WHOLESALE DISTRIBUTION OF VETERINARY MEDICINAL PRODUCTS BY AUTHORISED WHOLESALE DISTRIBUTORS AND VETERINARY SURGEONS

SECTION I (*Wholesale Distributors*)

DEFINITIONS

1. Wholesale dealing in veterinary medicinal products

Any activity which includes the purchase, sale, import, export, or any other commercial transaction in veterinary medicinal products, whether or not for profit, except for:

(*a*) the supply by a manufacturer of veterinary medicinal products manufactured by himself, or,

(*b*) retail supplies of veterinary medicinal products by persons entitled to carry out such supplies in accordance with Regulation 59 of S.L 437.47

2. GDP REGULATION

Commission Implementing Regulation (EU) 2021/1248 of 29 July 2021 as regards measures on good distribution practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

3. S.L 437.47

Subsidiary Legislation 437.47 Veterinary Medicinal Products Regulations of 12th November, 2004 as amended by Legal Notice 469 of 2004, Legal Notices 82 of 2006, and 23 and 360 of 2009, 179 and 470 of 2021

4. Regulation (EU) 2019/6

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11th December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC

5. VMPs

Veterinary Medicinal Products

1. WHOLESALE DISTRIBUTION AUTHORISATIONS

1.1	Requirement for a Wholesale distribution authorisations for all persons who distribute VMPs	*Article 99 of Regulation (EU) 2019/6*
1.2	Application for Wholesale distribution authorisations https://agrikoltura.gov.mt/en/nvl/Pages/openingNewRelatedBusiness.aspx https://www.servizz.gov.mt/en/Pages/Environment_-Energy_-Agriculture-and-Fisheries/Animal-Welfare/Veterinary-Services/WEB2447/default.aspx	*Article 100 of Regulation (EU) 2019/6*
1.3	Obtain VMPs only from holders of a manufacturing authorisation or from other holders of a wholesale distribution authorisation.	*Article 101(1) of Regulation (EU) 2019/6*
1.4	Distribute VMPs only to persons permitted to carry out retail activities in a Member State	*Regulation 60(13) of S.L 437.47, Regulation 58(4) of S.L 437.47*
1.5	Comply with the good distribution practice for veterinary medicinal products (GDP REGULATION) L_2021272EN.01004601.xml (europa.eu)	*Article 100(5) of Regulation (EU) 2019/6*

2. RESPONSIBLE PERSON (RP)

2.1	Services of Responsible Person (RP) employed with establishment	Article 100 (2) (a) and 101 (3) of Regulation (EU) 2019/6
2.2	Job description, responsibilities and tasks of the Responsible Person	*Article 8 of GDP*

		REGULATION
2.3	Copies of his/her qualification and further training available on the premises	*Article 8 of GDP REGULATION*
2.4	Working schedule of the Responsible Person. List any particular days and time RP is on the premises.	*Article 8 of GDP REGULATION*
2.5	Change in the contact details of the Responsible Person to ensure that the RP is reachable at any time	*(Article 8 of GDP REGULATION*

3. OTHER PERSONNEL AND TRAINING

3.1	Written individual job descriptions, responsibilities and tasks of all personnel involved in all stages of the wholesale distribution of VMPs	*Article 9 of GDP REGULATION*
3.2	Records of training that auxiliary personnel received (including both initial and continuing training	*Article 10 of GDP REGULATION*

4. VMP STORAGE, PREMISES & TRANSPORTATION

	A. Storage of VMPs (including temperature and environmental control)	
4.01	Area where VMPs are stored clearly demarcated	*Article 12 of GDP REGULATION*
4.02	VMPs stored separately from other products	*(Article 24 of GDP REGULATION*
4.03	VMPs in storage area appropriately stored (i.e. in original boxes, fully labelled, no loose blister, no mixed batches) and in organised fashion	*Article 24 of GDP REGULATION*
4.04	Presence of unlicensed VMPs present	*Chapter I of Title III of S.L. 437.47*
4.05	Containers of VMPs bear labels with sufficient information on identification of contents, handling and storage	*(Article 38 of GDP*

	requirements, precautions and in accordance with the local Regulations	*REGULATION for VMPs & Title II & Title III of S.L. 437.47*
4.06	Adequate date checking procedures in operation	*Article 24 of GDP REGULATION*
4.07	Appropriate stock rotation and first expiry/first out (FEFO) principle	*Article 24 of GDP REGULATION*
4.08	VMPs storage areas clean, free from contaminants and dry	*(Articles 12 & 13 of GDP REGULATION*
4.09	Stored samples of VMPs	*Article 32, Article 119, 4B of GDP REGULATION*
4.10	Case where wholesale dealer operates a veterinary pharmacy. The two storage facilities that should be kept separate and clearly demarcated	*Article 12 of GDP REGULATION*
4.11	VMPs stored at appropriate temperature, light and humidity levels	*Article 13 of GDP REGULATION*
4.12	Records of temperature and humidity levels in the storage area that are recorded on a daily basis.	*Article 13 of GDP REGULATION*
4.13	Initial temperature mapping exercise to locate the temperature monitoring equipment	*Article 13 of GDP REGULATION*
4.14	Storage of VMPs off the floor in storage areas and cold rooms	*Article 24 of GDP REGULATION*
4.15	Refrigerator or cold room	*Article 12 of GDP REGULATION*
4.16	Refrigerator used solely for VMPs requiring a storage temperature of 2-8 °	*Article 12 of GDP REGULATION*
4.17	VMPs in the refrigerator or cold room appropriately stored (i.e. in original boxes, fully labelled, no loose blister, no mixed batches) and in organised fashion	*Article 24 of GDP REGULATION*
4.18	Initial temperature mapping exercise carried out in the refrigerator/cold room before use in order to locate the temperature monitoring equipment	*Article 13 of GDP REGULATION*
4.19	Temperature of the refrigerator/cold room recorded on a daily basis and their records	*Article 13 of GDP REGULATION*

4.20	Refrigerator clean and defrosted and their records	*Article 14 of GDP REGULATION*

	B. Premises	
4.21	Variation of premises	
4.22	Approval of variations	
4.23	Precautions to prevent unauthorised persons to enter storage areas	*Article 12 of GDP REGULATION*
4.24	Pallets that are kept in a good state of cleanliness and repair	*Article 12 of GDP REGULATION*
4.25	Receiving and dispatch bays which are clearly demarcated	*Article 12 of GDP REGULATION*
4.26	Receiving and dispatch bays adequately separated and weatherproof	*Article 12 of GDP REGULATION*
4.27	Area for the unpacking of goods in warehouse	*Article 12 of GDP REGULATION*
4.28	Demarcation of expired, recalled and quarantined areas clearly away from other VMPs. Expired stock separated from other stock	*Article 12 & 24 of GDP REGULATION*
4.29	Clean, dustproof and impermeable flooring and walls	*Article 12 of GDP REGULATION*
4.30	Regular cleaning schedules	*Article 12 of GDP REGULATION*
4.31	Pest control programme	*Article 12 & 18 of GDP REGULATION*
4.32	Pest control records	*Article 12 & 18 of GDP REGULATION*
4.33	Trap sites demarcated on premises	*Article 12 & 18 of GD*
4.34	Are all points of access to the premises suitably served against pest entry	*Article 12 & 18 of GDP REGULATION*
4.35	Warehouse connections with premises used for activity other than storage, or supply of VMPs	*Article 12 of GDP REGULATION*

4.36	Supply of wholesome drinking water	Inspired by *Articles 11 and 18 of GDP REGULATION*
4.37	Controlled water temperature	Inspired by *Articles 11 and 18 of GDP REGULATION*
4.38	Sink in working order	Inspired by *Articles 11 and 18 of GDP REGULATION*

	C. Storage of Narcotics and Psychotropic substances	
4.39	Narcotics and psychotropic substances	*Articles 12, 22 & 29 of GDP REGULATION*
4.40	Lock and key storage facilities	*Articles 12, 22 & 29 of GDP REGULATION*
4.41	Unique key kept by the Responsible Person	*Articles 12, 22 & 29 of GDP REGULATION*

	D. Hygiene of Personnel	
4.42	High levels of personal hygiene and sanitation by personnel	*Article 11 of GDP REGULATION*
4.43	Appropriate clothing relevant to the activities carried out by personnel	*Article 11 of GDP REGULATION*

	E. Waste disposal	
4.44	Accumulation of pharmaceutical and non-pharmaceutical waste	*Article 12, 18 & 25 of GDP REGULATION*
4.45	Procedures in place for safe disposal of pharmaceutical and non-pharmaceutical waste	*Article 12, 18 & 25 of GDP REGULATION*
4.46	Procedures of waste disposal in line with the local Regulations	*Article 12, 18 & 25 of GDP REGULATION; Regulation 87of S.L.*

		437.47
4.47	Training of staff to deal with waste and is appropriate protective equipment available (including gloves, overalls	*Article 10 of GDP REGULATION*

	F. Transport	
4.48	Transport vehicles fit for transportation of VMPs	*Article 37 of GDP REGULATION*
4.49	Transport of VMPs requiring refrigeration	*Article 10 of GDP REGULATION*
4.50	Validation of transport procedure under temperature controlled conditions	*Article 10 of GDP REGULATION*
4.51	Precautions taken when outside temperature is above 24 °C	*Article 10 of GDP REGULATION*

	G. Toilet facilities	
4.52	Toilet with flushing apparatus	Inspired by *Articles 11 and 18 of GDP REGULATION*
4.53	Toilet and flushing clean and in good working order	Inspired by *Articles 11 and 18 of GDP REGULATION*
4.54	Water, soap, nail brushed and hand drying facilities	Inspired by *Articles 11 and 18 of GDP REGULATION*
4.55	Toilet used as storage area	Inspired by *Articles 11 and 18 of GDP REGULATION*

5. QUALITY SYSTEM, PROCEDURES & RECORD KEEPING

	A. Quality System & Procedures	
5.1	Quality System	*Article 4 of GDP REGULATION*
5.2	Approval of the Quality System by Responsible Person approved the Quality System	*Article 8 of GDP REGULATION*

5.3	Organisational structure/ chart	*Article 4 of GDP REGULATION*
5.4	Management commitment statement & responsibilities	*Article 4 of GDP REGULATION*
5.5	Role, responsibility and duties of RP	*Article 8 of GDP REGULATION*
5.6	Training plan of personnel	*Article 10 of GDP REGULATION*
5.7	Line to Authorisation/Registration/MA Holder	*Article 20 of GDP REGULATION Regulations 4-12,58 of S.L. 437.47; Articles 5(6), 58 & 116 of Regulation (EU) 2019/6)*
5.8	Procedure of reporting (line of communication) to Authorisation/Registration/MA Holder	*Article 20 of GDP REGULATION ; Regulation 58 of S.L. 437.47; Article 100 of Regulation (EU) 2019/6)*
5.9	Procedure for verification of eligibility and approvals of suppliers & customers	*Articles 21 & 22 of GDP REGULATION*
5.10	Procedures dealing with registrations/authorisations, extensions and withdrawals of VMPs distributed locally	*Article 20 of GDP REGULATION for VMPs; Regulations 5(6), 42-45, 48, 49, 51, 52 & 116 of Regulation (EU) 2019/6; Regulations 4(2) & 7 of S.L. 437.47 of 2021;*
5.11	Procedure to carry out self-audits & RP reports thereof	*Articles 6, 8, 35 & 36 of*

		GDP REGULATION
5.12	Reports of external assessments (if any)	*Article 6 of GDP REGULATION*
5.13	Procedure for documenting and investigating deviations	*Articles 4, 8 & 36 of GDP REGULATION*
5.14	Reports and corrective actions of deviations (if any)	*Articles 4, 8 & 36 of GDP REGULATION*
5.15	Procedure for appropriate corrective and preventive actions (CAPA) following audits and complaints	*Articles 4, 8, 29 & 36 of GDP REGULATION*
5.16	Management of outsourced activities (if any)	*Article 5 of GDP REGULATION*
5.17	Procedure for investigating and resolving complaints & records/reports thereof	*Article 29 of GDP REGULATION*
5.18	Procedure for handling returned VMPs	*Article 30 of GDP REGULATION*
5.19	Procedures and documentation for tracing defective/recalled VMPs	*Article 32 of GDP REGULATION*, Article 100(2) (C)of Regulation (EU) 2019/6, Regulation 58(3A) of S.L 437.47
5.20	Procedures for handling falsified VMPs	*Article 31 of GDP REGULATION*
5.21	Procedure dealing with cleaning	*Article 18 of GDP REGULATION*
5.22	Procedures dealing with expired items and waste disposal	*Articles 18 & 25 of GDP REGULATION*
5.23	Procedure for pest control (vermin plan)	*Article 18 of GDP REGULATION*

5.24	Procedure for temperature mapping of storage areas, and refrigerators/cold rooms and reports thereof	*Article 13 & 14 of GDP REGULATION*
5.25	Procedure for maintaining, checking and recording storage conditions of storage areas and refrigerators/cold rooms (including calibration and maintenance of equipment)	*Articles 13, 14, 16 & 18 of GDP REGULATION*
5.26	Procedures covering date checking stock rotation	*Articles 18 & 24 of*
5.27	Procedure of handling VMPs covering receiving, picking of correct VMPs and dispatching	*Articles 12, 18, 23, 24, 26, 27*
5.28	Transportation procedure of VMPs including cold-chain VMPs	*Articles 37, 38 & 39 of GDP REGULATION*
5.29	Validation procedure of transportation system and report thereof	*Articles 16, 37, 38 & 39*
5.30	Results of the validation of the transportation procedure *(Article 16 of GDP REGULATION for VMPs)*	

	B. Record keeping	
5.31	Registers of incoming and outgoing transactions	*Regulation 58(3) of S.L. 437.47*
5.32	Keep detailed records	*Article 101(7) of Regulation (EU) 2019/6*
5.33	Information of incoming and outgoing registers/transactions	*Regulation 58(3) of S.L. 437.47*
5.34	Annual audit to compare incoming and outgoing VMPs	*Article 24 of GDP REGULATION & Regulation 58(3) of S.L. 437.47)*
5.35	Records of customers containing address, phone numbers and means of communication inside and outside working hours (in case of recalls)	*Article 32 of GDP REGULATION*
5.36	Direct supply of VMPs to the end user	*Article 101 of Regulation (EU) 2019/6; Regulation 58A of S.L. 437.47 of*

		2021).
5.37	Sales and purchase register for drugs listed in the Second Schedule of the Drugs (Control) Regulations and drugs falling under the Dangerous Drugs Ordinance	*Article 12, 22 & 29 of GDP REGULATION*
5.38	Records of expired goods	*Article 25 of GDP REGULATION*
5.39	Records of breakages and spillages	*Article 25 of GDP REGULATION*
5.40	Records of waste disposal	*Article 25 of GDP REGULATION*
5.41	Records of daily storage conditions	*Articles 12 & 24 of GDP REGULATION*
5.42	Records of maintenance and calibration of equipment used to maintain and record storage conditions kept	*Article 14 of GDP REGULATION*
5.43	Records of distribution of VMP and samples	*Article 32 of GDP REGULATION; Regulation 4B of S.L. 437*
5.44	Records of recalled VMPs and/or reports of adverse reactions	Regulation 4(6) of S.L 437.47

SECTION II (*Veterinary Surgeons*)

By way of derogation from Article 106(1) of Regulation (EU) 2019/6 (Marketing Authorisation) , where there is no authorised veterinary medicinal product in a Member State for an indication concerning a non-food-producing animal species (Article 112) or a food producing species (Article 113) or food-producing aquatic species (Article 114) the veterinary surgeon responsible may, under his or her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animals concerned with veterinary medicinal product or even medicinal product in order of decreasing priority. One of the choices is for the veterinary surgeon to procure veterinary medicinal products from other countries.

As per regulation 10(9) and 11(11) of Subsidiary Legislation 437.47 when the veterinary surgeon has recourse to these provisions (9) When a veterinary surgeon has recourse to the provisions the activity undertaken by the veterinary surgeon is excluded from the scope of the definition of wholesale distribution. Still, in order to ensure and preserve the quality of the products the veterinary surgeon should follow a number of basic rules that are inspired from the Good

Distribution Practice ‘s principles. These include the guidelines in the table below. Although the guidelines are intended to be limited to the requirements that the veterinary surgeon should have to procure veterinary medicinal products directly from other countries, some of the guidelines overlap with the requirement that veterinary surgeons should comply with when they perform retail activity. This is understandable as to get the veterinary medicinal products from any source the veterinary surgeon should be in a position to ensure that their quality is preserved.

In the latter case there are already legal obligations for all retailers (including veterinary surgeons) as per Article 103 (Retail of veterinary medicinal products and record keeping) and Article 104 (Retail of veterinary medicinal products at a distance). Subsidiary Legislation.437.106 Private (Veterinary Establishments) contains also provisions related with the handling of veterinary medicinal products. These are regulations 8(1)(d), 8(2)(a), 9(1)(f), 9(3)(f), 10(2)(e)(f) and 10(3)(j). These legal provisions are mainly on labelling, storage conditions and record keeping (minimal requirements)

It is to note that the ‘cascade articles’ (112, 113 and 114) do not consider the issue of pricing. That is, if a product is available in Malta but can be obtained at a cheaper price by the veterinary surgeon from another country these legal provisions do not apply.

Special provisions also apply for immunological veterinary medicinal products as per Article 110 of Regulation (EU) 2019/6. The safeguards associated with this provision is to minimise the risk of introducing new pathogens in Malta though immunological products and to report any findings of possible introduction or re-introduction of pathogens in the EU to the EU Commission.

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