LEGS Webinar, 24th November 2020 – The Quality of Veterinary Pharmaceuticals for Livestock Response in Emergencies.

Outstanding Questions

1. **Question**: re the volumes of veterinary pharmaceuticals bought by livestock keepers (from many sources, including cross-border) not associated with projects, is this known or estimated per target area?

   Answer: This was not covered by the Discussion Paper. Information total volumes of veterinary pharmaceuticals purchased worldwide and distribution can be found here: https://www.grandviewresearch.com/industry-analysis/veterinary-medicine-market
   Further information on scale of illegal/counterfeit medicines can be found here: https://healthforanimals.org/downloads/library/document.pdf

2. **Question**: I would very much welcome additional detail with regards to point 7 on the regulatory framework. What would be in your view the key elements of an appropriate regulatory framework in relation to the quality of AMs (taking into consideration the full supply chain)

   Answer: The regulatory framework with respect to the whole supply chain should cover three important aspects:
   - which pharmaceuticals are licenced in a given country for which species,
   - requirements with regards to manufacturing, importing, selling, prescribing and administration of different classes of pharmaceuticals,
   - post market monitoring mechanisms.

   In my view, there are two key elements to take into account in order for a regulatory framework to be successful:

   (1) Licensing decisions must be tailored to End-Use Environment
   The regulatory framework determines which pharmaceuticals are licensed for use - in which species for which condition. Licensing decisions should take into account pharmaceuticals' properties with respect to human food safety (both toxicology of drug residues and also AMR potential), animal and user safety, as well as their effectiveness. The assessment of effectiveness goes beyond the pure effectiveness of the chemical in laboratory conditions but also covers the **conditions of in field treatment** – for example for areas with high temperature variation and no cold chain, licensing of medication should take into account the need to withstand high temperature ranges.

In addition, licensing of a particular pharmaceutical should take into account the **environmental impact** of its manufacturing and disposal. For example widespread use of dicloflenac in cattle in south Asia led to a severe decline in vulture populations as a result of kidney failure due to consumption of carcasses containing diclofenac.[1] Countries on the Indian subcontinent began banning diclofenac in 2006 and since then, vulture populations in the region have started to recover.

Therefore, there is no one solution fits all- when it comes to licensing pharmaceuticals it is important that the specificities of a country, its environment, livelihoods, the natural environment and wildlife are taken into account.

(2) Successful implementation of licensing decisions and regulations requires **effective post market monitoring mechanisms** in order to ensure compliance throughout the supply chain (quality of veterinary pharmaceuticals, compliance of pharmacies with regulations, tests for veterinary drug residues in food etc.), as well as to monitor for adverse reactions and potential development of AMR in foodborne micro-organisms. Monitoring needs to be combined with solid legal dispositions for enforcement (enabling imposition of penalties, sanctions and other methods) in order to have an effect on compliance.

3. **Question**: What have you found in your research are the greatest obstacles to access to essential medicines in LMIC?

   Answer: The research focussed more specifically on ensuring the quality of medicines accessed/procured for emergency interventions in the livestock sector. The issue of access would also depend on who you are referring to – PVPs, animal health service providers, livestock owners?

4. **Question:** How can we help some of the donor policies to be more local focused than look more punitive especially for small organizations e.g. USAID/OFDA (BHA)

   Answer:
   Practitioners can play a role in raising awareness among donors with regards to the importance of local procurement of medicines with (i) convincing arguments, (ii) evidence-based decision making.
   (1) Convincing arguments:
   - Local procurement helps support local emerging supply chains. Repeated imports from abroad and free distribution will disrupt local markets with the risk of putting pharmacies, vets, frontline animal health service providers, and local manufacturers and wholesalers out of business;
   - Local procurement linking community-based animal health workers with vets/pharmacies is more sustainable in the long term as it fosters the establishment of a supply chain with which community-based animal health workers can replenish their stocks in the long term

[1] https://www.nature.com/news/cattle-drug-threatens-thousands-of-vultures-1.19839

- Local procurement is often faster than importing from abroad

(2) Evidence based decision making:

- Undertaking laboratory testing on locally procured medicines to assess quality (see Microsoft Word - final_LEGS operational research report.docx (livestock-emergency.net)
- Data from monitoring and evaluation of veterinary pharmaceutical supply systems and chains
- Impact assessment of animal health service delivery systems and projects on livestock diseases
- Somalia case study in the Veterinary Pharmaceuticals discussion paper: the experience of VSF was that procurement through local suppliers was always timely (despite pre-qualification procedure of (USAID/OFDA)
- Practitioners can continue to collect positive case studies and share their findings in order to raise awareness on this issue.

5. **Question**: You mention nutrition as an important part of preventing of illness. How should an assessment of nutrition form part of a LEGS assessment? Both macro nutrients and mineral/vitamin status?

   Answer: The LEGS Handbook Chapter 6 Technical Standards for Ensuring Feed Supplies https://www.livestock-emergency.net/wp-content/uploads/2012/01/LEGS-Handbook-2nd-edition-web-version-1.pdf provides information relating to feeding and nutrition assessment. Please also see the 'How to do it Manual' published by FAO for more practical and detailed information about feeding and nutrition during emergency situations. http://www.fao.org/documents/card/en/c/fb4eadbb-8243-459b-b239-579f3315295a/

6. **Question:** You mention importance of treating animals which are just sick, and thus the issue here is to work out which animals are sick. What methods would you recommend for working this out? The Five Point Check//FAMACHA systems are effective for this in goats and sheep.

   Answer: This question refers in particular to treatment with respect to parasites. Indeed, in order to prevent the development of anthelmintic resistance it is essential not to do blanket treatments as a preventative measure but only to treat sick animals. This requires a clinical diagnosis by an animal health professional before administration.

   The ultimate gold standard would be an egg count from a faeces sample however this is not realistic or practical in the field in most circumstances. In which case clinical analysis using proxy indicators is the best approach to use. The FAMACHA system is such a system-focussing on clinical signs of anaemia (eye colour). It is only relevant for the identification of Haemonchus Contortus parasite load. Yes, the Five Point Check is an excellent tool for small ruminants as it covers a wider spectrum of clinical signs and parasite types.

   For cattle, in general adults have immunity to intestinal parasites so they do not usually require treatment (exception for fluke which is only for areas which have fluke worm). Young stock may require targeted treatment for intestinal parasites. RUMA (Responsible Use of Medicines in Agriculture Alliance) has a number of guidelines including for cattle which can

be consulted online: https://ruma.org.uk/wp-content/uploads/2014/11/Manual-9-controllingwormsandliverfluke070211.pdf

7. **Question**: Is there a way to coordinate provision of quality veterinary drugs when multiple partners engage in emergency response?

   Answer: It is advisable for partners (NGOs, donor programmes and projects) working within a given region to meet regularly in order to coordinate their responses to have a harmonised approach.

   It is important to work closely with local government animal health services, wholesalers and private veterinary pharmacies from the planning stages so that all key stakeholders using a similar approach to procurement of veterinary medicines. For example a joint list of medicines (same concentration /dose, and administration route for given drug) can help avoid confusion in the long term at the community based animal health worker, if they are working always with the same pharmaceuticals concentration and therefore can be sure they get correct dosage. This will also make aware raising within the community easier, if a limited list of drugs is being used.

   Agreeing to support and strengthen the local supply chain is important, as if one partner imports drugs, this can disrupt efforts to support the local supply chain. The same approach should be applied with regards to payment of services / drugs - a coherent approach is valuable.

8. **Question:** Mine is more of a comment than a question that our experience in Zimbabwe (LMIC) mapping of both the distribution channel of both quality veterinary medicines and poor substandard medicines is important in order to have the full picture and formulate sustainable interventions.

   Answer: Yes, this comment is very relevant. This recommendation is also made in the discussion paper. Participatory mapping of the supply chain providing an overview of **all actors** and the **flows** of pharmaceuticals within both the **formal and informal supply chain** landscape. It should also cover the **decision basis underlying the commercial linkages**: actors may choose to purchase from a particular wholesaler/PVP because of convenience distance-wise, trust, reliability of the pharmaceuticals, credit options, preferred type and packaging of pharmaceuticals provided.

   With a full understanding of the situation then an appropriate response can be developed

9. **Questions:** From your presentation we understand that there are hotspots for AMR in Africa. Do we also have an idea of the molecules (specific antimicrobials) that are frequently involved?

   Answer: Please consult Boeckel et al (2019), Global trends in antimicrobial resistance in animals in low- and middle-income countries, Science (2019) Vol 365, Issue 6459

10. **Question:** What are the alternatives to antibiotics for the treatment and prevention of Bacterial Diseases.

    Answer: This depends on the bacterial disease. A key element is to focus on prevention: good animal husbandry, good nutrition, vaccination, good biosecurity. In some cases where there is a risk of a bacterial infection there are alternatives for antibiotics. For example, in the case of wounds, regular cleaning, using antiseptic and providing a clean environment for the animal are all important in order to prevent the need to use antibiotics.

    However, if an animal clearly has a bacterial infection, animal health practitioners should not hesitate to use antibiotics (for example clinical mastitis). Strategies to prevent AMR do not mean stopping to use antibiotics: it means selective use of antibiotics only for bacterial infections – and ensuring the right antibiotic, at the right dosage, is chosen for the particular condition and given for the full treatment period (and that the withdrawal period is respected if a food producing animal)

11. **Question:** What are the livestock management practices to be followed without the use of antibiotics as the growth promoters.

    Answer:
    - Understanding seasonal and climatic disease threats relevant to a particular area so that prevention measures, such as vaccination, can be put in place.
    - Focus on nutrition: keeping herd at optimum body condition score appropriate for the stage of production
    - Hygiene: keep livestock in clean and dry environment in order to reduce exposure to disease (this includes pasture, housing, handling areas and equipment used on livestock)
    - Biosecurity: in order to prevent introduction of new infectious diseases, if this is feasible in the production system
    - Genetics: use breeds best adapted to local conditions and with strong disease resilience
    - Isolate and treat sick animals quickly in order to reduce opportunity for disease spread to the rest of the flock/herd/group. Seek support from animal health service providers