Guidance Document on the Provision of e-veterinary-dispensary Services

This document utilizes key principles from existing guidelines and standards for the supply and delivery of medications for human patients and for e-pharmacies[1] licensed by the Health Sciences Authority (HSA), which have been adapted to the veterinary and animal sector in Singapore.

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The National Parks Board ("NParks") accepts no liability for any errors or omissions in this document, or for any action / decision taken or not taken as a result of using this document. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

1. Scope

1.1. The scope of online veterinary dispensary services (referred to as "e-vet-dispensary" subsequently in this document) does not allow the supply of controlled drugs.

1.2. It also does not apply to the following: (a) wholesale supply of medications intended for use in animals; and (b) dispensing and supply of medications by veterinarians for animals under their care, for example, by veterinary telemedicine providers and mobile veterinary services.

2. Definitions

2.1. "e-vet-dispensary" refers to any electronic means of providing dispensary services for health products intended for use in animals, which include, but are not limited to, the following:

   a. Allowing consumers to purchase or submit purchase orders for health products intended for use in animals;
   b. Interpreting, evaluating and validating prescriptions issued by veterinarians for the use of medications in animals;
   c. Labelling, dispensing and supplying medications for use in animals according to instructions provided by the prescribing veterinarian

2.2. "Poisons" refer to substances specified in the Poisons List of the Poisons Act (Cap. 234).

2.3. "Therapeutic Product" refers to any substance as defined in the First Schedule to the Health Products Act (Cap. 122D).

2.4. "Veterinarian" is a person who is licensed under section 53 of the Animals and Birds Act (Cap. 7) to treat, vaccinate or inoculate any animal or bird.

[1] e-pharmacies are online pharmacy services provided by licensed pharmacies in Singapore using a secured online platform. HSA regulates such services by ensuring compliance to the HSA Guidance Note on Supply of Registered Therapeutic Products through e-pharmacy.

3. General

3.1. The e-vet-dispensary service should be operated in Singapore and hosted on a Singapore domain name.

3.2. The e-vet-dispensary should be hosted on an independent website and not on any third-party marketplace.

3.3. Prescription veterinary medicines and non-prescription/ancillary products should be hosted on different pages. A separate and dedicated subdomain/subdirectory should be used to host the sale of prescription veterinary medicines.

3.4. The term 'pharmacy' should not be used for the purpose of veterinary dispensary services.

3.5. The retail supply of products must comply with the legal requirements stipulated in the relevant legislation, such as the Health Products (Therapeutic Products) Regulations, Poisons Act and Rules, Medicines Act, and Misuse of Drugs Act and Regulations.

3.6. Only a veterinarian can provide advice on the treatment of animals, including an animal's health condition and suitability of the use of medications in an animal.

3.7. Veterinarians in e-vet-dispensaries are not permitted to issue prescriptions to animals that they have not attended to or examined, nor modify a prescription without prior consultation with the prescribing veterinarian.

3.8. All operational procedures and protocols required for the provision of e-vet-dispensary services should be clearly mapped out and made available to regulatory authorities for evaluation.

3.9. Any outsourced activities or services should meet the requirements for the e-vet-dispensary operations. There should be regular audits by the e-vet-dispensary on the competency and work of the outsourced service provider.

3.10. A veterinarian must be appointed to oversee the overall e-vet-dispensary service operations. The veterinarian is overall responsible for the services of the e-vet-dispensary, including the proper storage, packaging, and supply of products.

4. Security and Integrity of Information Technology (IT) System

4.1. The infrastructure of the e-vet-dispensary, including all Information Technology (IT) hardware (e.g. computers, scanners, printers, fax machines) and software (e.g. dispensing software, inventory management systems) should be appropriately set up such that the security and integrity of the system are maintained.

4.2. A closed-loop system to transmit the e-prescription directly and securely from the prescribing veterinarian to the e-vet-dispensary should be used (refer to **Annex A**). Alternatively, the e-vet-dispensary should have protocols and procedures for validating prescriptions and dispensing medications if prescription is transmitted to the e-vet-dispensary by the customer.

4.3. The IT system should be capable of generating an audit trail to easily detect changes made to electronic records.

4.4. The IT system should be capable of easily tracing activities and attributing the authorised personnel to the execution of dispensary activities.

4.5. There should be proper controls on storage and backup of data.

4.6. The IT system must have measures to ensure the privacy and security of all electronically transmitted patient and client information and that patient and client confidentiality is not compromised. All such information captured during operations must be maintained in accordance with current regulations governing personal data.

4.7. e-vet-dispensaries must undertake cybersecurity measures to prevent any loss of personal data, medication records and other sensitive information.

4.8. The IT system must have measures that prevent unauthorised issuance of prescriptions, fraud or forms of abuse involving prescription of medications.

5. Documentation and Records

5.1. There should be written procedures for all aspects of the e-vet-dispensary service operations, including but not limited to, processing and validating prescriptions, personnel training, stock storage, stock handling and control, deliveries, labelling, disposal of products, addressing product complaints, product recall, counterfeit/adulterated/unwholesome products, returned products, audits and self-inspection, and IT systems security. All documents should be clear and unambiguous and produced for AVS' inspection as required.

5.2. Documents should be reviewed regularly and be kept up to date. When a document has been revised, a system should exist to prevent the use of the superseded version.

5.3. Adequate records on inventory movement such as receipt and distribution, returned products, recalled products etc, should be kept and should contain sufficient details to provide traceability of the product such as product name, batch numbers, dates of transaction and quantities received/supplied. Documents should be retained for a duration of 3 years and be readily retrievable.

5.4. There should be adequate controls to avoid uncontrolled document changes after approval. Any alteration made to the entry should be signed and dated, and the alteration should permit the reading of the original information.

5.5. Where used, e-prescriptions should contain a secure and encrypted electronic signature of the prescribing veterinarian that is verifiable by the e-vet-dispensary to allow authentication, without which e-prescriptions should be verified with the prescribing veterinarian or veterinary clinic (refer to Annex A).

5.6. Any prescription should contain the following information at minimum to be considered as valid:

a. Date of issue and time period in which the prescribed medication may be supplied
b. Name and signature of prescribing veterinarian, with the signature following the format as described in Point 5.5. for e-prescriptions
c. Address of veterinary clinic/business
d. Details of the identity of the person to whom the prescription is issued, including the person's name, contact details, and identity card, passport or other identification document number
e. Details that enable the identification of the animal or group of animals for which the prescription is intended for. For example: breed, species, address of the premises in which the animal(s) is kept, (for individual animals) name, microchip number or similar identification devices, (for group of animals) batch or house number, or similar identification devices

f. Details of the medication including the name or active ingredient(s), strength and formulation of the product, quantity prescribed, the frequency of dosage, the instructions as to the administration of the medication, the drug withdrawal period for production animals (if applicable) and any necessary warnings
g. Where the prescribing veterinarian intends for the prescription to be repeated, an indication of the number of times, and the time period between which, the prescribed medication may be supplied
h. A declaration that the prescription is "For animal treatment only"

5.7. The prescription once issued, should not be amended, except by the prescribing veterinarian who issued it.

5.8. For hardcopy prescriptions given by the prescribing vets to pet owners for the purpose of obtaining the medications from e-vet-dispensaries, the original signed prescription needs to be presented for verification of its authenticity upon delivery of the products. Should it not be presented for verification, the products cannot be handed over to the customer.

5.9. The e-vet-dispensary must ensure that the hardcopy prescription is not re-used by:
a. Collecting the original signed single-use prescription, or
b. Indicating by means of official company stamp, on the original signed repeat prescription, that part of this prescription has been filled. An image will be taken of this as verification.

5.10. All e-prescriptions, physical hardcopies of single-use prescriptions, as well as soft copy images of repeat prescriptions filled must be kept for a period of 3 years.

6. Handling, Storing, Labelling, Packing and Delivery of Medication

6.1. e-vet-dispensaries are encouraged to follow HSA's Good Distribution Practice (GDP) requirements for the handling and storage of medications.

6.2. Medications must be handled and stored with appropriate security measures, in clean, hygienic, and neat storage areas with the appropriate environmental conditions (e.g. temperature, humidity, etc).

6.3. e-vet-dispensaries are encouraged to comply with the requirements in the Singapore Standard on Guidelines for the Supply and Delivery of Medication (SS 644).

6.4. Medications must be properly packed to protect the products from heat, light and moisture to prevent deterioration.

6.5. Medications to be supplied should be labelled with adequate details on its intended recipient and used in accordance with the prescription issued by the veterinarian. The details include, but are not limited to:
a. a declaration that the product is "For animal treatment only";
b. date of supply;
c. product name;
d. product quantity;
e. animal's details;
f. details of the person to whom the medication is supplied; and
g. dosing instruction, including dose, dosing frequency, route of administration and indication(s).
h. Cautionary labels (if necessary)

6.6. Medications should be transported in such a way that:
    a. their identification and label are not lost;
    b. they do not contaminate, and are not contaminated by, other products or materials;
    c. adequate precautions are taken against spillage, breakage, tampering or theft; and
    d. they are secure and not subject to unacceptable degrees of heat, cold, light, moisture or other adverse influence, nor to be attacked by microorganisms or pests.

6.7. Adequate precautions should be taken to ensure that deliveries are made directly to the intended recipients, such as verification of identities, and advanced notice and documentation of alternate authorised recipients. Deliveries containing medications are not permitted to be left at unattended locations.

7. Disposal

7.1. Destruction of products should be carried out in accordance with the national legislative and regulatory requirements and with due consideration to protect the environment.

7.2. Adequate records of disposed products should be kept, including details such as amount and date disposed, and name of personnel responsible for the disposal.

8. Product issues

8.1. e-vet-dispensaries should have protocols in place for documenting, promptly investigating and following up on issues such as product complaints, suspected adverse effects, product defects, product recalls, returned products, and known or suspected counterfeit products.

9. Internal audits

9.1. Regular internal audits should be conducted to monitor the implementation of e-vet-dispensary services for compliance with in-house written procedures, relevant guidance notes and legislative requirements.

9.2. Corrective and preventive actions (CAPA) should be taken and followed up for continual improvement. Any CAPA taken should be sufficiently documented and include information such as details of the event or incident, personnel involved in the event or incident, personnel overseeing the institution of the actions, dates, and details of any implicated products such as product name and batch number.

9.3. There should be ongoing review of incident/near-misses reports and outcomes related to the e-vet-dispensary services and operations, including the outsourced services.

10. Advertisement

10.1. Advertising refers to the publication, dissemination, or conveyance of any information for the purpose of promoting, whether directly or indirectly, the sale or use of that product by any means or in any form.

10.2. Advertising of prescription medications is not permitted.

10.3. Advertising of non-prescription medications must not:

a. Make any false or misleading claims or representations
b. Make unsubstantiated claims
c. Make claims that mislead by emphasis, contrast or omission with regard to the safety, quality or efficacy of the medication
d. Make claims that give rise to any unrealistic expectations regarding the effectiveness of the medication
e. Make claims that cause fear, alarm or distress to the public
f. Encourage inappropriate or excessive use of the medication
g. Suggest guaranteed results without side effects
h. Encourage incorrect use or self-treatment of serious diseases and discourage from seeking a licensed veterinarian's advice
i. Falsely claim any endorsement by public authority
j. Include endorsements or recommendations by any veterinary professional or a person of celebrity, social or professional status
k. Use the names or logos of the National Parks Board or the Animal and Veterinary Service
l. Offer refunds, in full or partial amounts, to users of the medication

Annex A: Diagram illustrating supply chain of e-vet-dispensary