**Minutes of 342nd meeting of Registration Board held on 30th November, 2024.**


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DRUG REGULATORY AUTHORITY OF PAKISTAN
PRIME MINISTER'S NATIONAL HEALTH COMPLEX.
PARK ROAD, CHAK SHEHZAD
ISLAMABAD.

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342nd meeting of Registration Board was held on 30th November, 2024 with the directions of PM office w.r.t. visit of Belarus delegation headed by President of Belarus, through zoom link in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister's National Health Complex Park Road, Chak Shehzad, Islamabad.

The meeting was chaired by Dr. Obaidullah, Director, Pharmaceutical Evaluation & Registration Division, DRAP / Chairman, Registration Board, DRAP. The meeting started with recitation of the Holy Verses.

The meeting was attended by the following:

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| 1. | Mr. Iftikhar A. Choudhary, Ex-Chief Pharmacist, Punjab University, Lahore. | Member |
| 2. | Malik Muhammad Saleem, Ex Deputy Manager Production. Rhone Poulenc Rorer Pakistan. Rawalpindi. | Member |
| 3. | Mr. Syed Adnan Rizvi, Director, Drugs Testing Laboratory, Govt. of Sindh, Karachi. | Member |
| 4. | Dr. Ali Jan, Director, Drugs Testing Laboratory, Govt. of Baluchistan Quetta. | Member |
| 5. | Jam Muhammad Aslam, Additional Draftsman, Law & Justice Division, Islamabad. | Member |
| 6. | Mr. Ghulam Mujtaba, Deputy Director, Representative of IPO, Islamabad. | Member |
| 7. | Mr. Babar Khan, Director, Biological Evaluation & Research Division, DRAP. | Member |
| 8. | Ch. Zeeshan Nazir Bajar, Director, Quality Assurance & Lab Testing Division | Member |
| 9. | Mr. Salateen Waseem Philip, Deputy Director, Representative of MD&MC Division, DRAP. | Member |
| 10. | Hafiz M. Ali Tayyab, Additional Director (PE&R), DRAP. | Member/ Secretary |
| 11. | Dr. Qurban Ali, Former Director General, National Veterinary Laboratories, Islamabad. | Co-Opted Member |
| 12. | Dr. Muhammad Akram, Animal Husbandry Commissioner, M/o National Food Security & Research, Islamabad. | Co-Opted Member |

Director, BE&R assisted by respective Mr. Muhammad Ashfaq, Deputy Director to present the agenda of Biological Evaluation & Research Division.

**Item No. I. Division of Biological Evaluation & Research**

**Case No. 1: Imported veterinary biological products imported from non- reference countries**

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| **1.** | **Name and address of Importer** | **M/s Prix Pharmaceutica 26 Abbot Road Lahore** |
| | Detail of DSL | M/s Prix Pharmaceutica 26 Abbot Road Lahore<br>Godown Address: Plot No. 5, Pharm City 30km, Multan Road, District Lahore<br>Valid upto 12-06-2027 |
| | Name and address of Manufacturer | As per form 5A<br>M/s. BEL VITUNIPHARM OJSC 26A Sovetskaya Str. Dolzha Village Vitebsk District, Vitebsk Region, 211039, Republic of Belarus<br>As per FSC:<br>OJSM "Belvitunipharm" 26 A Sovetskaya str. Village Dolzha Vitebsk district, Vitebsk region, 211309, Republic of Belarus. |
| | Name of exporting country | Republic of Belarus |
| | Brand Name +Dosage Form + Strength | **Bolshevak Virus Vaccine**<br>Polyvalent inactivated cultural vaccine against infectious Rhinotracheitis, Bovine viral Diarrhea, Parainflunza-3, Respiratory syncytial, Rota- and Coronavirus infections of cattle<br>Each strain is at least 51g TSD 50/ml (CM3) |
| | Diary No. Date of R&I & Fee | Rs. 75000/- Dated 05-07-2024 & Rs. 225,000/- Dated 27-11-2024 |
| | Composition | AVIRULENT FORMALDEHYDE INACTIVATED STRAINS OF INFECTIOUS RHINOTRACHEITIS, VIRAL DIARRHEA, PARAINFLUENZA-3, RESPIRATORY-SYNCYTIAL, ROTA-AND CORONA VIRUS |
| | Pharmacological Group | Vaccine |
| | Me-too | N/A |
| | Type of Form | Form-5A |
| | Finished Product Specification | In-house |
| | Shelf Life | 18months (2-8$^0$C) |
| | Document Details | Following documents are submitted:<br>a. Copy of FSC issued by Belarus Chamber of Commerce and Industry dated 17-11-2023<br>b. Copy of Certificate of Conformity issued to Open Joint Stock Company " BelVitunipharm" By Bureau Quality Certification valid until 20/03/2025 |
| | Pack size | 200ml |
| | Remarks of Evaluator:<br>a. Copy of FSC issued by Belarus Chamber of Commerce and Industry expired dated 06-12-2023, not notarized and attested by embassy. | |

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| | b. Copy of Certificate of Conformity issued to Open Joint Stock Company "BelVitunipharm" By Bureau Quality Certification, not notarized and attested by embassy.<br>c. Sole agency agreement is not notarized and embassy attested.<br>d. Submitted fee is Rs.75,000/- remaining fee Rs.225,000/-is required. |
| | **Decision of 341st meeting of Registration Board:**<br>*Animal Husbandry Commissioner apprised that applied product / formulation has new strains which have not been yet reported in local livestock population, therefore the Board referred the Bolshevak virus vaccine for opinion of M/o National Food Security and Research regarding the need of vaccine in local livestock population and submission of remaining documents by the applicant.*<br>**Updated Status of the Case:**<br>In light of decision of the Registration Board, M/o National Food Security and Research, was requested to furnish their opinion vide letter No. F. No.3-16/2024-DD(BE&R) dated 27th November, 2024. Accordingly, the M/o National Food Security and Research, vide their letter No.2-5/2006-EPID, dated 29th November, 2024, has opined as under;<br>"The undersigned is directed to refer to Drug Regulatory Authority of Pakistan letter No. 3-16/2024-DD-B&R) dated 27th November 2024 on the subject cited above regarding registration of BOLSHEVIK VIRUS VACCINE and to state that the product may be recommended on the condition that its administration is restricted to animals involved in international trade or farms with imported livestock, subject to satisfactory verification of the vaccine's quality and safety parameters and immunodynamics/ immunokinetic, for which relevant data is available with DRAP"<br>**Proceedings of 342nd meeting:**<br>The Board was apprised that the applicant has requested for change in the applied pack size of the product from 200ml to 100ml. |
| | **Decision:**<br>**In light of the opinion of the M/o National Food Security and Research, the Board after thorough deliberation approved the product with the condition that the administration of the vaccine shall be restricted to animals involved in international trade or farms with imported livestock.**<br>**The Board further decided that the registration letter shall be issued after submission of the following;**<br>**a. Comments / Recommendations of Dr. Qurban Ali and Animal Husbandary Commissioner, M/o National Food Security and Research regarding safety parameters and immunodynamics/ immunokinetic of the vaccine.**<br>**b. Fee and relevant documents by the applicant regarding change in pack size.** |

**Item No. II. Division of Pharmaceutical Evaluation & Registration**

**Case No. 1: Veterinary pharmaceutical products imported from non- reference countries**

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| **1.** | Name and address of Importer | M/s. QAS International, GT Road, Gujranwala |
| | Detail of DSL | Name: M/s QAS International<br>Address: Opposite Kings Mall, Near Wapda Town, GT Road, Tehsil and District, Gujranwala<br>License No; 09-341-0134-103105D<br>Validity: 13-03-2028.<br>Status: License to sell drugs as a Distributor |
| | Name and address of Manufacturer | Manufacturer:<br>STOVEK LLC 222600,REPUBLIC of BELARUS MINSK REGION,STOLBTSY,ZADVORJENSKAY STR.,2,OFFICE 678 (017) 1725000 |
| | Name of exporting country | Republic of Belarus |
| | Brand Name +Dosage Form + Strength | TRIVIDGEKT 5% TRV solution for injection |
| | Diary No. Date of R& I & fee | Rs. 75,000/- (Slip No 5254213071) |
| | Composition: | Each ml contains:<br>50.0 mg of aRNase (1,5-bis- [N, N-1- (4-tetradecyl ) diazoniabicyclo [2.2.2] octyl] pentane tetrobromide) |
| | Pharmacological Group | Antiviral |
| | Finished Product Specification | As per innovator Specifications |
| | Shelf Life | 2 Years |
| | Document Details | Dossier submitted in Biological Division |
| | Pack size | The veterinary drug is packed in glass vials of 10, 20, 30, 50, 100, 200, 400 ml, hermetically closed with rubber stoppers and tamper resistant aluminum caps. |
| | Demanded Price | Decontrolled |
| | Reference Regulatory Authority Availability | N/A |
| | Products already registered in Pakistan | Not verifiable |

**Remarks of Evaluator:**

Registration Board in its 340th meeting discussed the product from same manufacturer in oral solution dosage form in 30mg/ml strength and Board decided as under:

Decision: Keeping in view the approval status of applied formulation in Republic of Belarus, Registration Board approved the instant product with shelf life of 2 years' subject to compliance with current import policy. Registration letter shall be issued upon submission of fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024. Moreover, referred the case for expert opinion from Ministry of National Food Security & Research, Islamabad regarding the guidance on the precautionary measures for use of applied formulation in feeding animals.

Submitted for consideration of the Board.

**Decision of 341st meeting of Registration Board:**

Registration Board deliberated that applied formulation is new chemical entity (anti-viral) for which M/o National Food Security & Research has already asked for review of such therapies. As applied formulation has not been approved in any of reference regulatory authorities hence the Board referred the applied product to the M/o National Food Security & Research for assessment of safety and efficacy parameters in feeding animals.

**Updated Status of the Case:**

In light of decision of the Registration Board, M/o National Food Security and Research, was requested to furnish their opinion vide letter No. F. No.3-2/2024-I&V-II dated 27th November, 2024. Accordingly, THE M/o National Food Security and Research, vide their letter No. No.2-5/2006-EPID-P-006 dated 29th November, 2024, has opined as under;

> "The undersigned is directed to refer to Drug Regulatory Authority of Pakistan letter No. 3-2/2024-I &V-II dated 27th November 2024 on the subject cited above and to state that: Artificial ribonucleases (aRNAases) are engineered molecules designed to mimic the RNA-cleaving function of natural ribonucleases (RNAases). These synthetic agents hold promise for advanced therapeutic applications, including targeted RNA degradation in gene therapy, cancer treatment, and antiviral therapies.However, these aRNAases are still in the experimental or early clinical trial phases in advanced research hubs like the United States, European Union, and China. No country except Russian region has yet approved their widespread use in animals for therapeutic purposes. Since the risk of unintended RNA cleavage resulting in unanticipated toxicity or immune responses cannot be ruled out, therefore the Regulatory frameworks must ensure a comprehensive evaluation of risks and benefits before approving such drugs for use. Keeping in view the limited research and unanticipated toxicity or immune responses but potential application of TRIVIDGEKT 5% TRV solution for injections in animals following information is requested to further processing the case:
> a. Furnish the pharmacodynamics and pharmacokinetics studies on aforementioned drug;
> b. Provide pharmacological and safety data in different classes of animals and published case studies, field trials, or reviews about the product's use in food producing animals."

**Decision:**

**The Board after considering the response of M/o National Food Security and Research deferred the case and advised to forward the comments to the applicant for their response.**

The meeting ended with vote of thanks to and from the Chair.

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