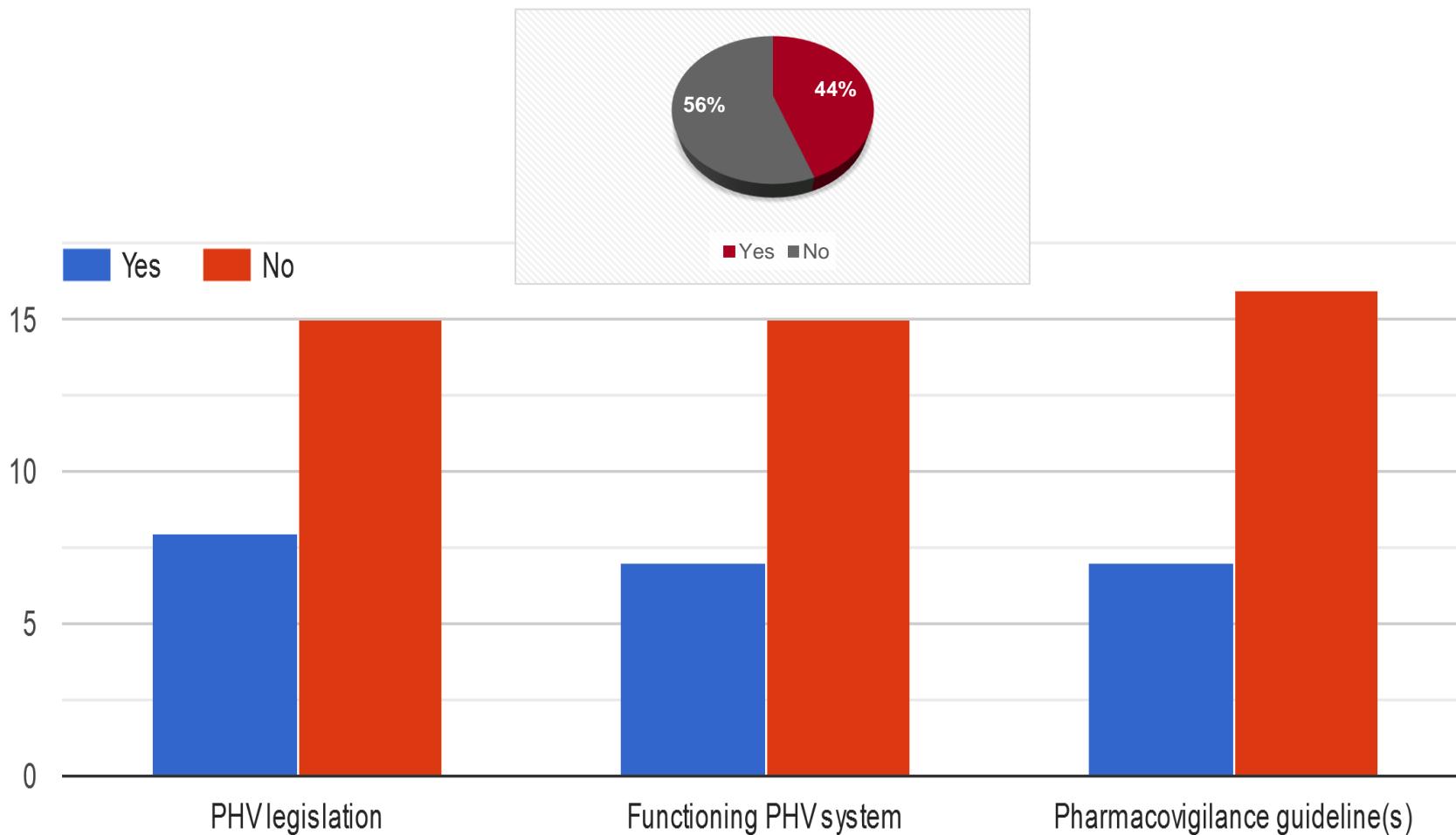
1. Does your country currently have a designated governmental body for registration of veterinary products, or is there work in progress to develop it? [Designated governmental body for registration of veterinary products]



2. If you have designated governmental body for registration of veterinary products; do you have a database or list for all authorized/registered veterinary medicinal product [List/Database of registered veterinary products available]



3. Do you have pharmacovigilance (PHV) legislation implemented in your country, and a functioning pharmacovigilance system? Do you have a PHV guideline(s) that are used in the post-marketing activities? [PHV legislation]

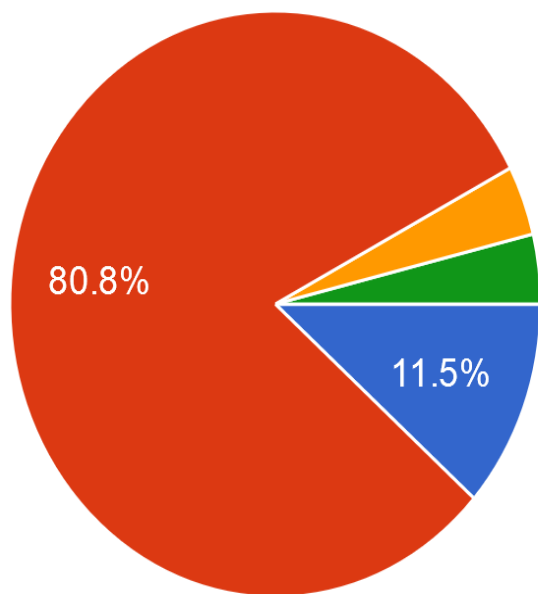


3. Do you have pharmacovigilance (PHV) legislation implemented in your country, and a functioning pharmacovigilance system? Do you have a PHV guideline(s) that are used in the post-marketing activities? [PHV legislation]

key elements of the pharmacovigilance system

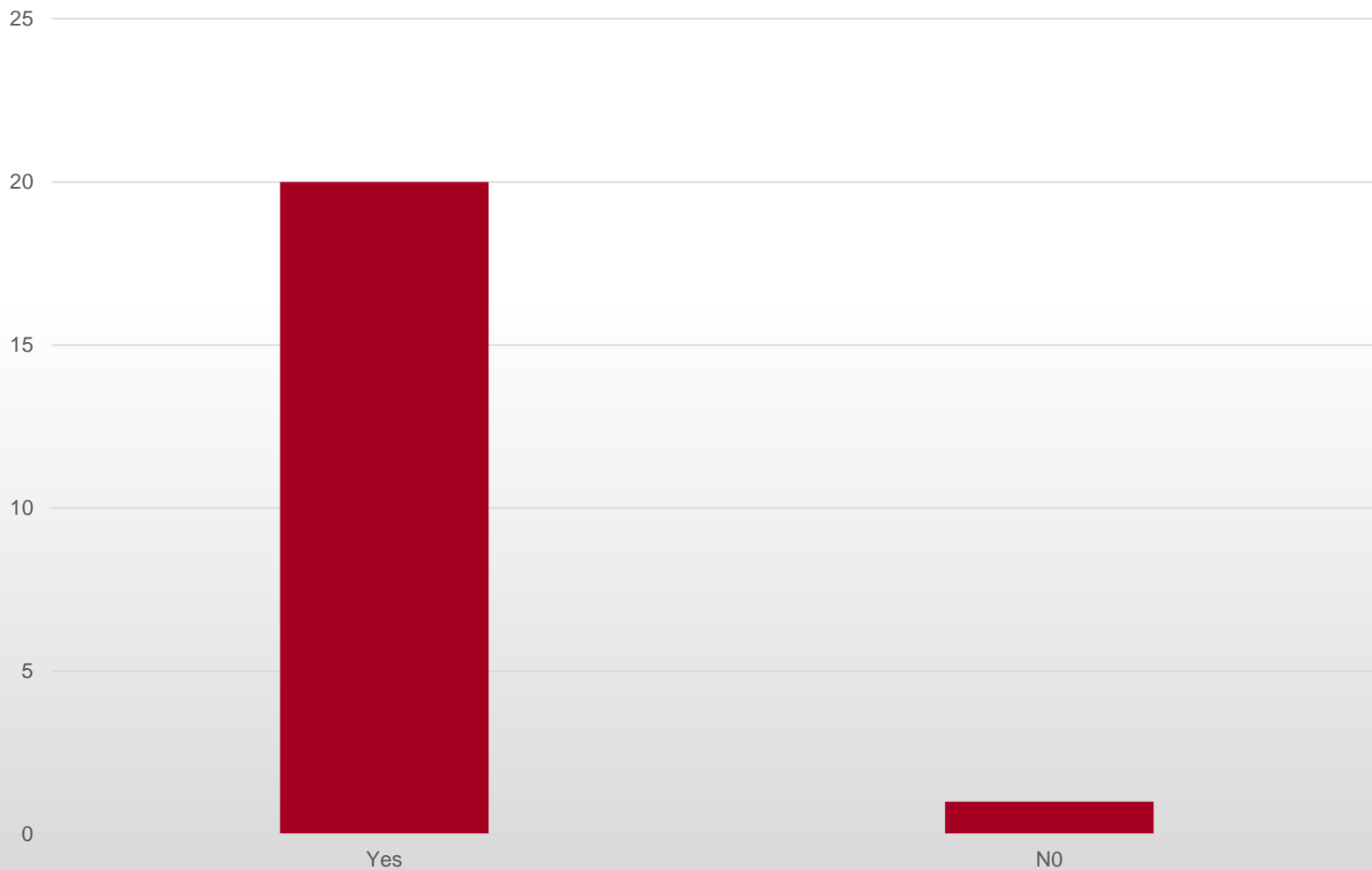
- Marketing authorization holder, User, Veterinarian, report system
- Legal requirement for registrants to report AERs
- Notifications and Responses
- Through Committee for Veterinary Drugs and products
- Reporting system, investigation, database, trend monitoring
- Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
- Appointed selected field veterinarians as authorized officers, One of their activities is pharmacovigilance

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?

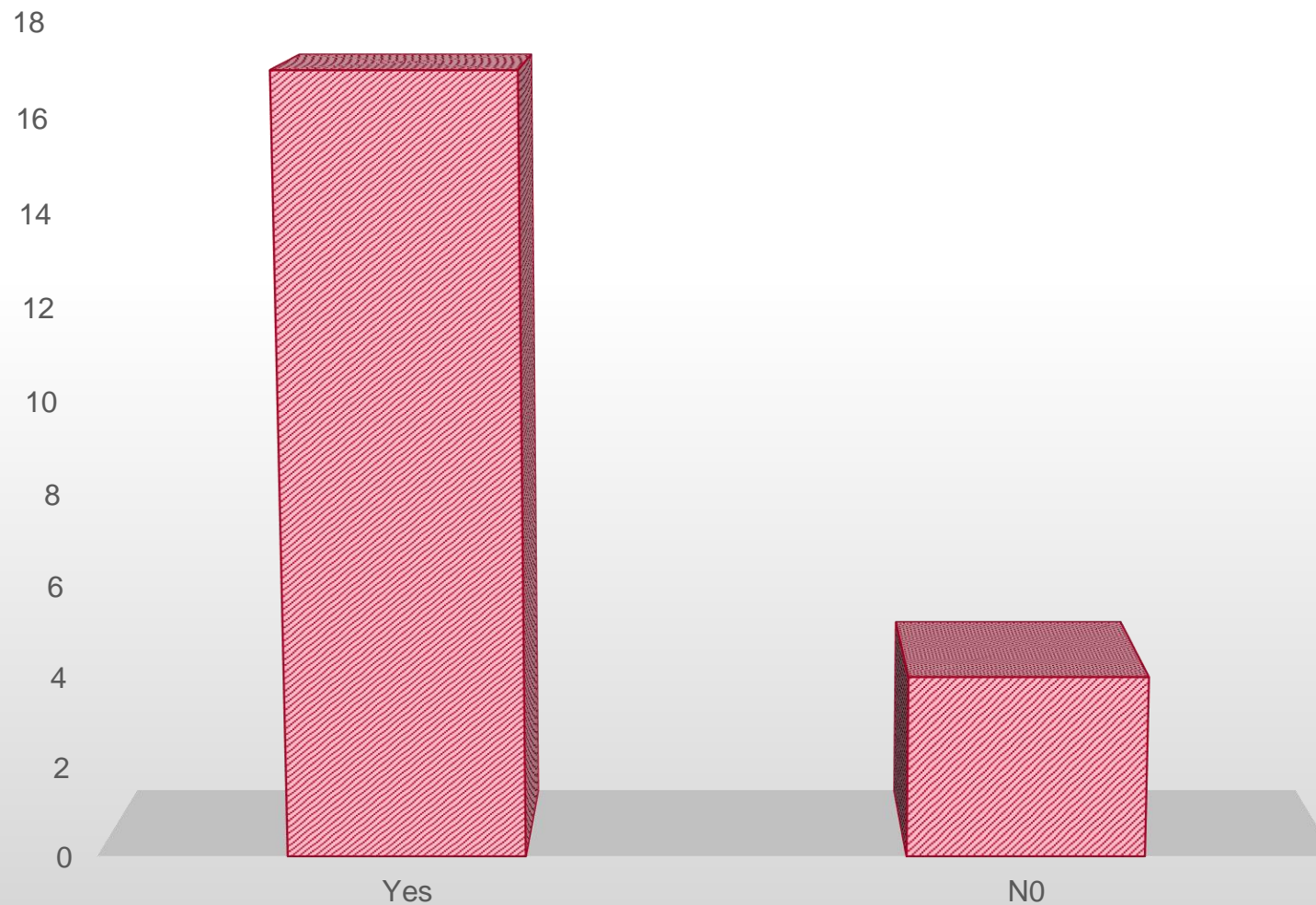


- Coordination among different stakeholders in order to avoid too many disharmonized systems to be developed
- Prepare a chapter in the OIE Manual or Code on the minimum requirements how to set up a basic pharmacovigilance system
- be included as critical competency in OIEPVS Gap analysis
- Develop global PV notification system and database

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



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



Further thoughts

- Advocacy aimed at political support
- Appropriate legislation is a key factor to implement a pharmacovigilance system
- Looking forward to seeing others experience on this
- Drafted pharmacovigilance system guidelines but is not validated yet
- Advocacy for development of database on use of veterinary drugs
- Public laboratory should be strengthened
- Good chance for my country to develop our Pharmacovigilance system
- Useful for many, If FP in our region could share a practicing piece of legislation on pharmacovigilance , which can be taken as an example

Thank you for your attention



— TO HANDLE —
ANTIMICROBIALS
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