Decisions of Veterinary Drug Control Authority Applicable to Importers, Local Manufacturers of VMPs

S.N.	Decision	VDCA Reference No:
	Applicable to VMP Importers	
01	Obtaining following samples for each pack size for registration of new veterinary medicinal products (VMPs) *Obtaining 9 samples for registration of new VMPs with a volume/weight of less than 500ml/500g (exclude vaccines) *Obtaining 3 samples for registration of new VMPs with a volume/weight of 500ml/500g and above (exclude vaccines).	249.4.1
02	In order to encourage local production of VMPs, registration of similar products will be discouraged unless there is any specific reason. Registration of such product will not be considered, if the number of locally available similar products (both imported and locally manufactured) with same active ingredient, dosage form, strength and presentation is equal to 5.or above, at the time of application.	254.4.2 (Amended by 261.4.3)
03	Registration of veterinary test kits/devices was approved	258.4.1
04	Decided to revise the previous recommendation on remaining shelf life of imported VMPs at the time of clearance (60%); to reduce the same for products with more than 2 years of total shelf life (Minute No: 252.16.22 Decided to accept 60% remaining shelf life, with a minimum period of 6 months, Exception: 04 months for live Coccidia vaccines) at the time of clearance for all Veterinary pharmaceuticals was approved unless and otherwise any deviation with justifications for any special circumstances have been mentioned.	258.4.5
05	Registration procedure for Veterinary Devices (including Test Kits and Wound Care Products) was initiated. Guidelines, Applications and Checklists were circulated among relevant importers.	262.17.7
06	On submission of import free sale renewal dossiers, copies of the commercial invoices of the previous imports of the last 3 years should also be submitted with the dossier	267.4.2
07	Decided not to consider the user permit applications from small animal practitioners unless they are registered as private clinics at the DAPH. The decision will be executed since the 1st of January 2024	269.4.5
08	If the user permits are requested by private clinics, the submission of DAPH registration numbers of those is mandatory	273.4.2
09	When an importer is registered for importation of Biologicals for the first time, their storage facility with cold chain maintenance should be observed prior approval.	276.4.1
10	Dossier applications for Coccidia vaccines will be accepted for registration by the VDCA. The usage guidelines of the label/pack insert should be available in 3 languages (Sinhala, English, Tamil) with the clause “Do not use with Anticoccidials” upon application submission	279.4.2
11	Dossier applications for live Mycoplasma vaccines will be accepted for registration by the VDCA	279.4.3
12	Local agent’s logo/trade mark with the address should be printed on the VMPs upon releasement of them to the market	279.4.4

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Applicable to Local Manufacturers of VMPs		
13	Obtaining environmental certificate from central or provincial environmental authority for all local manufacturers of VMPs.	249.4.8
14	Decided to allow maximum 2 years for clinical trials and get the free sale registration for locally manufactured products	261.4.4
15	It was decided that a sample of the first batch of locally manufactured VMP should be submitted to the VDCA by each applicant after obtaining the manufacturing license for the same. Thus, it should be incorporated as a condition in the license issued.	262.4.2
16	In order to facilitate the local manufacturers of VMPS, with reference to Stability Test, it was decided, At first instance- Accelerated Stability Test also could be accepted At renewals - Real Time Stability Test is mandatory	262.4.4
17	Regarding the products approved for local manufacturing, before applying for free sales the manufacturer should submit a sample to VDCA for evaluation	267.4.1
18	Decided to get the information of pH value and TFM value of locally manufacturing veterinary soaps with both manufacturing and free sales application dossiers	269.4.1
19	The Calibration of machines and their correction factors should be available at the time of GMP inspection at the local VMP manufacturing sites	271.4.1
20	For the veterinary disinfectants requesting import free sale registration, the literature trials performed on same active ingredients and strengths (proven by the independent analysis reports) could be accepted	272.4.1
21	In the first registration the local manufacture free sales license will be issued for I year and in subsequent renewals it will be issued for 3 years.	274.4.1
22	The VDCA manufacture licenses of local VMPs that do not obtain free sales within 3 years from the issuance will be terminated by the committee	274.4.3
23	The contract manufacturers of VMPs should renew their certificates at the same time that the manufacturers renew their manufacture licenses of the original products. The contract products will be given a VDCA code which is related to the VDCA code of the original product.	274.4.4
24	The VDCA manufacture licenses of local VMPs that do not obtain free sales within 3 years from the issuance will be terminated by the committee. If more time is required in the production lines the manufacturer should request in writing to the VDCA with justifiable reasons.	275.4.1
25	Decided to prepare a new regulation for the contract manufacturing of Veterinary pharmaceuticals and Biologicals	277.4.1
Applicable to both Importers and Local Manufacturers of VMPs		
26	Pharmaceutical companies must have a consultant veterinarian with a Sri Lanka veterinary council registration number as appeared in the gazette, and he/she should endorse technical dossiers/documents.	249.4.5

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27	Proof of professional qualifications of consultants (other than veterinarians), producing relevant degree certificate to registrar, when the applications are submitted for new registrations.	249.4.6
28	Obtaining documentary evidence to prove the permission/authorization from his/her employer to work as a veterinary consultant in private sector pharmaceutical institutions when the consultant veterinarian is a government employee.	249.4.7
29	Nomination of one person for each pharmaceutical firm for communication with VDCA through emails and letters. Communications by other individuals than the nominated person will not be taken into consideration.	250.4.1
30	Prevention of the registration of new products having Flumequine and discontinuation of import recommendations and the renewal of already registered products having Flumequine as an active ingredient.	255.4.2
31	Decided to make the VCSL registration number of consultant veterinarians of pharmaceutical companies a mandatory requirement in their certifications of documents when submitted to VDCA	261.4.2
32	The decision taken on the number of VDCA licensed VMPs of similar category under 254.4.2 is amended releasing the barrier for locally manufacture of VMPs and hereafter be effective as follows. "In order to promote local manufacture of VMPs, it was decided to suspend new import free sale registration dossiers on VMPs except under special occasion, when there are 5/more than 5 imported products with the same active ingredient/s, dosage form and strength/s, irrespective of the number of locally manufactured VMPs of similar category (no such restriction for the application of local manufacture registration)."	261.4.3 (Amended by 266.4.1)
33	Decided that only maximum 3 months could be allowed as the lapse time for submission of renewals from the date of expiry of a particular VMP, but only in acceptable terms and occasions.	261.4.5
34	Decided not to approve the local manufacture of VMPs containing compounds with possible health hazards (ie; Malachite Green, Formalin) and to discontinue already licensed products having the same at the time of renewal.	262.4.1
35	It was decided that one sample of the most recent batch of each product for renewal of both 'Import and Free Sale' and 'Local Manufacture and Free Sale' should be submitted with the application	263.4.2
36	Decided to revise the decision at the minute number 261.4.3 as follows. *"In line with the government policy of promoting the local manufacturing, the import requests exceeding five numbers of VMPs having the similar active ingredients, strengths, dosage forms and the presentations of the registered locally manufactured VMPs, will not be accepted at the submission".*	266.4.1
37	If the strengths of the ingredients of a VMP are in the standard level and the applicant can submit its own and independent product analysis reports from an accredited analytical laboratory proving the composition as the same, it was decided to approve the product for free sales without submitting clinical efficacy trial reports	269.4.2
38	The requests for manufacturer/supplier changes of VMPs can be approved/rejected by the Registrar/VDCA	273.4.3
39	Approvals through appeals in free sales requests should only be approved for one year	274.4.2

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40	Regarding the free sale renewal applications, the VDCA will follow up the current procedure up to 1st January 2025. After 1st January 2025, if there are no imports/sales in the previous consecutive three years or delay in submission of the application more than 3 months, the product must be re-registered as a new product adhering to all the VDCA guidelines.	275.4.2
41	It was decided that VDCA could appoint subcommittees as needed to obtain expert opinions	277.4.2
42	If the application dossiers submitted to the VDCA contain incorrect information, the consultant signed for the local agent will be subjected to 6 month prohibition to appear as a consultant signing documents to be submitted to the VDCA	279.4.1