NIGERIA

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

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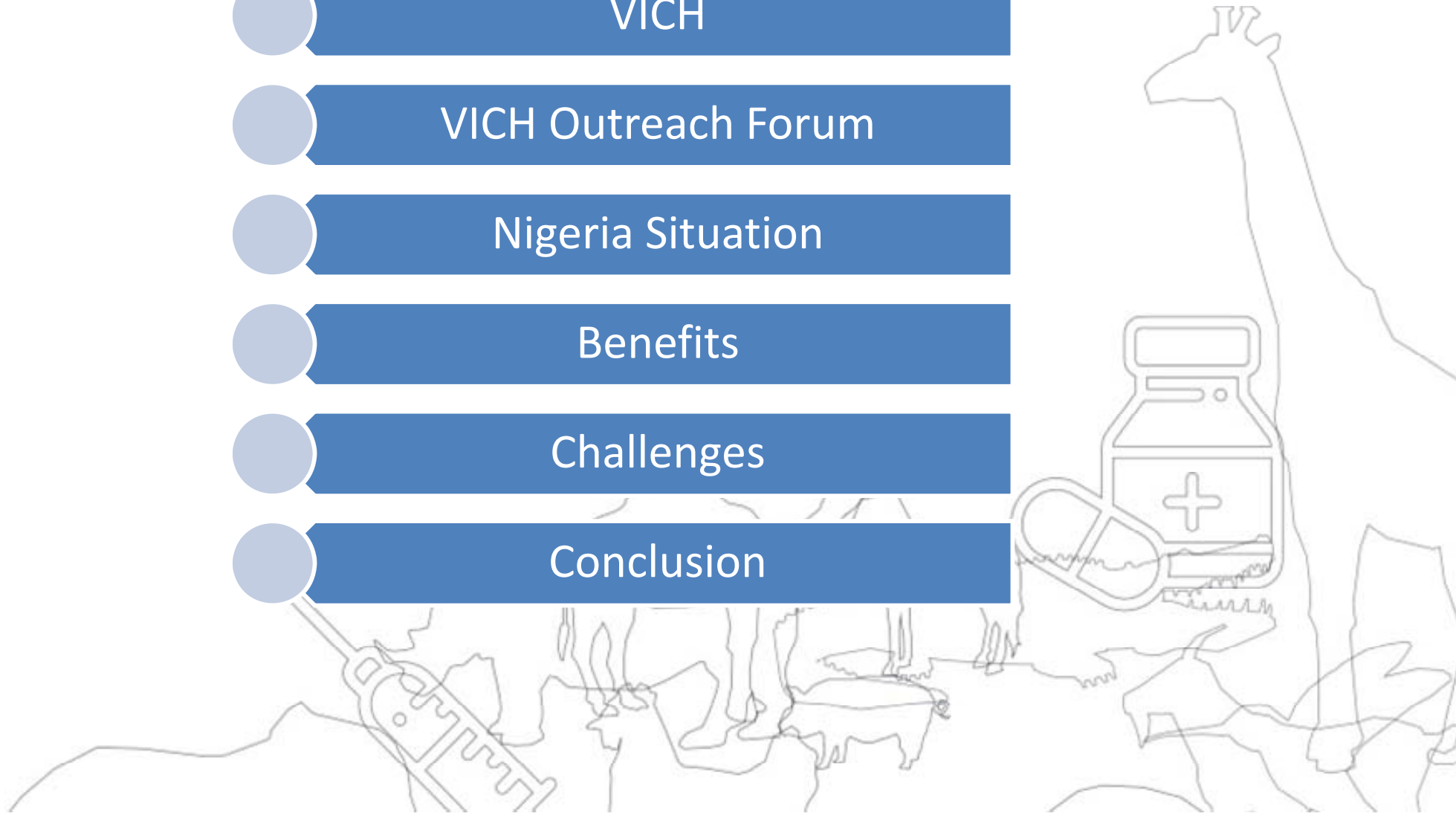
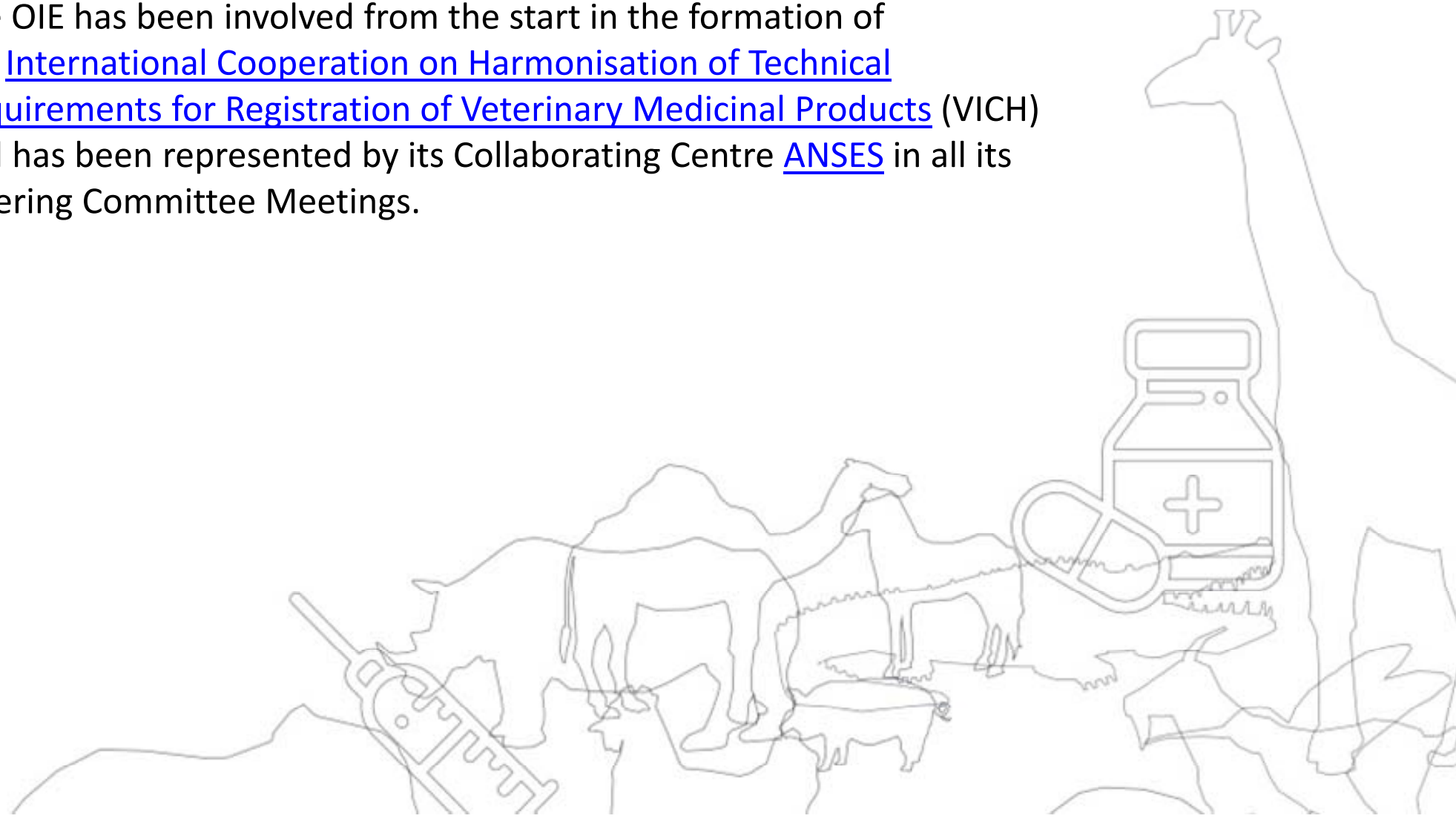


Introduction

- The OIE has been involved from the start in the formation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and has been represented by its Collaborating Centre ANSES in all its Steering Committee Meetings.

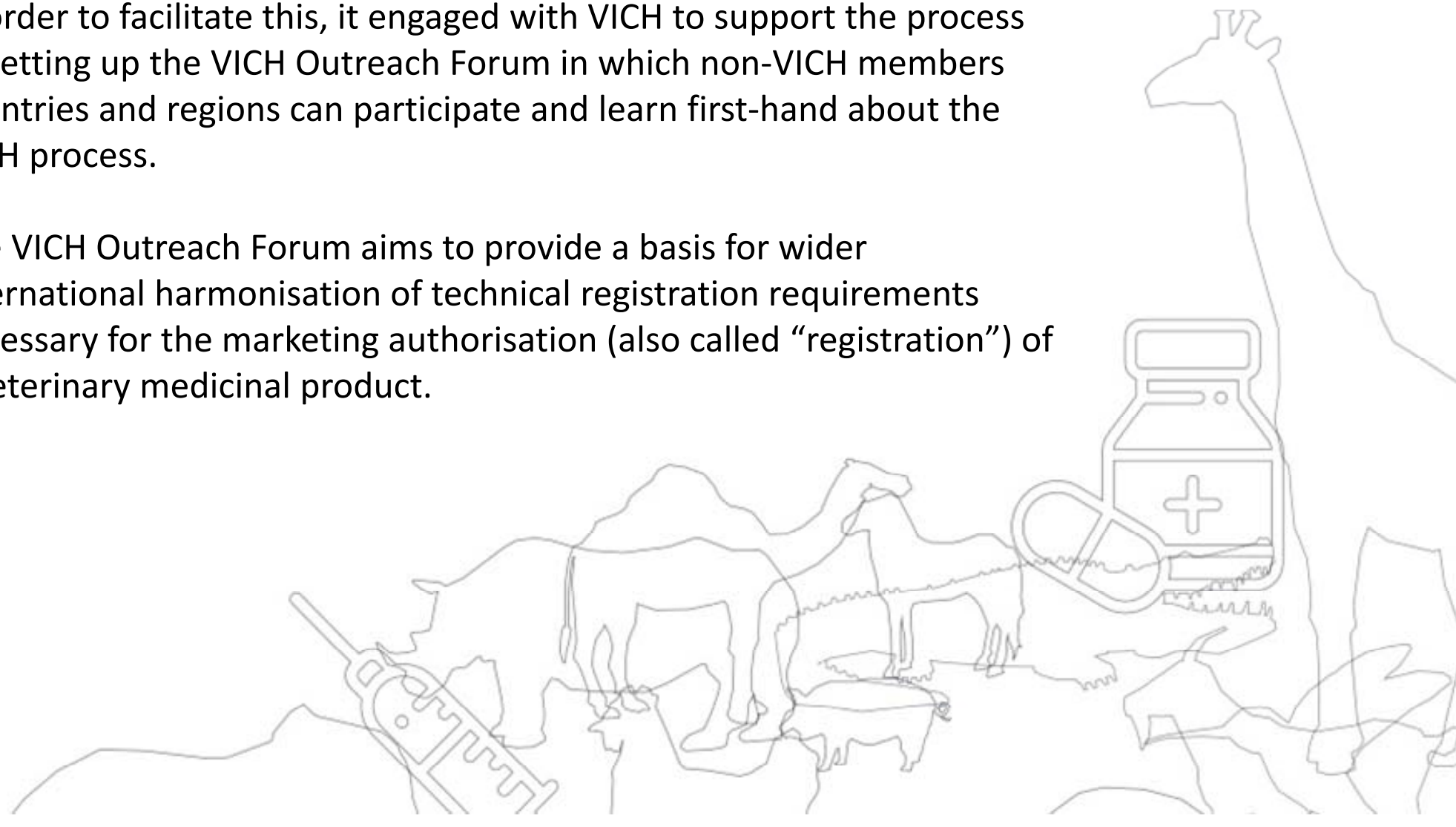


Introduction (cont...)

- As indicated in the OIE 5th Strategic Plan, the OIE encourages the use of VICH Guidelines by its Members Countries

- In order to facilitate this, it engaged with VICH to support the process of setting up the VICH Outreach Forum in which non-VICH members countries and regions can participate and learn first-hand about the VICH process.

- The VICH Outreach Forum aims to provide a basis for wider international harmonisation of technical registration requirements necessary for the marketing authorisation (also called “registration”) of a veterinary medicinal product.



What is VICH?

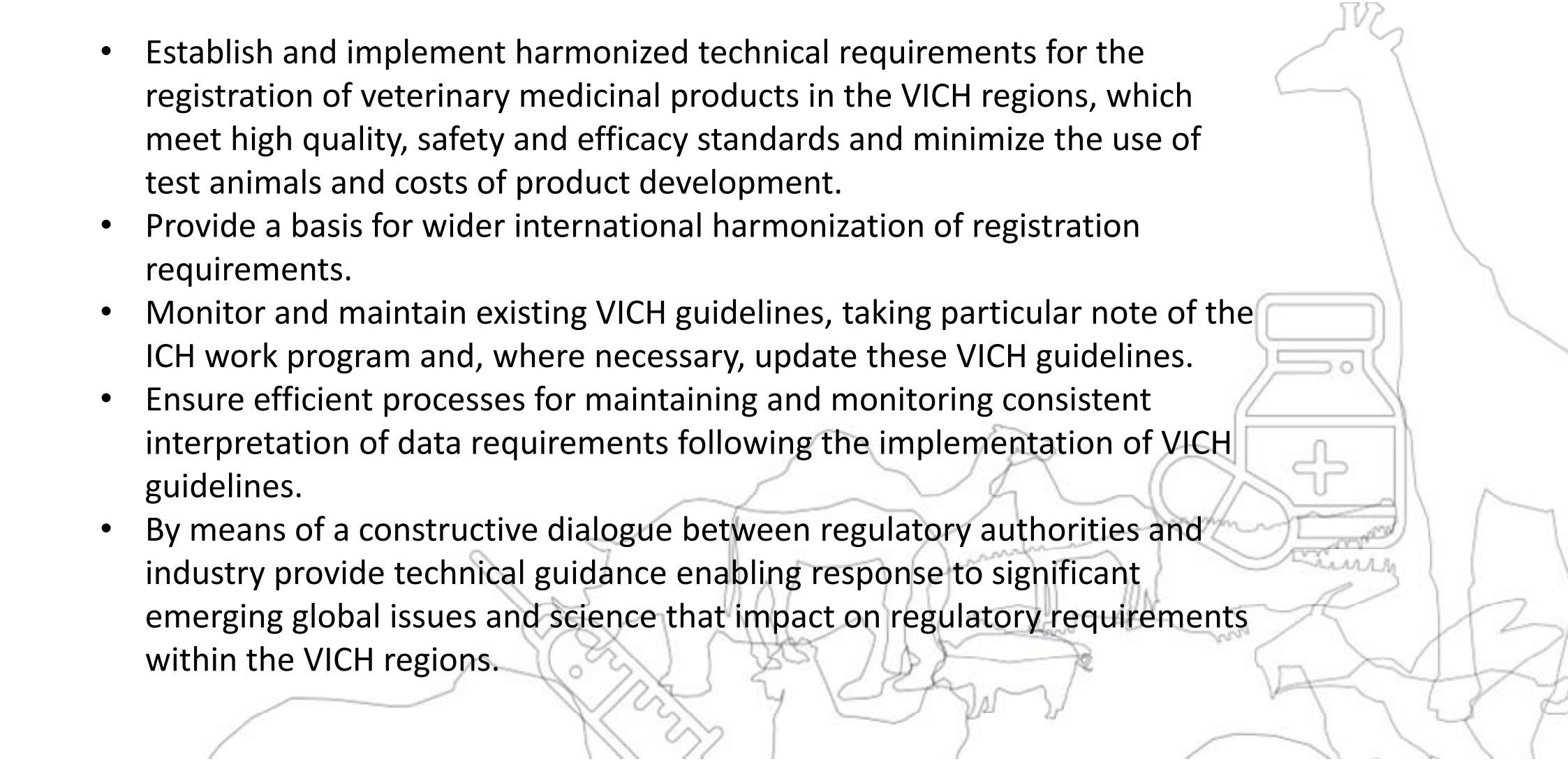
- The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration.

- VICH was officially launched in April 1996. It has 5 main objectives.

The Objectives of VICH

The objectives of the VICH are along the same lines as those of the ICH. The VICH will:

- Establish and implement harmonized technical requirements for the registration of veterinary medicinal products in the VICH regions, which meet high quality, safety and efficacy standards and minimize the use of test animals and costs of product development.
- Provide a basis for wider international harmonization of registration requirements.
- Monitor and maintain existing VICH guidelines, taking particular note of the ICH work program and, where necessary, update these VICH guidelines.
- Ensure efficient processes for maintaining and monitoring consistent interpretation of data requirements following the implementation of VICH guidelines.
- By means of a constructive dialogue between regulatory authorities and industry provide technical guidance enabling response to significant emerging global issues and science that impact on regulatory requirements within the VICH regions.



What is the VICH Outreach Forum?

- The Outreach Forum is composed of countries and regional organisations that have expressed an interest in the work of VICH and are motivated to participate in the activities of the VICH Outreach Forum. Currently approximately 14 countries and 4 regional organisations are participating (or have been invited).

- The VICH Outreach Forum meets in the margins of VICH Steering Committee meetings, which take place approximately every 9 months in one of the VICH member countries/regions. The Forum meetings are chaired by the VICH host country in collaboration with OIE, recognising the OIE's membership in VICH as well as its broader mandate.

Current members of the Outreach Forum

- **Countries**
  - Argentina, Brazil, China (Pep. Rep. of), India, Korea (Rep. of), Mexico, Morocco, Nigeria, Russia, Saudi Arabia, Chinese Taipei, Tanzania, Thailand, Uganda, Ukraine and Zimbabwe.

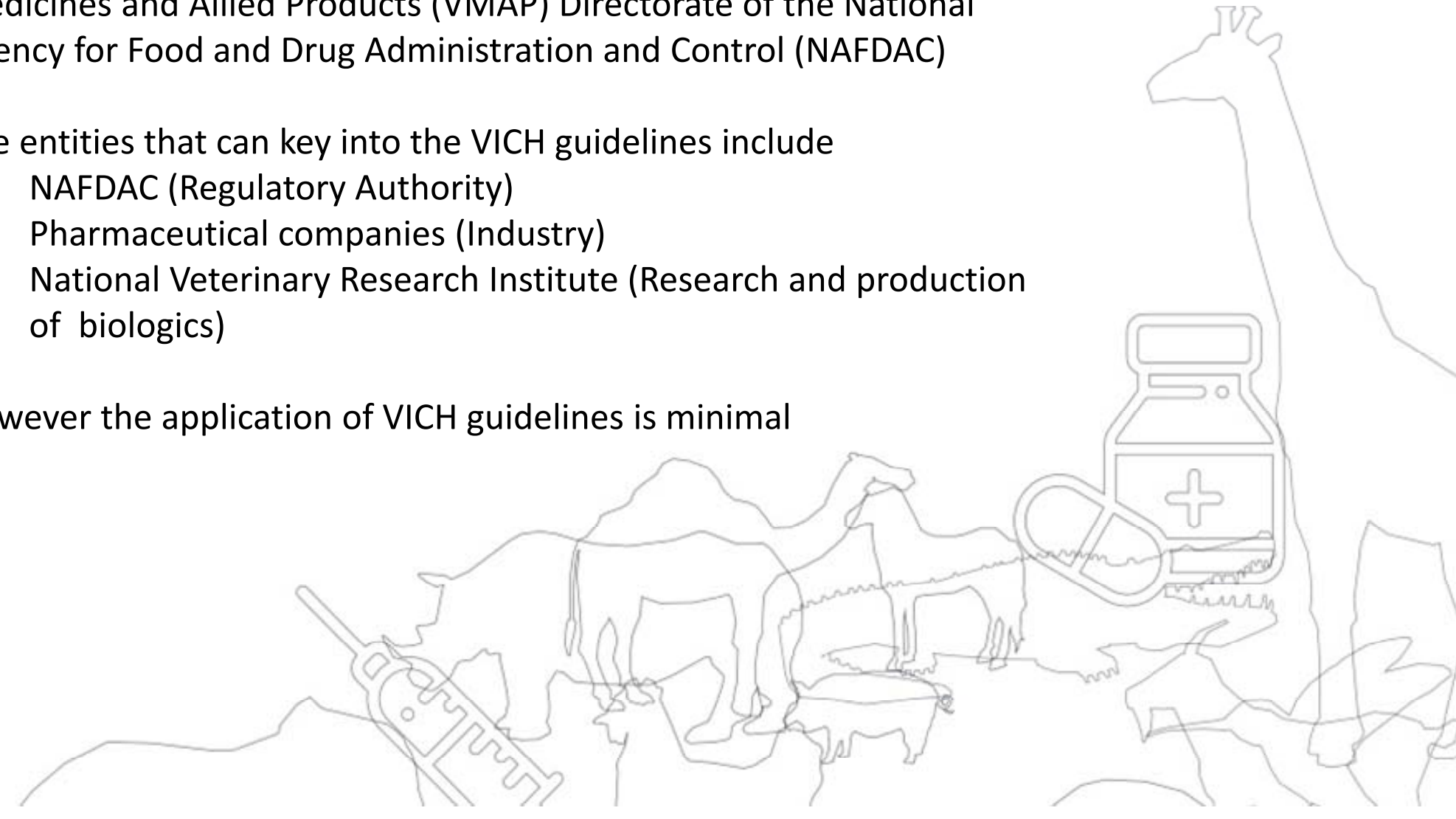
- **Regional Organizations**
  - ASEAN (representing Asia)
  - CAMEVET (representing the Americas);
  - WAEMO/UEMOA (representing West Africa)

Nigeria – Current Situation

- Nigeria is a member of the VOF at the instance of the Veterinary Medicines and Allied Products (VMAP) Directorate of the National Agency for Food and Drug Administration and Control (NAFDAC)

- The entities that can key into the VICH guidelines include
  - NAFDAC (Regulatory Authority)
  - Pharmaceutical companies (Industry)
  - National Veterinary Research Institute (Research and production of biologics)

- However the application of VICH guidelines is minimal



Benefits

- *VOF members report that technical requirements set in the GLs are increasingly gaining importance for the registration of VMPs*

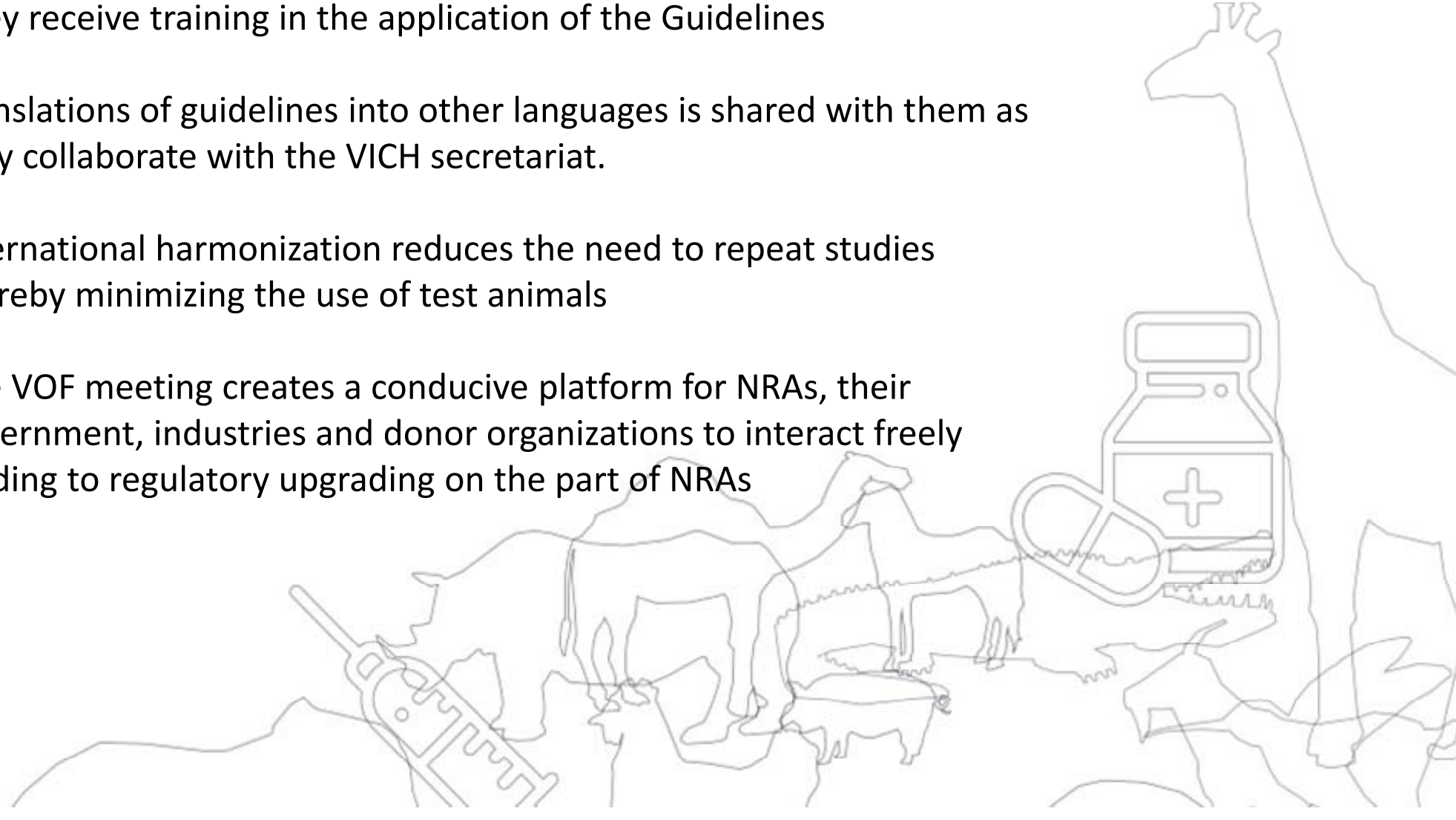
- The key issues of interest to the non-VICH countries coming together in the Forum are to better understand and actively contribute to the VICH Guideline development process. Submit comments to draft guidelines during the public consultation phase (step 4 of the VICH process)

- As regulatory authorities deal with new, emerging and innovative global issues, their comments help provide more regulatory certainty and improve the science that supports the GLs.

- Suggestion of topics for new Guidelines

Benefits (cont ...)

- They provide feedback on the acceptance of existing guidelines and to discuss practical issues related to VICH guidelines
- They receive training in the application of the Guidelines
- Translations of guidelines into other languages is shared with them as they collaborate with the VICH secretariat.
- International harmonization reduces the need to repeat studies thereby minimizing the use of test animals
- The VOF meeting creates a conducive platform for NRAs, their government, industries and donor organizations to interact freely leading to regulatory upgrading on the part of NRAs

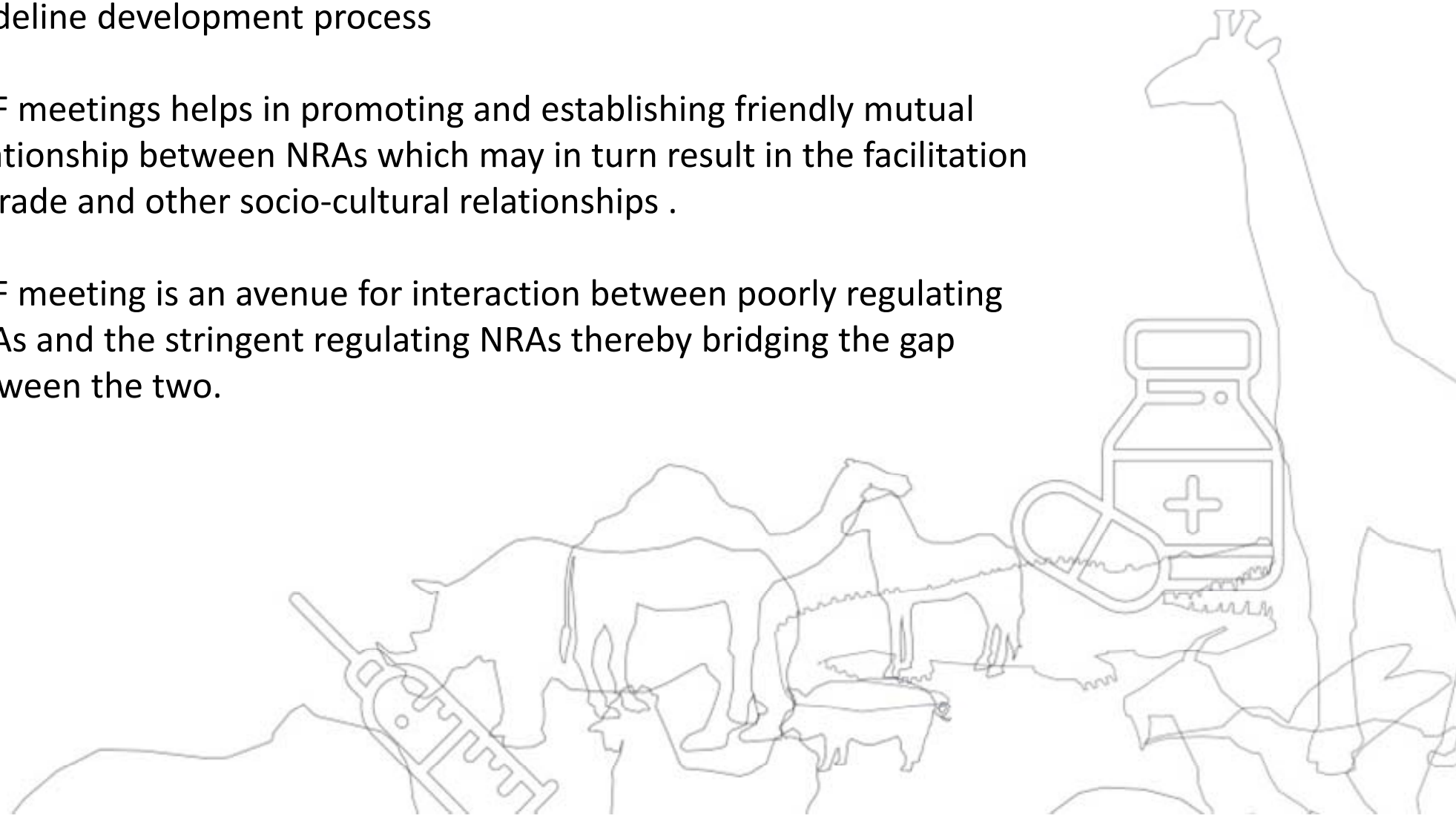


Benefits (cont ...)

- During VOF meeting, experts from the tripartite train VOF members on the implementation of old guidelines and engage them on the guideline development process

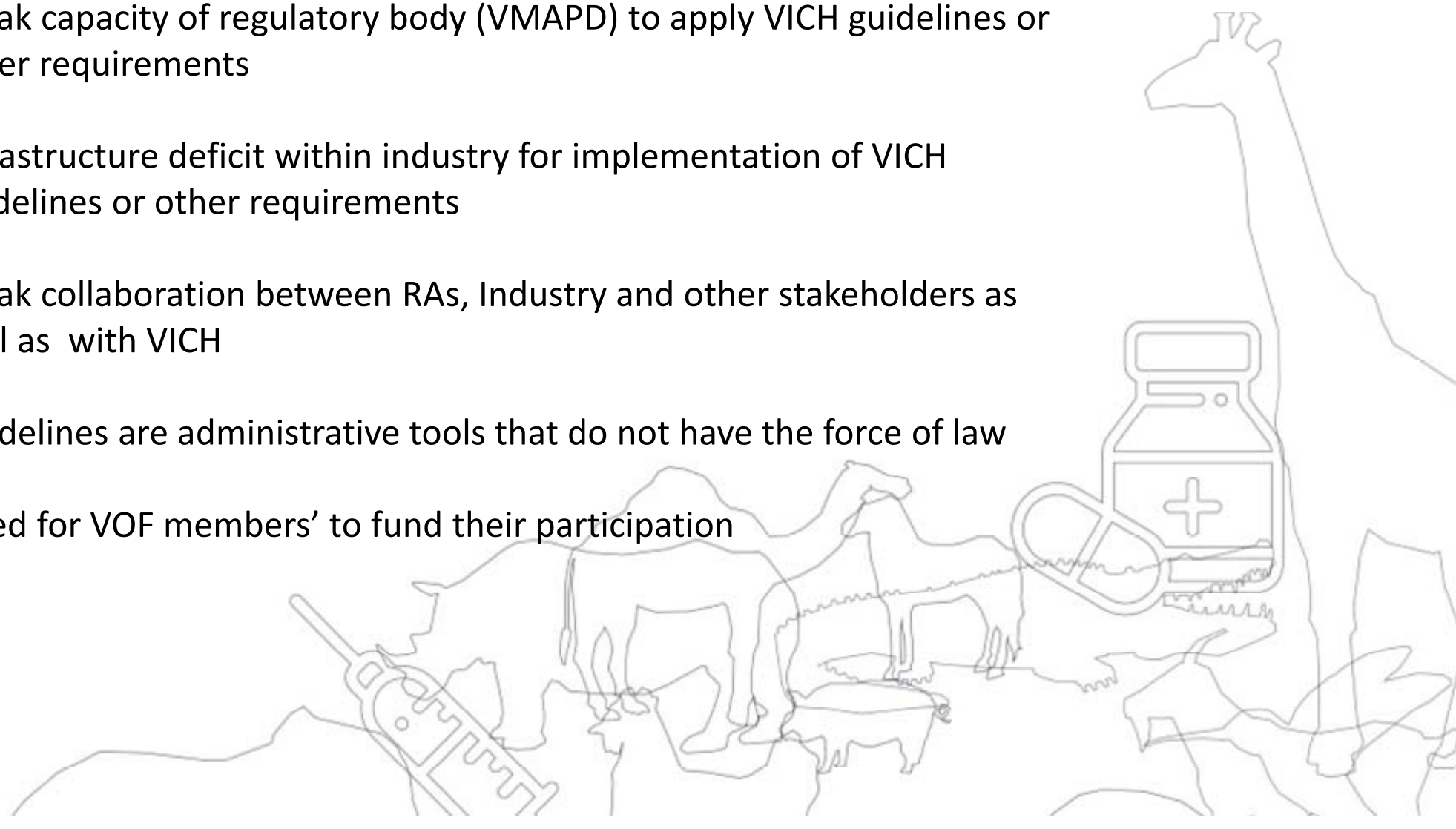
- VOF meetings helps in promoting and establishing friendly mutual relationship between NRAs which may in turn result in the facilitation of trade and other socio-cultural relationships .

- VOF meeting is an avenue for interaction between poorly regulating NRAs and the stringent regulating NRAs thereby bridging the gap between the two.



Challenges

- Inadequate knowledge about VICH and how to become an Outreach Forum member
- Weak capacity of regulatory body (VMAPD) to apply VICH guidelines or other requirements
- Infrastructure deficit within industry for implementation of VICH guidelines or other requirements
- Weak collaboration between RAs, Industry and other stakeholders as well as with VICH
- Guidelines are administrative tools that do not have the force of law
- Need for VOF members' to fund their participation



Conclusion

- For more countries to become VOF members and key into application of VICH guidelines some of these issues need to be addressed:
    - Need for advocacy and awareness creation among stakeholders by VICH
    - Networking of RA, Industry and Research institutions for application of VICH guidelines
    - Advocacy to Regional Economic Communities (RECs) especially in the area of harmonization of VMP regulation

thank You

merci beaucoup

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