

Minutes of 341st meeting of Registration Board held on 26th November, 2024.

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

341st meeting of Registration Board was held on 26th 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 and welcome notes for new members of the Registration Board.

The meeting was attended by the following:

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.	Dr. Tehseen Fatima, Dow College of Biotechnology, Dow University of Health Sciences, Karachi.	Member
4.	Mr. Syed Adnan Rizvi, Director, Drugs Testing Laboratory, Govt. of Sindh, Karachi.	Member
5.	Mr. Imranullah Khan, Director, Drug Testing Laboratory, Peshawar, Government of Khyber Pakhunkhwa.	Member
6.	Jam Muhammad Aslam, Additional Draftsman, Law & Justice Division, Islamabad.	Member
7.	Mr. Ghulam Mujtaba, Deputy Director, Representative of IPO, Islamabad.	Member
8.	Mr. Babar Khan, Director, Biological Evaluation & Research Division, DRAP.	Member
9.	Ch. Zeeshan Nazir Bajar, Director, Quality Assurance & Lab Testing Division	Member
10.	Mr. Salateen Waseem Philip, Deputy Director, Representative of MD&MC Division, DRAP.	Member
11.	Hafiz M. Ali Tayyab, Additional Director (PE&R), DRAP.	Member/ Secretary
12.	Dr. Qurban Ali, Former Director General, National Veterinary Laboratories, Islamabad.	Co-Opted Member
13.	Dr. Muhammad Akram, Animal Husbandry Commissioner, M/o National Food Security & Research, Islamabad.	Co-Opted Member

Mr. Muhammad Sarfraz Nawaz, Deputy Director, presented the agenda of PE&R Division. Director, BE&R assisted by respective 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

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 Godown Address: Plot No. 5, Pharmacity 30km, Multan Road, District Lahore Valid upto 12-06-2027
	Name and address of Manufacturer	As per form 5A M/s. BEL VITUNIPHARM OJSC 26A Sovetskaya Str. Dolzha Village Vitebsk District, Vitebsk Region, 211039, Republic of Belarus As per FSC: OJSM Belvitunipharm, 210034 vitebsk, transportnaya str., 9 office 5, Republic of Belarus
	Name of exporting country	Republic of Belarus
	Brand Name + Dosage Form + Strength	BELRAB In-activated Anti-Rabies Vaccine Inactivated strain rabies virus 71 BelNIIEV-VGNKI
	Diary No. Date of R&I & Fee	Rs. 75,000/- Dated 05-07-2024
	Composition	Rabies Virus antigen 90%, Adjuvant Hydrate of Aluminum oxide 10%, Formalin 0.3% of the total amount of antigen
	Me-too	Biocan-r of Snam International, Rabisin of Saadat Internation
	Pharmacological Group	Vaccine
	Type of Form	Form-5A
	Finished Product Specification	In-house
	Shelf Life	18months (2-8°C)
	Document Details	Following documents are submitted: a. Copy of FSC issued by Belarus Chamber of Commerce and Industry dated 17-11-2023 to 16-11-2024 b. Copy of Certificate of Conformity issued to Open Joint Stock Company “ BelVitunipharm” valid until 20/03/2025
	Pack size	10 doses, 10ml
	Remarks of Evaluator:	a. Copy of FSC issued by Belarus Chamber of Commerce and Industry, not notarized and attested by embassy b. Copy of Certificate of Conformity issued to Open Joint Stock Company “BelVitunipharm” By Bureau Quality Certification, not notarized and attested by embassy. c. Sole agency agreement is not notarized and attested by embassy. d. Submitted fee is Rs.75,000/- remaining fee Rs.225,000/-is required.
	Discussion:	

	<p>The Board discussed that multiple rabies vaccines are available in Pakistan however in order to ensure the safety of the applied rabies vaccine, there is need to conduct safety trials in target population before commercialization of the product.</p> <p>Decision: Registration Board considered the application submitted by the firm and approved the BELRAB In-activated Anti-Rabies Vaccine. Registration letter shall be issued after submission of remaining fee, verification of local cold storage facility, dosage form specific GMP inspection as per SOP etc.</p>	
2.	Name and address of Importer	M/s Prix Pharmaceutica 26 Abbot Road Lahore
	Detail of DSL	M/s Prix Pharmaceutica 26 Abbot Road Lahore Godown Address: Plot No. 5, Pharacity 30km, Multan Road, District Lahore Valid upto 12-06-2027
	Name and address of Manufacturer	As per form 5A M/s. BEL VITUNIPHARM OJSC 26A Sovetskaya Str. Dolzha Village Vitebsk District, Vitebsk Region, 211039, Republic of Belarus As per FSC: 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	Bolshevik virus vaccine Polyvalent inactivation cultural against bovine infectious Rhinotracheitis, Bovine viral Diarrhea, Parainflunza-3, Respiratory syncytial, Rota-AND Coronaviral infections of cattle Each strain is at least 51g TSD 50/ml (CM3)
	Diary No. Date of R&I & Fee	Rs. 75000/- Dated 05-07-2024
	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: c. Copy of FSC issued by Belarus Chamber of Commerce and Industry dated 17-11-2023 d. 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:	

	<p>a. Copy of FSC issued by Belarus Chamber of Commerce and Industry expired dated 06-12-2023, not notarized and attested by embassy.</p> <p>b. Copy of Certificate of Conformity issued to Open Joint Stock Company “BelVitunipharm” By Bureau Quality Certification, not notarized and attested by embassy.</p> <p>c. Sole agency agreement is not notarized and embassy attested.</p> <p>d. Submitted fee is Rs.75,000/- remaining fee Rs.225,000/-is required.</p>
	<p>Decision: 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 Bolshevik 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.</p>

Item No. II. Division of Pharmaceutical Evaluation & Registration

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

1	Name and address of Importer	M/s. QAS International, GT Road, Gujranwala
	Detail of DSL	Name: M/s QAS International Address: Opposite Kings Mall, Near Wapda Town, GT Road, Tehsil and District, Gujranwala License No; 09-341-0134-103105D Validity: 13-03-2028. Status: License to sell drugs as a Distributor
	Name and address of Manufacturer	Manufacturer: 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	TRIVIDGECT 5% TRV solution for injection
	Diary No. Date of R&I & fee	Rs. 75,000/- (Slip No 5254213071)
	Composition:	Each ml contains: 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 with this strain.
<p>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.</p>	
<p>Decision: 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 food producing animals.</p>	

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