2nd Public Hearing of the Committee on Agriculture, Food, and Agrarian Reform

Chairperson: Sen. Cynthia A. Villar

4 December 2023, Monday, 10 a.m., Pecson Room, Senate

Re: Proliferation of the Unauthorized Sale of African Swine Flu Vaccine in the Market While Still on Trial

Background

- The public hearing on the proliferation of the unauthorized sale of African Swine Flu (ASF) vaccine in the market while still on trial continues.

- Concerned government officials, stakeholders of the swine industry, and KPP Powers Commodities, Inc. officers were invited to the first public hearing to shed light on the issue.

- Several key issues surround the ASF vaccine, including disputes over jurisdiction (Bureau of Animal Industry vs. Food and Drug Administration) from importation to clinical trials, the roles of monitors, sponsors, and investigators in the clinical protocol, the approval date of the ASF vaccine in Vietnam, BAI's press release date on its approval, and whether shedding occurred during the initial trial.

Highlights of the 1st Public Hearing

- The jurisdiction over veterinary drugs became the subject of debate due to conflicting statements from the Bureau of Animal Industry (BAI) and the Food and Drug Administration (FDA). The FDA claimed that BAI had authorized the importation of ASF vaccine and test kits, signed by BAI Director Dr. Limson, while the FDA granted approval for importation. This highlighted the need for alignment and cooperation between BAI and FDA.

- The Department of Justice (DOJ) issued Opinion No. 15, Series of 2023 on May 5, 2023, affirming the FDA's jurisdiction in inspecting and monitoring veterinary drug products.
Sen. Francis Tolentino emphasized that the FDA cannot delegate its function to another agency or a private entity, and only Congress can delegate functions. Therefore, the ongoing trial's clinical protocol should involve the FDA.

Regarding waivers, typically, the government issues waivers with conditions it will cover in case of issues, but this is not the case in the ASF vaccine clinical trial. Senator Villar pointed out that farms were made to sign a waiver (Waiver and Confirmation of Participation AVAC ASF Life Attenuated Vaccine), absolving KPP Commodities, Inc. of accountability in case of adverse events during the clinical trial.

Senator Villar raised questions about the purpose of the waiver document distributed by the supplier. Was it for trial use only or sale? Why was a private entity handling it instead of BAI or FDA? What motivated the private entity if it was for field trials? Were the trials free for participating farms, and why was there no independent third party involved?

Based on these concerns, Rep. Nicanor Briones suggested that the clinical trials might be a disguise for commercial inoculation of affected swine.

**Possible Points for Discussion**

1. **ASF Status**: Current situation pertaining to the African Swine Fever (ASF) in the Philippines, other Asian countries, and a global overview of ASF prevalence;

2. **ASF Vaccine Clinical Trial**: Updates on the ongoing clinical trial of the ASF vaccine, including any current challenges, future plans, the trial's timeline, and details about the clinical protocol (who oversees it, sponsors it, and investigates it) in relation to DOJ Opinion No. 15, Series 2023, dated May 5, 2023;

3. **Jurisdiction Clarification**: Clarification, collaboration, and coordination of the respective roles and jurisdictions of the FDA and BAI (Bureau of Animal Industry);

4. **Phase 1 Trial Shedding Report**: Report on any shedding incidents that occurred during Phase 1 of the trial;

5. **Expiration of ASF Vaccines**: Addressing the fate of the remaining ASF vaccines, particularly considering their expiry date in March 2024;

6. **Accountability**: Examining the accountability of the authorities and individuals involved in the ASF vaccine trial;

7. **Supplier Conflict of Interest**: Investigating any potential conflicts of interest related to the supplier's involvement in the trial; and

8. **ASF Vaccine Use Clarification**: Clarifying whether the 300,000 imported ASF vaccines are intended solely for clinical trial purposes or for commercial use.