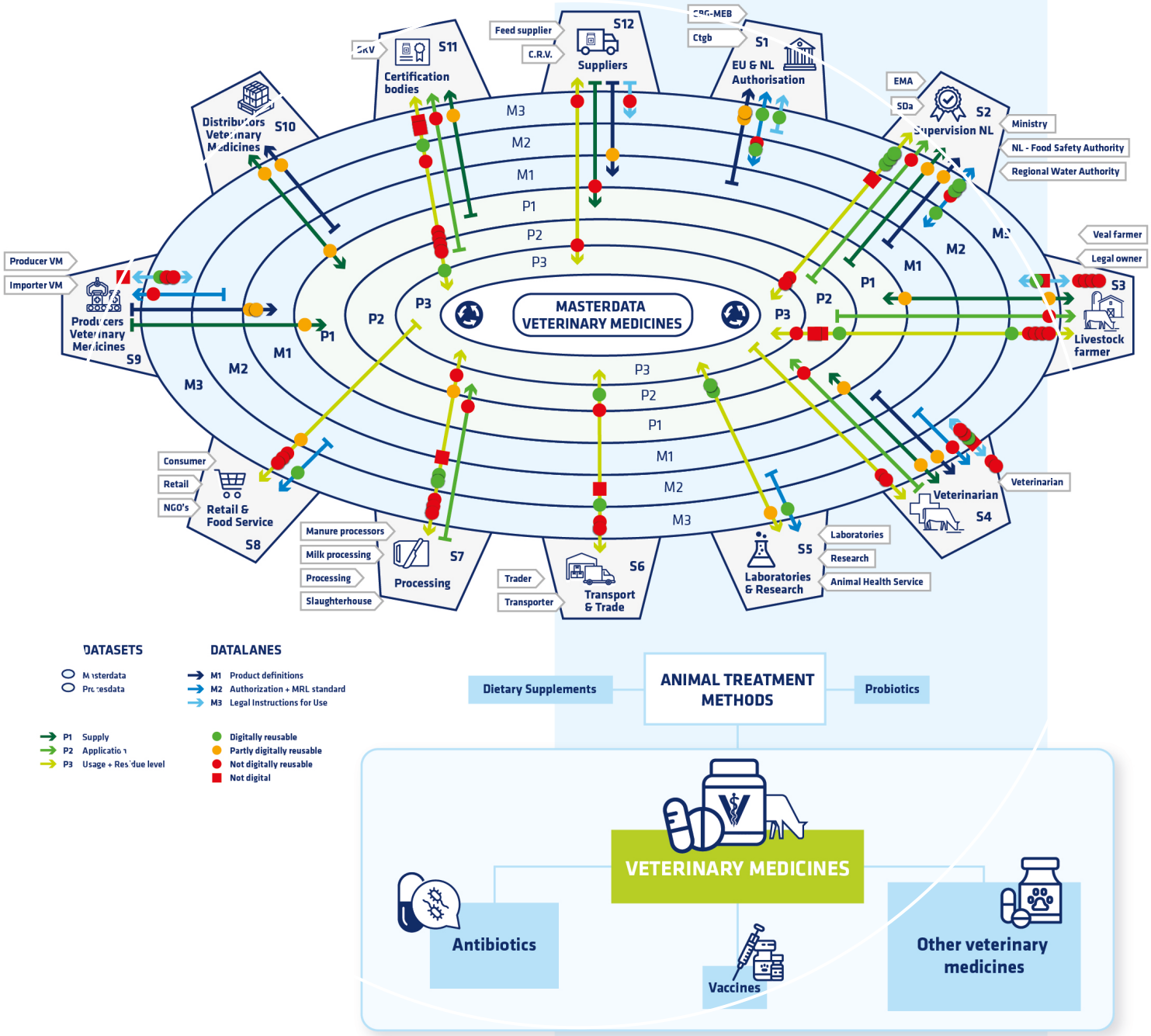

Trusted Source pilot Fresh Upstream

Domain exploration of veterinary medicine information

J.W.P.M. (Jan) Vogels, J. (Johan) den Engelse

PUBLIC

WAGENINGEN
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Domain exploration of veterinary medicine information

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Foreword

In the *Trusted Source* project, several pilots are looking at the availability, reliability, and completeness of information in various (agricultural) chains. The Fresh Upstream pilot has been investigating data related to veterinary medicines. The assignment was to conduct a domain exploration, with a particular focus on master data. The basic question was what information is readily available and in what systems or messages this information appears.

As a basis for this domain exploration, several so-called 'awareness workshops' were held with alternating representation from the calf and pig chain. During these workshops, an attempt was made to paint as complete a picture as possible of the data-providing and data-carrying actors within the sectors. In addition, the data flows themselves were also mapped in a so-called information roundabout (Figure 19). Several interviews were conducted in addition to these workshops.
We wish to especially thank interviewees Frank Verheijen, Marijn Poldermans, Hans Lunenborg, Rik Vlemminx, Bart Peijnenburg, Jan van Balkom, everyone who participated in the awareness workshops, and FIDIN (Fabrikanten Importeurs Diergeneesmiddelen Nederland - Dutch Veterinary Medicines Suppliers and Producers).

Summary

The *Trusted Source* project examined the provision of information on veterinary medicines. How can the information, especially from producers of veterinary medicines and pursuant to legislation, reach the users of this information as well and unambiguously as possible? These users are livestock farmers, veterinary medicine producers, distribution chains and trade entities, and indirectly consumers. The fact that there is no uniform legislation for registration of veterinary medicines throughout Europe, let alone the rest of the world, makes it a hugely complicated and time-consuming task to map it out completely.[1] Therefore, for the purposes of this project, we have limited ourselves to data exchange for the Netherlands and legislation within the European Union and the European Economic Area.

1.1 Master data

Master data (static data) on veterinary medicines mainly concern information on their registration and instructions for use. This information should be registered and accessible in only one place to increase digital quality and reusability.
This report shows that the landscape in the field of master data is highly fragmented, especially in the European field. For instance, the European initiatives EMA Medicines database, EMA's veterinary medicine database, and Veterinary Mutual Recognition Information (VMRI) Product Index database all represent information on veterinary medicine registrations. The latter two were merged into the Union Product Database on 28 January 2022. Some of the medicines from the EMA Medicines database are (manually) copied into the *Diergeneesmiddeleninformatiebank* (hereinafter referred to as the Veterinary Medicines Information Bank) (registrations for the Dutch market). To improve this, these two databases should be linked in order to avoid errors and delays.
Within the master data, we can make a distinction between registrations of veterinary medicines (the medicines *themselves*) and consumer units of these medicines (the articles/packaging of the medicines as they are traded, for example with a barcode/GTIN). Registrations of veterinary medicines in the Netherlands are found in the Veterinary Medicines Information Bank and consumer units in the Branchecodetable (source file, also for the FIDIN Online Repertorium, a website that draws information from the Branchecodetable). Thus, the Veterinary Medicines Information Bank does not contain GTINs. The data from the aforementioned sources should be linked to create a single central system. The Branchecodetable is an existing initiative in this area, but does not cover the entire Dutch market. It is recommended that the Veterinary Medicines Information Bank be expanded with consumer units or added to the Branchecodetable with the remaining portion of consumer units available on the market. It would also be possible to link up with the G-Standaard for consumer units of *human* medicines on the Dutch market by extending it to veterinary medicines. In the European field, such a system does not yet exist for veterinary medicines, but a system is in the making for human medicines. Veterinary medicines should be linked to this initiative.
The information in the systems is still mostly text-based, as this report shows. The switch must be made from free text fields to default values according to code lists, preferably shared as widely as possible.
On the technical side, the main challenge is to provide the existing systems with an API (Application Programming Interface) so that the information is directly digitally accessible. Only the FIDIN Repertorium (and thus indirectly the Branchecodetable) has recently introduced an initial version of an API.
So, in summary, steps can be taken in linking data sources, standardising information components, and providing APIs. To this end, various agencies such as the EU, CBG (Medicines Evaluation Board), and FIDIN will need to start working together.

[1] Regulation 2019/6 has been in effect since 28 January 2022. This regulation is binding on all member states. This will further harmonise the process for granting marketing authorisations. The old Directive 2001/82 left more room for national interpretation.

1.2 Process data

Process data for veterinary medicines concerns in particular supplies of medicines to and by veterinarians and use of medicines by veterinarians and livestock farmers. Data on resource deliveries is organised per animal sector and can be processed electronically through VETmessage messaging between the farm management systems and the central sector databases.
For process data on the use of veterinary medicines, registration on the use of antibiotics and vaccines is centrally organised. Since 2008, legislation has been in place to greatly limit and regulate the use of antibiotics to curb the danger of resistance. To protect human health, there must be a valid reason to deviate from a first-choice medicine in livestock production. In particular, the registration is used for benchmarking the prescribing behaviour of veterinarians and use among livestock farmers. The use of second-choice and especially third-choice products has decreased dramatically since the start of registration and benchmarking.
Registration of other products is organised differently. Here waiting periods must be adhered to when slaughtering the animals. Use of pesticides in the last 5 weeks before slaughter must be recorded and passed on to the processing facility using Food Chain Information (FCI) forms. In the case of antibiotics, this involves a 60-day period.
In addition to these legal regulations, there are various initiatives to register veterinary medicine use within the various animal sectors.

1.3 Recommended Steps

By means of APIs, both the Veterinary Medicines Information Bank of CBG and the EMA Medicines database should be disclosed. This will also allow the linking of Veterinary Medicines Information Bank of CBG to EMA Medicines to be completed.
FIDIN Online Repertorium is a source of information for users of veterinary medicines which can be accessed through GTIN. Unfortunately, this source does not cover all veterinary medicines on the Dutch market. FIDIN Online Repertorium now has an initial version of an API.
For European veterinary medicine products, align with the current development of a European system for human medicines.
One general recommendation is to use the GLN for the purpose of identifying production sites and for better (international) traceability of products. It is also important to use other standards such as GTIN and dispatch messages when trading the products.
By expanding the FIDIN Online Repertorium to include logistics data fields such as packaging dimensions (length, width, height and weight), the added value of the database can be greatly increased.
Finally, further standardisation is needed in the area of recording administration of veterinary medicines that is in line with the recording of antibiotic use.

2 Introduction

It is important for all links in the food chain to have the correct product information for veterinary medicines. This includes, for instance, information on the marketing authorisation of the veterinary medicine including use and safety instructions. A veterinarian or livestock farmer records the medicines supplied to him in his practice management system (PMS) and business management system (BMS), respectively.

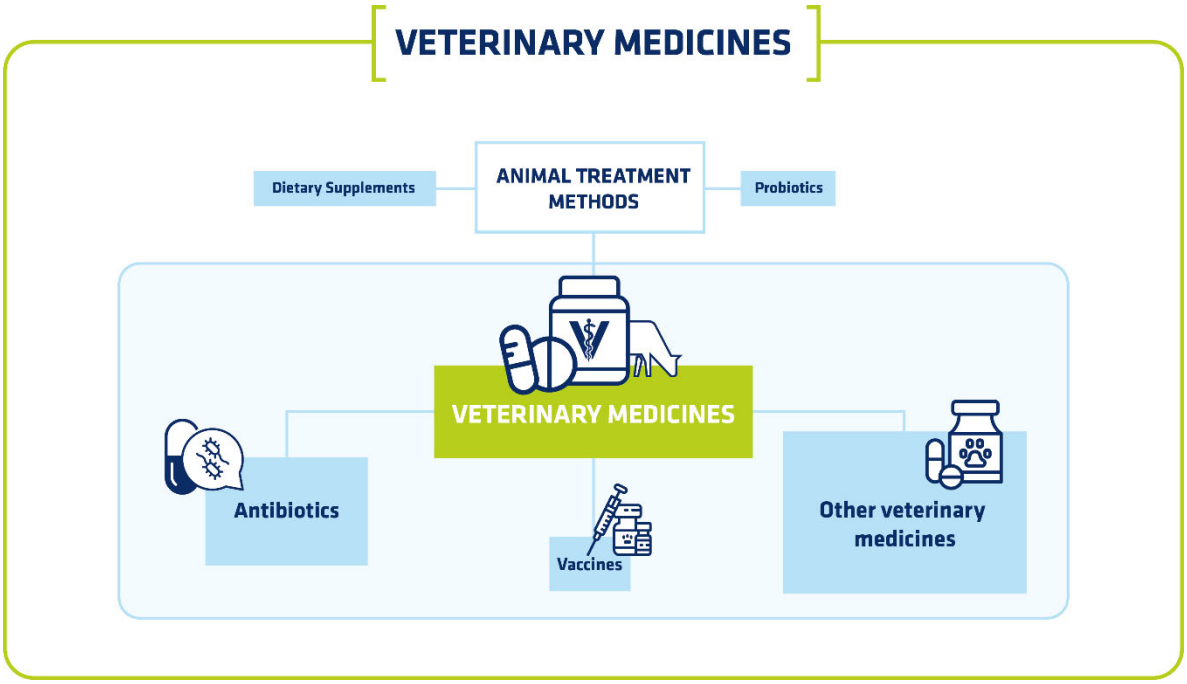

Figure 1: Distinction veterinary medicines. The sizes of the rectangles give a rough indication of the numbers of the specific medicines.

In the veterinary medicine chain, several medicines are distinguished. Veterinary medicines are any substances with a veterinary claim or agents intended to influence physiological functions [1]. Within veterinary medicines, antibiotics and vaccines can be distinguished as important groups, along with others. Other veterinary medicines include, for instance, iron preparations, tranquillisers, and wormers.
Veterinary medicines are included in animal treatment products. Nutritional supplements (micronutrients), probiotics and growth promoters are also included in animal treatment agents [2]. The use of growth promoters has been banned within the European Union for many years and is therefore excluded from this study. Nutritional supplements and probiotics are being investigated in the 'Feed Domain Exploration' (in progress).[2] Figure 1 provides an overview of the concepts included, as well as a rough indication of the numbers of the specific agents by using varying rectangle sizes.

In the world of medicines, one speaks of 'registration' of a product as a condition for marketing it. While in the case of plant protection products and biocides, one speaks of 'authorisation' of a product. Legally, both cases involve the granting of a licence to market a product. However, to ensure clarity, we will continue to use the term 'registration' in this report.

2.1 Legal framework

A marketing authorisation from the Minister of Agriculture, Nature and Food Quality is required in order to market a veterinary medicine in the Netherlands. The Bureau of Veterinary Medicines (Bureau Diergeneesmiddelen; hereafter abbreviated to as BD) of the Medicines Evaluation Board handles this duty. At the EU level, the Committee for Veterinary Medicinal Products (CVMP) of the European

[2] EC Regulation 1831/2003 on feed additives is relevant to dietary supplements and prebiotics and probiotics.

Medicines Agency (EMA) evaluates all veterinary medicines. The efficacy, safety, and quality of a product are examined before it is permitted to be marketed. If sufficiently substantiated, a registration is granted, officially allowing the product to enter the market.
A registration can be done at either the national or EU level. A producer chooses whether to be authorised only in the Netherlands, select member states, or throughout the entire EU [3]. Each member state has one member and one alternate member on the CVMP in the capacity of a scientist. The Dutch members work at the BD. Each country has its own decentralised authority authorised for registrations. In the Netherlands, this is the aforementioned BD [4]. Within the Netherlands, the Ministry of Agriculture, Nature and Food Quality (LNV) has the final responsibility [5].

2.1.1 Definition of veterinary medicine

The Animals Act (Wet Dieren) [1] defines what exactly falls under veterinary medicines and is therefore subject to the registration obligation. There are a number of categories of veterinary medicines that are exempt from this obligation. These categories are described in the Veterinary Medicines Decree (Besluit Diergeneesmiddelen) [6], in Art. 3.16-3.23 on exemptions or dispensations to market a veterinary medicine without an authorisation. These provisions are further elaborated [4] in Art. 3.6-3.12 of the Veterinary Medicines Regulation (Regeling Diergeneesmiddelen) [7]. The Act, the Decree, and the Regulation are all elaborations of Directive 2001/82/EC, supplemented by amendments to Directives 2004/28/EC and 2009/9/EC [8]. Directive 2001/82/EC was replaced on 28 January 2022 by Regulation 2019/6 [9], which allows the different EU member states to all be bound by the same regulation instead of further elaborating the directive in local legislation. There is now also a new Animals Act, a new Decree and a new Regulation is close to completion, in which everything that is currently in the Regulation has been/will be removed from the Act, Decree, and Regulation. An overview of the above cases is provided in Figure 2.
The Decrees *Houders van dieren* and the Regulation *Diergeneeskundigen* respectively concerning animal owners and veterinarians are beyond the scope of this report.

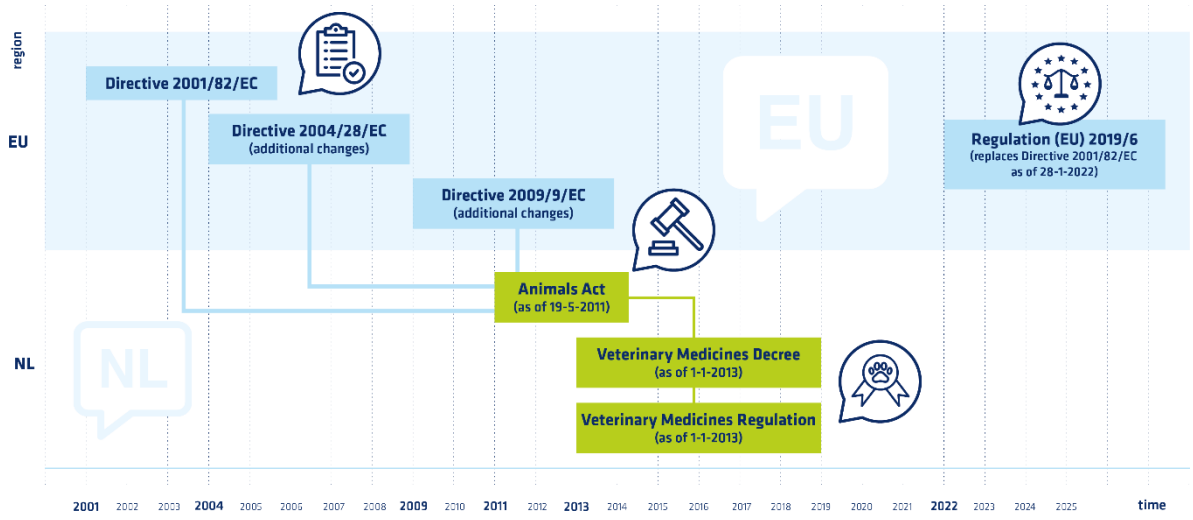

Figure 2: EU directives and regulations, and Dutch laws, decrees and regulations and how they are mutually derived from each other or succeed each other.

An important criterion for a product to be recognised as a veterinary medicine is if it makes contact with animals.

A product can have different purposes, for example, as a human medicine, veterinary medicine and/or biocide. An example of such an agent is iodine, which is used as a biocide to disinfect the hands of the attending physician, while it is also used on a patient as a (human) product to disinfect the skin before proceeding to surgery. For all these purposes, different applications for registration/authorisation must be made, i.e., as a human medicine, veterinary medicine and/or biocide [4].

2.1.2 Production of veterinary medicines

Production includes preparation, processing, handling, and packaging of veterinary medicines. Different types of registration procedures are distinguished, covering different regional levels (EU, national, multi-national):

- *Centralised Procedure (CP).* In this procedure, the EMA authorises veterinary medicines at the EU level. The product may be marketed in all member states. The registration number[3] of a centrally authorised product begins with 'EU' [4].
- *MRP (Mutual Recognition Procedure).* If a veterinary medicine is registered in one EU member state (decentralised procedure, see below), it can be more easily registered in other member states through the Mutual Recognition Procedure (MRP). There is then no need to go through a whole new registration process each time. In the MRP, veterinary medicines are evaluated and approved by the Reference Member State (RMS), usually the original member state where the product has already been decentralised. This is followed by a 90-day period during which the Concerned Member States (CMSs) review the assessment report [10]. The MRP is also known as the Repeat Use Procedure (RUP) when another Member State (MS) is added later as a CMS.
- *Decentralised Procedure (DCP).* In this procedure, a new product (not yet authorised anywhere in the EEA) is applied for authorisation in several member states. So it concerns an initial application [4]. Again, as in the MRP, one member state does the assessment as the RMS after which the CMSs evaluate the assessment report. A registration number of a decentralised admission begins with a country code, e.g. 'NL' for the Netherlands [4].
- *National procedure.* Registration of a veterinary medicine within one member state, by the competent authority in that state (the BD in the Netherlands). Prior to 2001, *all* registrations were national. Upgrading a nationally registered product in the context of European harmonisation is referred to as MRP (see above). The product is then assigned a new EU registration number [4].

Figure 3 provides an overview of these procedures.

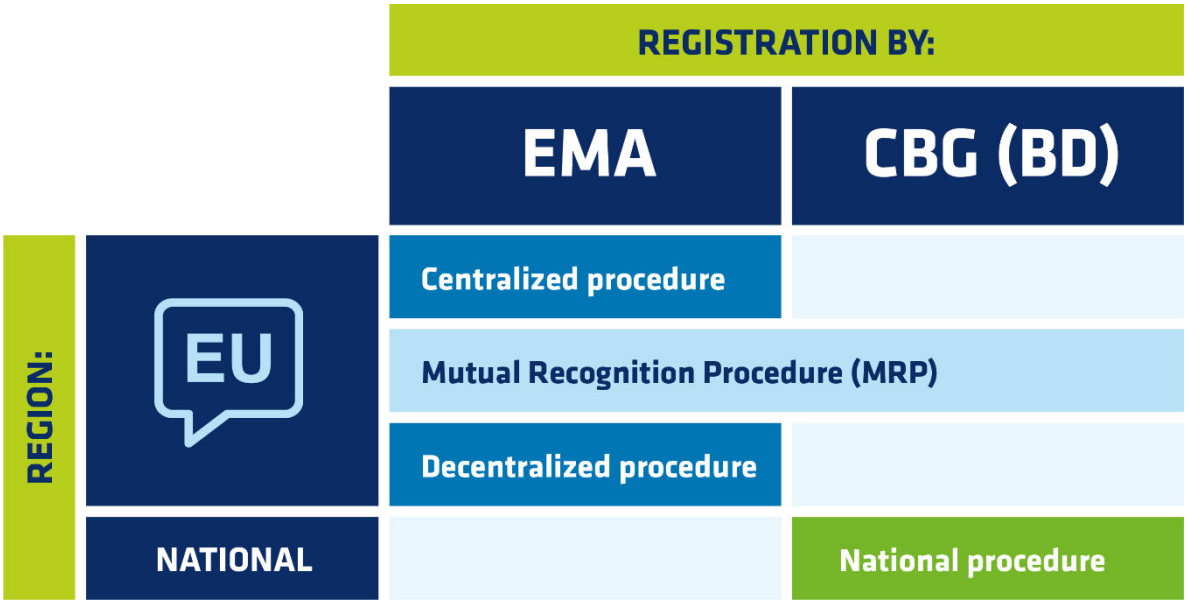

Figure 3: Registration procedures, categorised by region and registering authority (EMA or CBG).

For products produced after a patent has *expired*, a simplified application for registration can be made by referring to the original dossier. In such a case, not all examinations need to be redone. A simplified procedure is possible only with the consent of the original registrar.

[3] The regulation speaks of an authorisation number.

2.1.3 Distribution/channelling of veterinary medicines

Outside the production (manufacture) of veterinary medicines, authorisations are required for distribution/channelling of veterinary medicines. The following 'product flows' are distinguished [11][12]:

- *Wholesale.* A wholesaler must meet a series of requirements regarding such things as storage, maintenance, cleaning, indications on packaging (label information), setup, and registration. These requirements are wholesaler-specific, i.e., partly related to the nature of a wholesaler, namely, that it supplies market players.
- *Retail.* A retail business must also meet a set of requirements regarding storage, etc. (see Wholesale). These requirements are retail-specific and address non-professional customers in addition to professional customers. Pharmacies and veterinarians automatically carry a retail authorisation.
- *Cascade.* Under special circumstances, a veterinarian may apply a veterinary medicine registered for one species to another species for which it is not yet registered. This is subject to special conditions that we will not elaborate on in this report.

Wholesalers and retailers must maintain the following records for each incoming transaction (relating to veterinary medicines supplied to them):

- date of the transaction
- name of the veterinary medicinal product
- the REG NL number of the veterinary medicinal product
- batch number
- expiry date
- quantity received
- name of supplier.

The REG NL number is the registration number of a veterinary medicine, equivalent to the RVG number for human medicines. A wholesaler must also complete a registration if it supplies another wholesaler. In that case, the name and address of the recipient are registered in the above list instead of the supplier. Moreover, in the case of a retail business, the name and address of the recipient or the business number of the location where the animals are kept shall be recorded, as well as the prescription [11], [12].

In addition to products produced for the Dutch market, the regulation also allows for cross-border trade: so-called parallel trade. A wholesaler is allowed to source and repack identical products from another member state under conditions that meet the Dutch packaging requirements (Article 102 of Regulation 2019/6). For centrally authorised products (veterinary medicines registered for the entire EU), this is called parallel distribution. The rules for this are set by the EMA.

2.1.4 Categories of veterinary medicines

Veterinary medicines in the Netherlands are classified into two categories: prescription and over-the-counter medicines [13]. Prescription products are divided into three groups depending on the distribution channel.

The setup:

- **VRIJ**: This category of veterinary medicines is available without a prescription from a veterinarian, pet store or licensed dealer, and may be administered by the animal owner.
  Examples: flea medicines and wormers for small pets.
- **URA** (Prescription-only delivery): this category is available only with a prescription from a veterinarian at the veterinarian, pharmacist, or authorised dealer with a special retail authorisation.
  Examples: wormers for horses and farm animals, and some painkillers.
- **UDA** (To be issued exclusively by a veterinarian or pharmacist): available from a veterinarian or pharmacist only by prescription. However, the animal owner may administer the products themself.
  Examples: painkillers and anti-inflammatories.

- **UDD** (Administered exclusively by a veterinarian): only a veterinarian may administer these products to the animal. Under strict conditions, a livestock farmer may self-administer. Examples: medicines for intravenous use and antibiotics.

Figure 4 shows the channelling of the four categories, and who may administer the products.

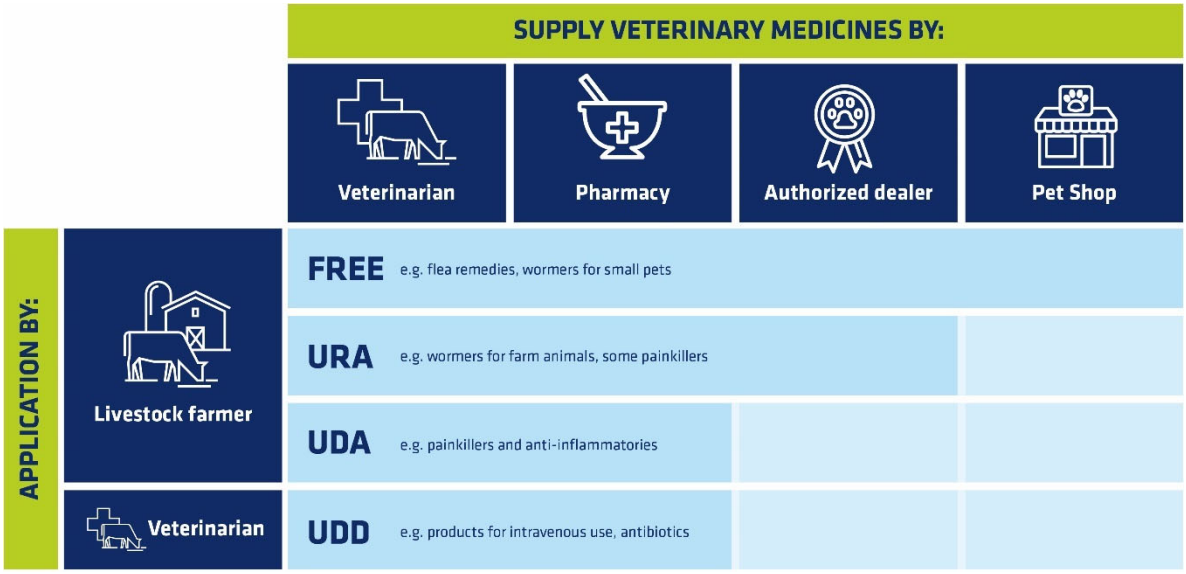

Figure 4: Supply and administration of the four channel categories of veterinary medicines.

2.1.5 Residues in products of animal origin

Veterinary medicines applied to food-producing animals are subject to rules regarding the MRLs (Maximum Residue Limits) of the active substances in products. Rules for setting MRLs are laid out in Regulation 470/2009/EC. The European Commission, on the advice of the aforementioned Committee for Veterinary Medicinal Products (CVMP), as part of the EMA, establishes the MRLs [14]. The MRLs of these substances are listed in the Annex of Regulation 37/2010/EC where the MRL of a substance has been set or it has been decided that a substance does not (need to) have an MRL. The RIVM (National Institute for Public Health and the Environment) carries out registrations of veterinary medicines and determines MRLs on behalf of the competent authorities based on risk analyses. The NVWA (Netherlands Food and Consumer Product Safety Authority) monitors for misuse of veterinary medicines by measuring whether residues of veterinary medicines in food of animal origin remain below the permitted MRLs [8].

Residues can also end up in manure through animal excretion, such as antibiotics. The application of slurry to fields and pastures can potentially lead back to the spread of veterinary medicines into soil, groundwater and leaching into surface water, including through wastewater from animal housing. At present, much is still unclear about the effects of residues of veterinary medicines in soil [15][16]. Since 2004, an environmental assessment (ecotox) has been mandatory. Products that are too harmful to the environment will not receive a marketing authorisation. No databases can be found on the spread of manure and its solution in water. A reporting requirement exists for manure transport. The transported manure must be weighed and sampled, after which it is analysed for nitrogen and phosphate, and, for instance, carriers of infectious animal diseases[17].

2.1.6 Inspection

The NVWA and Health and Youth Care Inspectorate (IGJ) inspect the quality of (animal) medicines [4]. The NVWA checks veterinarians, traders and livestock owners, and detects illegal trade [18]. Regarding production, the BD sets the criteria (production quality requirements). The NVWA (in the name of the Ministry of Agriculture, Nature and Food Quality (LNV)) supervises and outsources to IGJ. The IGJ conducts production inspections (GMP; Good Manufacturing Practices). This is done in cooperation with the BD, once every three years on location. Pharmacovigilance inspections (inspections for adverse reactions) also take place. Among other things, they pay attention to the reporting of side effects in a European database. Quality deficiencies of veterinary medicines are reported to the BD, who then consults with IGJ on whether there should be a recall. This has never occurred beyond wholesale [4]. Wholesale and retail authorisations are inspected by the BD, first on

site and then upon relocation. Furthermore, modification requests are made on paper. Occasionally there may be another on-site inspection. In summary, the BD is engaged in veterinary pharmacovigilance, lot inspections, and issuance of certificates [4]. As an authorising body, the BD calls to account producers of veterinary medicines if they do not meet the stringent quality requirements (especially contamination of raw materials). In doing so, authorisations may be suspended or revoked. It inspects wholesale and retail licenses [4]. Figure 5 provides an overview of the controlling authorities and what actions they perform on which actors.

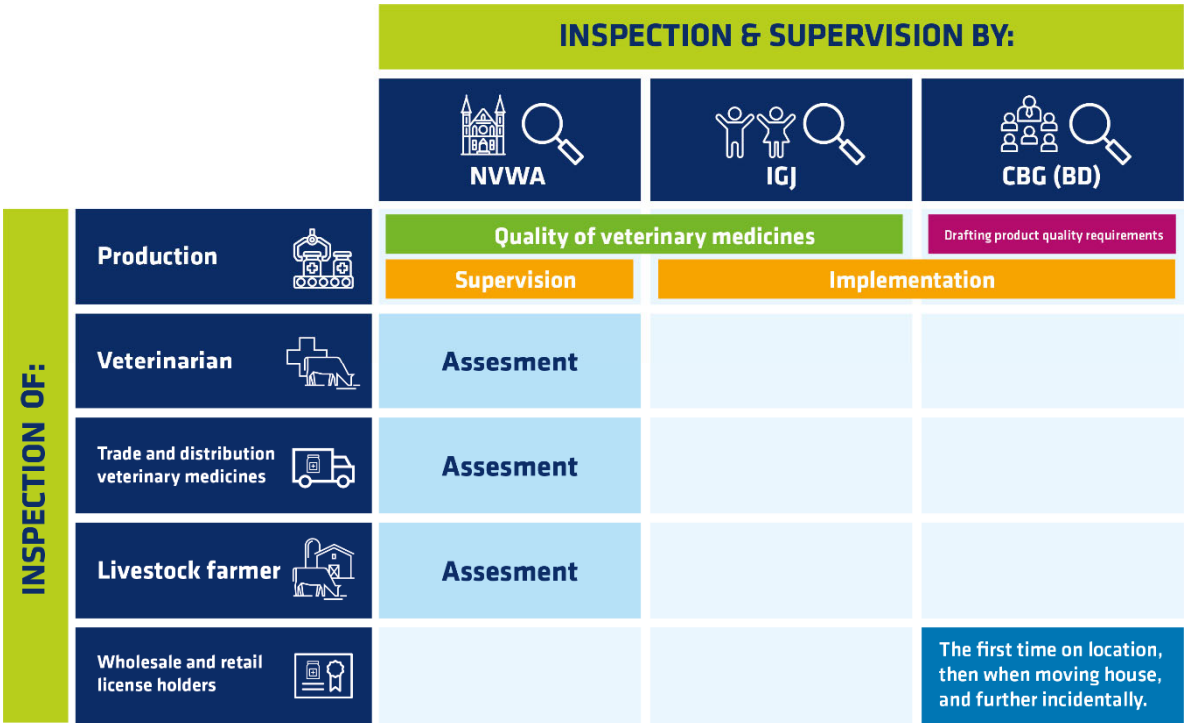

Figure 5: Inspection and supervision of veterinary medicines.

There are databases in the field of inspection. EudraGMDP, an EU initiative, contains information on producers, traders and distributors, GMP, GDP (Good Distribution Practice) [19], and establishments. Mutual recognition agreements exist for international recognition of inspections concerning veterinary medicines. The database will also become mandatory in the veterinary sector through the new Veterinary Medicines Regulation 2019/6 (28 January 2022).
Farmatec is a Dutch initiative with the same functionality as EudraGMDP but only for human medicines. Farmatec is part of CIBG[4], the controlling body for licences (production, wholesale), but also quality, availability, etc. of human medicines [20]. Farmatec does not do anything with product registrations, but checks whether certain sites of factories are suitable to produce a certain veterinay medicine. Veterinary activities are vested in the Bureau of Veterinary Medicines (BD) [4].

[4] The original meaning of CIBG no longer covers the activities. Only the abbreviation is used.

3 Network Analysis

In this chapter, we provide an overview of the various supply chain partners involved in the veterinary medicine domain (see Figure 6). We base this overview on literature reviews, results of the awareness workshops (see later in this report), and interviews with various individuals in the agricultural sector.

Figure 6: Actors in veterinary medicines.

The development and production of veterinary medicines takes place worldwide by various producers. In addition to veterinary medicines, these producers often produce human medicines.

Before a producer can market a veterinary medicine, a registration must be obtained for a veterinary medicine. This requires pharmacological[5], toxicological[6] and clinical[7] studies to be conducted at a certified research facility. Registration applications can be for the entire EU or for a specific country, in the Netherlands, these applications are handled at the Bureau of Veterinary Medicines (BD), part of the Medicines Evaluation Board (CBG).

[5] Pharmacology or drug science is a sub-science of pharmacy concerned with studying the combination effect, or interactions, between pharmacological substances and physiological processes (Wikipedia).
[6] Toxicology studies toxic substances and their effects on humans, animals, and the environment (Wikipedia).
[7] Clinical research involves the testing of treatments or other medical 'interventions' on humans or animals.

Veterinary medicines usually reach livestock farmers through veterinarians via distributors, however, for non-prescription and URA medicines, this can also be through authorised dealers.
In addition to administering veterinary medicines, veterinarians also advise on the use of these products. Veterinarians and livestock farmers record the supply and use of prescription products in their Practice Management Systems (PMS) (see previous chapter). Prescription and non-prescription streams are described in the previous section (categories of veterinary medicines). The Business Management Systems (BMS) of livestock producers and veterinary medicine suppliers may also contain this information. These various management systems are provided by ICT solution providers.

The livestock farmers' products find their way to retail and consumers through cooperatives, processors and traders. In this chain, samples of the products are examined by laboratories to make sure that residue levels of veterinary medicines do not pass an EU-established upper limit (MRL, Maximum Residue Limit).

Certifiers examine whether a company meets a particular certification scheme to be allowed to use a quality label. Examples of these labels include Beter Leven (https://beterleven.dierenbescherming.nl/), On the way to PlanetProof (https://www.planetproof.nl/), EKO (https://www.eko-keurmerk.nl/), and Weidemelk (https://www.weidemelk.nl/nl/).

Livestock farmers supply their products directly, or through trading parties, to slaughterhouses or the processing industry. The services of transporters are deployed for the transportation of animals and products.

The quality of the products is controlled by certified laboratories. These can be independent laboratories or laboratories of the processing industry itself. The NVWA supervises the processes of the processing industry.
The SDa (Netherlands Veterinary Medicines Institute) is a private initiative by the business community that sets standards for the use of antibiotics in animal husbandry. One monitors usage data and processes in the chain and establishes benchmark indicators for antibiotic use [21].

Ultimately, the final products (food and other products of animal origin) are delivered to retail and food service companies.

Many chain partners in this chain are represented by trade associations. Producers and importers of veterinary medicines have united within FIDIN (Fabrikanten Importeurs Diergeneesmiddelen Nederland - Dutch Veterinary Medicines Suppliers and Producers). FIDIN currently has 17 members. The companies within FIDIN are an important source of information on veterinary medicines and are therefore important within this study.
Veterinarians are represented by the Royal Dutch Society for Veterinary Medicine (KNMvD), among others. Livestock farmers have united within industry organisations such as LTO (general), POV (pigs), NMV (dairy cattle), DDB (cattle), NVP (poultry), NZO (dairy), ZuivelNL and Gemzu (dairy).

In Figure 19, the actors and their information needs and information supply are represented in a so-called information roundabout.
Annex 1 contains a number of lists by the main actors within the veterinary medicines sector.

4 Digital information storage

In the field of digital information storage, a distinction is often made between master data and process data. Master data are basic data that, unlike process data, are more or less independent of time and batches/lots, such as consumer unit information, customer information, etc. Process data normally refer to master data, and add time, place, batch/lot-specific information, such as production dates, container numbers, etc. Finally, reference data can be distinguished; reference data relate to background knowledge to master and process data, such as classifications of diseases, taxonomies of organisms, etc. (lookup tables).

4.1 Master data

In the case of veterinary medicines, master data in particular are the information on registration and instructions for use of those medicines. It is very important that this data is registered only once and maintained in a single place.

Registration of veterinary medicines is handled by two agencies. The EMA is responsible for the European registrations and the BD for the Dutch ones. In addition to information on national authorisations, the Veterinary Medicines Information Bank of the BD also includes information on European authorisations marketed in the Netherlands or *also* in the Netherlands (see also description of legal framework). From 28 January 2022, the information on all veterinary medicines authorised in the EEA can also be found in the Union Product Database (UPD).

Unlike plant protection products and biocides, the active substances in (animal) medicines are not formally approved in advance. They are only described, and registered in EU SRS (European Substance Reference System). EU SRS is a database for active substances in medicines, and is part of SPOR (Substances Products Organisations Referentials). To apply for registration, the substance must first be declared and included in EU SRS. The EMA includes a new substance in that database *with reservations*. The Veterinary Medicines Regulation refers to this database [4]. In fact, the *actual* approval of an active substance is part of the registration of the *entire* (animal) medicine, whether at CBG or EMA, and for each (animal) medicine anew.
For the processing in veterinary medicines for food-producing animals, the active substances must additionally be listed in the Annex to Regulation (EU) 37/2010.

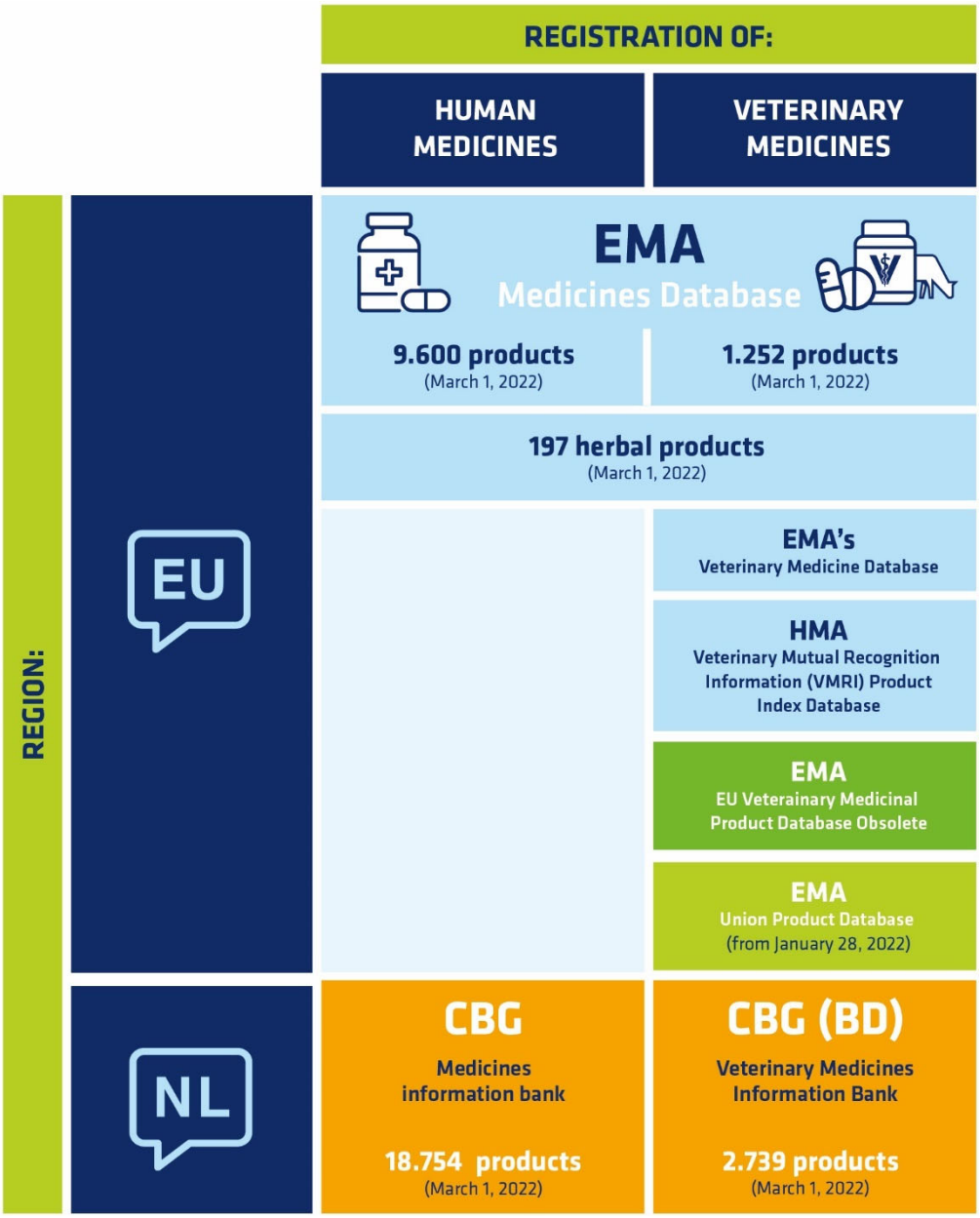

Figure 7: Authorities involved in the registration of veterinary medicines.

Figure 7 provides an overview of veterinary medicine authorities and databases, by region (EU, NL). Below we describe the data sources mentioned as well as systems and data sources which in turn refer to them, such as data sources on consumer units (articles) of veterinary medicines available on the market, and refer to registrations of the veterinary medicines. The purpose of this type of system is to improve the exchange and comparison of data.
The system of counting products in the EMA Medicines database is different from how it is counted in the Veterinary Medicines Information Bank. Different doses are included separately. The number of products corresponds to about 430 substances. These products also appear in the Veterinary Medicines Information Bank [4].

4.1.1 Veterinary Medicines Information Bank

The CBG manages the Medicines Information Bank (human) and the Veterinary Medicines Information Bank (https://www.diergeneesmiddeleninformatiebank.nl/). This latest data source (see Figure 8) contains information on more than 2,739 veterinary medicines, including vaccines and homeopathic veterinary medicines (reference date 1 March 2022). Excipients are listed as a separate data field in the internal database, but in the public Veterinary Medicines Information Bank they are only listed in

the Summary of Product Characteristics (SPC) and package insert, not as a separate data field. All registered veterinary medicines must be in the database.
Products for which the marketing authorisation has been withdrawn – usually because a better alternative has become available (usually because of product improvements) – are removed from the Veterinary Medicines Information Bank. It includes about 50-80 veterinary medicines per year (72 in 2019). They do however remain present in the underlying, internal database.
The system costs of registering a veterinary medicine amount to approximately €500 annually, payable by the authorisation holder.
Batch numbers do not appear in the database for veterinary medicines except for vaccines, for which batch numbers are indeed stored [4].
The Veterinary Medicines Information Bank is updated weekly [22].

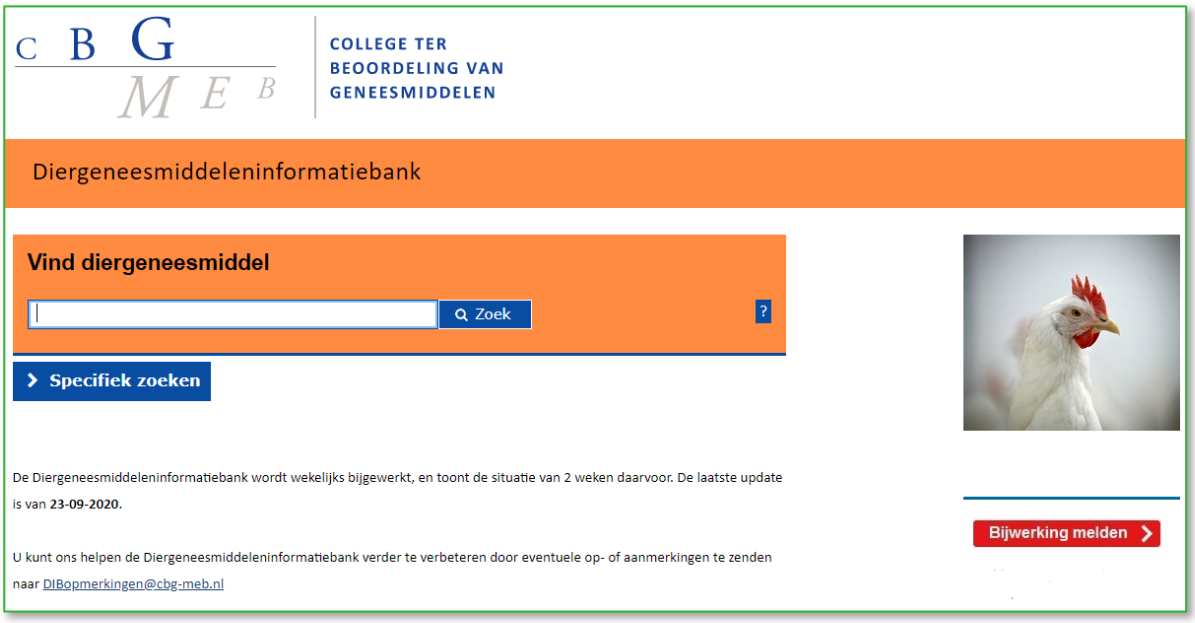

Figure 8: Veterinary Medicines Information Bank of the CBG.

The data in the Veterinary Medicines Information Bank is manually retrievable through the CBG website.
The data source provides the data fields below, where we provide descriptions of the values of these data fields, using example values. However, this data is not retrievable by automated means (e.g., through an API).
The underlying database of the Veterinary Medicines Information Bank stores doses in a formalised way, i.e. not as a sub-part of a text.

	Value
Productnaam (Product name)	'Onsior 6 mg tabletten voor katten'
Registratienummer (Registration number)	'REG NL 102258'
Afleverstatus (Delivery status)	'Uitsluitend verkrijgbaar bij een dierenarts of op recept van een dierenarts bij een apotheek'
Farmaceutische vorm (Pharmaceutical form)	'Tablet'
Toedieningsweg (Administration route	'Oraal gebruik'
ATCvet code)	'QM01AH91 – Robenacoxib'
Handelsvergunning houder (Marketing authorisation holder)	'Elanco GmbH'
Datum inschrijving handelsvergunning (Date of marketing authorisation registration)	'16 december 2008'
SPC, etiket en bijsluiter (SPC, label and package insert)	Link naar een pdf
Werkzame stof (Active ingredient; may be multiple)	
Substantie (Substance)	'ROBENACOXIB'

	Value
Concentratie (Concentration)	'6 mg/stuk'
Hulpstoffen (Excipients)	
Sunstantie (Substance)	'CELLULOSE, MICROCRYSTALLINE (E 460)'
Concentratie (Concentration)	''

Registration number and ATCvet-code (Anatomical Therapeutic Chemical veterinary)[8] refer to unique codes here. The international system of the ATCvet-code is based on the global ATC classification for substances used in human medicine [23], [24]. It involves a taxonomy of substances. Vaccines also appear in the classification (code QI). The Fink-Gremmels Directory described later is a tool where the ATCvet classification can be searched in the FIDIN Online Repertorium also described later on down. In the Veterinary Medicines Information Bank, the data field 'ATCvet-code' is used not only to represent the relevant code but also to represent the active substance. This makes the data field less digitally reusable, as it must be parsed upon use. The remaining data fields are or appear to be more text-based, making it more complicated to access data. 'SPC, label and package insert' refer to one document, which is also challenging in terms of digital reusability.

4.1.2 EMA Medicines database

EU-wide information on veterinary medicine registrations is stored in the Medicines database of the EMA (https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Veterinary; see Figure 9). The information is copied manually by CBG into the CBG's Veterinary Medicines Database (see previous section). There is no direct link between the two databases. When the information in the EMA database is updated, there is a risk that the information in the CBG database becomes outdated due to manual copying. The EMA database contains information on 1252 veterinary medicines, 9600 human medicines, and 197 herbal medicines (reference date 1 March 2022).
The EMA Medicines database is updated at least daily [25]. However, the data on the site is not available through an API.

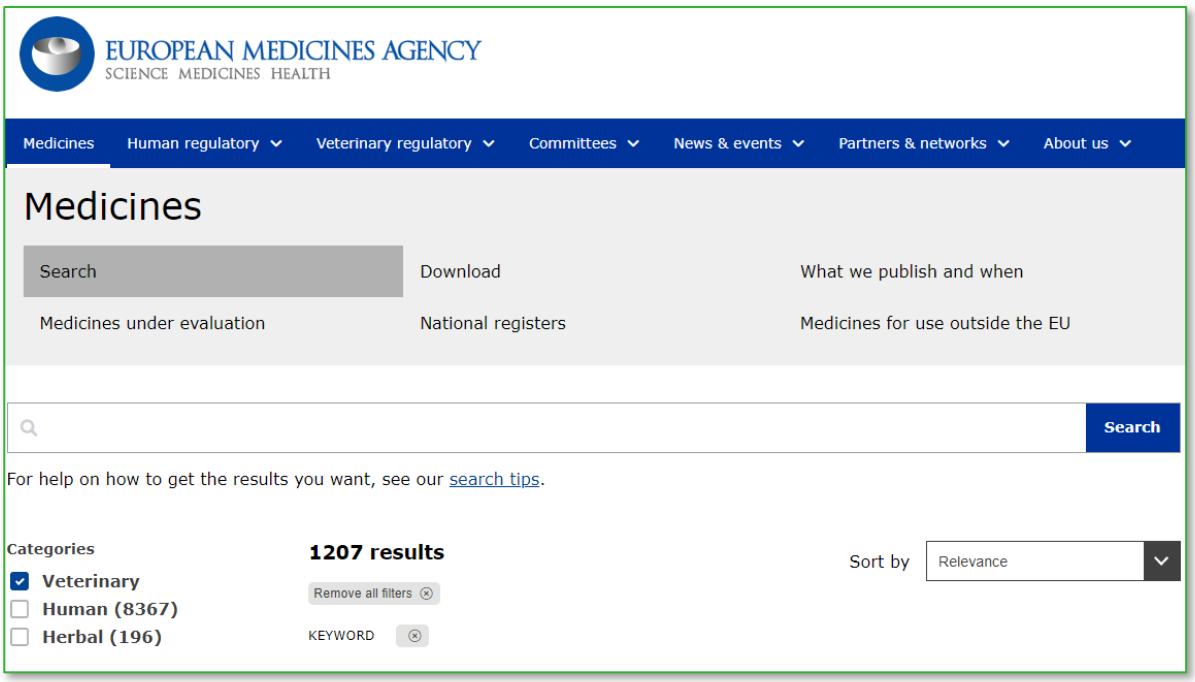

Figure 9: EMA Medicines database.

The results page of the EMA database contains the following items: 'Overview', 'Authorisation details', 'Product information' and 'Assessment history'. 'Overview' provides an introduction to this page ('a

[8] https://www.whocc.no/atcvet/

summary of the European Public Assessment Report (EPAR)') and questions and answers about the search result, e.g. 'What is Equilis Prequenza used for?', with answer 'Equilis Prequenza is used to vaccinate (...) and afterwards by yearly revaccinations.'), in text form. Finally, the EPAR is provided ('Summary for the public'), in the form of a link to a PDF and date of the last update. The PDF is available in 21 languages. This is followed by the authorisation details, in form format with data fields containing values. The table below presents these data fields with descriptions of their values.
An additional section 'Product information' contains links to sections of the EPAR in the form of PDFs, concerning 'Product information' and 'All authorised presentations', available in 24 and 23 languages respectively. Furthermore, the 'Pharmacotherapeutic group' (e.g., 'equine influenza virus') and 'Therapeutic indication' (e.g., 'Active immunisation of horses (...) excretion after infection'), become presumptively free text sections. Finally, there is the 'Assessment history' section that provides links to PDFs on the registration history and marketing authorisation of the products. All of these data fields are difficult to reuse digitally because they are (or appear to be) text-based.

	Value
Product details	
Name	'Equilis Prequenza'
Agency product number	'EMEA/V/C/000094'
Active substance	'Equine influenza-virus strains: A/equine-2/South Africa/4/03, A/equine-2/Newmarket/2/93'
International non-proprietary name (INN) or common name	'Vaccine against equine influenza in horses'
Species	'Horses'
Anatomical therapeutic chemical veterinary (ATCvet) codes	'QI05AA01'
Publication details	
Marketing-authorisation holder	'Intervet International BV'
Revision	'9'
Date of issue of marketing authorisation valid throughout the European Union	'08/07/2005'
Contact address	'Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer The Netherlands'

'Agency product number' and 'Anatomical therapeutic chemical veterinary (ATCvet) codes' refer to unique international codes. For 'Revision' and 'Date of issue of marketing authorisation valid throughout the European Union' formal data types are used (integer and date respectively). All of these data fields are therefore digitally reusable. The remaining data fields are or appear to be more text based, making it more difficult to reuse data.

4.1.3 EMA's veterinary medicine database

EMA's veterinary medicine database[9] contains information on veterinary medicine registrations at the EU level. Unfortunately, the link to the database is not working, so we were unable to analyse this database.
In the future, under new Regulation 2019/6 (see statutory framework), this database will be merged with the Veterinary Mutual Recognition Information (VMRI) Product Index database of the Heads of Medicines Agencies (HMA) (described in a subsequent section). The database that will then emerge, the Union Product Database, will contain information on all veterinary medicines authorised in the EU and the European Economic Area (EEA). This information will be provided by the nationally competent authorities of the member states and the EMA. This database will also be hosted by the EMA. The database should be ready for use from 28 January 2022 [4].

[9] http://ema-wip.emea.eu.int/ema/index.jsp?curl=pages/medicines/landing/vet_epar_search.jsp&mid=WC0b01ac058001fa1c

4.1.4 EU Veterinary Medicinal Product Database

This concerns an older initiative by EMA to create a European database (http://vet.eudrapharm.eu/vet/searchbykeyword.do; Figure 10) of human and animal treatment products. CGB also contributed to this in the past. The human part has already been replaced by the so-called Art.-57 database (under Art. 57 of Regulation (EC) 726/2004 on common procedures for the authorisation and supervision of the use of human and veterinary medicinal products and establishing a European Medicines Agency) [26]. The veterinary section will be replaced by the Union Product Database by 2022.

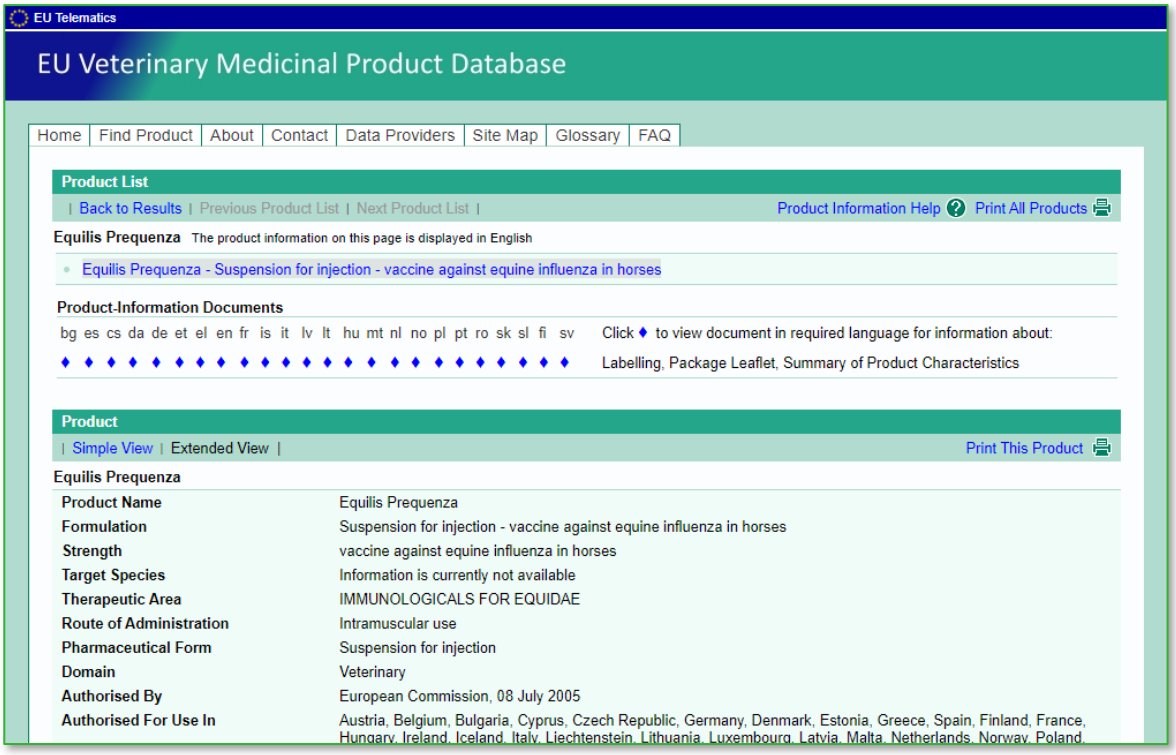

Figure 10: EU Veterinary Medicinal Product Database.

4.1.5 Veterinary Mutual Recognition Information (VMRI) Product Index database

The VMRI Product Index (https://mri.cts-mrp.eu/veterinary/; see Figure 11) database of the Heads of Medicines Agencies (HMA), the association of national authorising bodies such as CBG, contains information on veterinary medicines authorised at the national level [27]. These veterinary medicines are authorised in the member states of the European Union, according to the mutual recognition procedure. The database will be updated 'on a regular basis', with the goal being on a weekly basis[28]. The VMRI Product Index database was filled by only a few member countries and therefore died a gentle death years ago.
The database will be merged with EMA's Veterinary Medicine Database (described in the previous section). For further details, see the previous section.

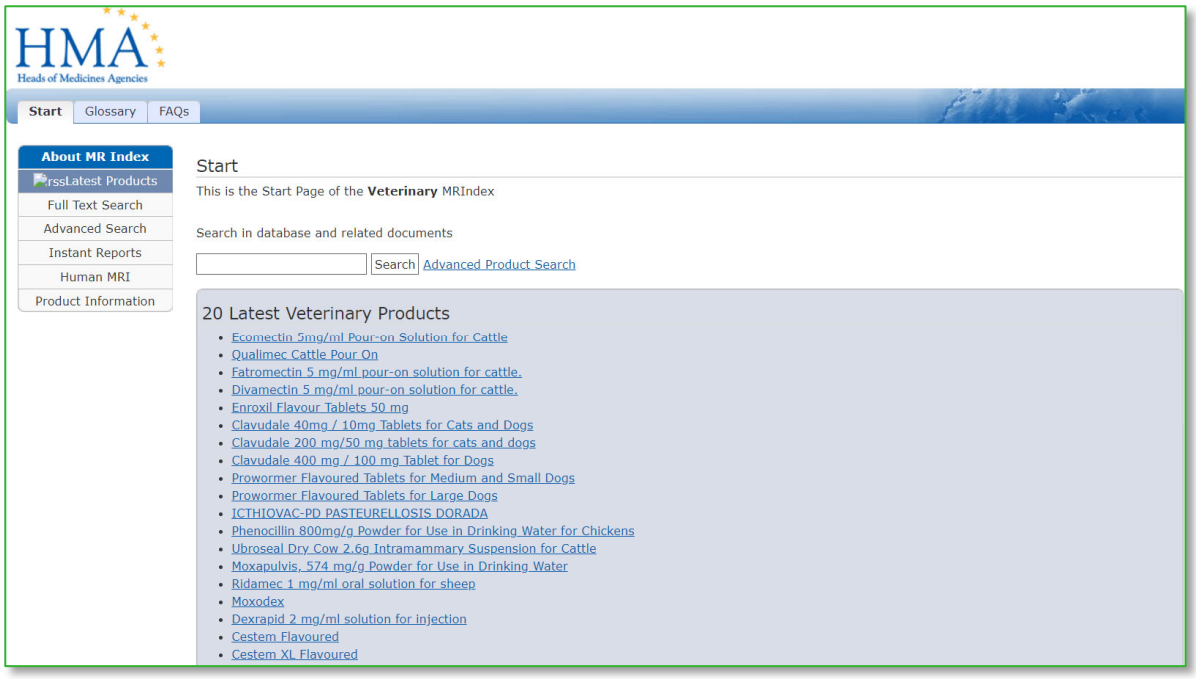

Figure 11: VMRI Product Index database of the Heads of Medicines Agencies (HMA).

Data fields in this database are listed below, with descriptions of their values.
The database can export search results to CSV and Excel, is not available through an API.

Table 1: Data fields and example of contents of the Heads of Medicines Agencies (HMA) database.

	Value
Product Name in the RMS	'Clavudale 40mg / 10mg Tablets for Cats and Dogs'
MR Number	'IE/V/0504/001'
Date of outcome	'05.01.2012'
Application type level	'Other Generic application'
Active Substances	'moxicillin 40 g clavulanic acid 10 g'
Form	'Tablet'
MA Holder in the RMS	'Dechra Regulatory B.V. Handelsweg 25 5531 AE Bladel The Netherlands'
RMS	'Ireland'
Date of last change	'11.12.2020'
ATC-Code	'QJ01CR02 amoxicillin and enzyme inhibitor'
Species	'Cats Non Food Dogs Non Food'
Domestic Product Name (for each 'CMS Country', e.g. 'Belgium')	'Clavudal 40 mg/10 mg'
PAR document	Link to a PDF plus a date in parentheses
FinalSPC document	Link to a PDF plus a date in parentheses

'MR Number' refers to a (unique) code. The data field 'ATC-Code' not only represents the ATCvet code, but also contains a description. This complicates digital reuse of the code because the description must first be removed from it. Information via codes is easily reusable digitally, though less so via descriptions (due to possible different wording, spelling errors, etc.). For 'Date of outcome' and 'Date of last change', data types of the date type (German format) are used. This data field is also easily reusable digitally. 'Application type level' appears to contain values from a list. A list is easily reused digitally, but is often less widely used. The remaining data fields are or appear to be more text based,

making it more difficult to reuse data. In particular, the information in PDFs (data fields 'PAR document' and 'FinalSPC document' is difficult to reuse digitally because the information will have to be extracted from a long text.

4.1.6 Fink-Gremmels Directory

The Fink-Gremmels Directory (https://www.fg-repertorium.nl/repertorium; Figure 12) contains information on veterinary medicines and veterinary care products offered in the Netherlands by members of FIDIN (Vereniging van Fabrikanten Importeurs Diergeneesmiddelen Nederland - Association of Dutch Veterinary Medicines Suppliers and Producers). The chapters that provide information on diseases and treatments were provided by the staff of the Department of Pharmacology, Pharmacy and Toxicology (VFFT) of the Faculty of Veterinary Medicine in Utrecht, under the direction of Prof. J. Fink-Gremmels. The chapters are organised according to the structure of ATCvet (see Veterinary Medicines Information Bank).
For the veterinarian, the chapters are a practical tool to arrive at a responsible veterinary medicine choice [29].
The *Repertorium Online bijsluiters* are a reference tool for veterinarians and animal owners, at the article (EAN) level (https://repertorium.fidin.nl/) [30].

Figure 12: Fink-Gremmels Directory.

The Fink-Gremmels Directory provides the ATCvet classification of veterinary medicines digitally and searchably to complement the FIDIN Online Repertorium (see the next section), a database that contains information on consumer units (articles) of veterinary medicines. The page of a class, e.g., 'QA06A Laxantia', indicates the path of superclasses, e.g., 'QA Digestive tract and metabolism > QA06 Laxantia > QA06A Laxantia.' Each of the terms can be clicked on. Detailed textual information follows for the top two superclasses. At the lowest level, no textual information is given, but you can click to consumer units from that class, and arrive at the FIDIN Online Repertorium. Links to more specific classes are also provided, with links to veterinary medicines that appear in them. An example of a class is 'QA06AA Huid/slijmvliesverzachtende middelen' and of a veterinary medicine 'QA06AA01 Paraffine'.

4.1.7 FIDIN Online Repertorium

The FIDIN Online Repertorium (see Figure 13) can be used to search for information from the package inserts of animal treatment products produced or supplied by companies affiliated with FIDIN. [30]
The Fink-Gremmels Directory and the FIDIN Online Repertorium are an initiative of the FIDIN. Consumer unit information is extracted from the Branchecodetable (see next section), to which the FIDIN Online Repertorium is linked [31].

The site offers search options through entering a GTIN (EAN / GS1-13) or by scanning a barcode with a camera on a PC, laptop or phone.
Moreover, it is possible to filter by target animal, active substance, type of administration or supplier, etc. and a search term can be entered. For example, for the animal group 'Pigs - Piglets', 227 consumer units are found.
The information is organised on the site into standardised sections and is recently available through an initial version of an API. The package inserts are not available in PDF format.
The online repertorium contains information on the same products as in the Branchecodetable. Only the products that are no longer on the market are no longer shown, but are still present in the underlying database [32].

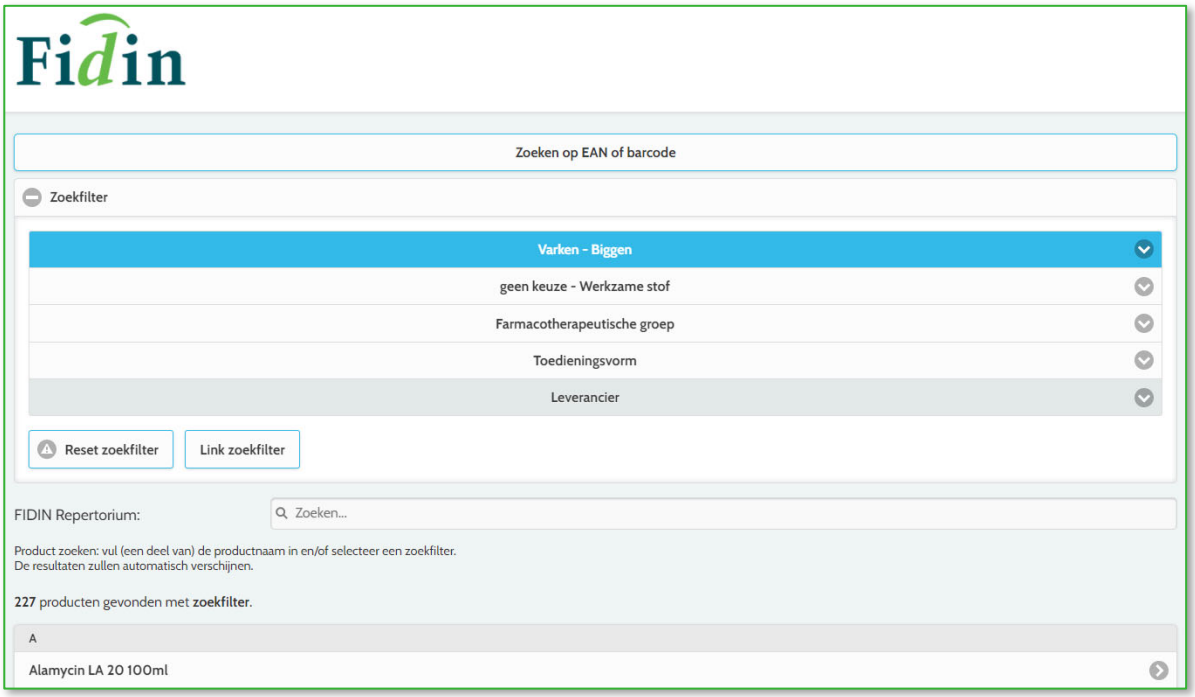

Figure 13: FIDIN Online Repertorium.

Clicking on the currently selected class 'QA06A Laxantia' in the Fink-Gremmels Directory (see previous section) will take us to the FIDIN Online Repertorium, where in the search filter the 'Pharmacotherapeutic group' has already been specified as 'Laxantia - QA06A'. The remaining four data fields in the search filter are then not further fixed (lists can be selected):

- 'Doeldier' ('Target Animal'), e.g. 'Geit - Onbekend / niet uitgesplitst'.
- 'Werkzame stof' ('Active substance'), e.g. 'abamectine'.
- 'Toedieningsvorm' ('Form of administration') for example 'auriculair'.
- 'Leverancier' ('Supplier'), for example 'NL_Bayer Healthcare, Animal Health'

It is also possible to search the online directory by GTIN (data field 'EAN').
Then the search results will show the consumer units (articles) that meet the search filter. For example, if we click on 'Paraffine vloeibaar 1 liter' ('Paraffin liquid 1 litre'), the following data fields will appear, with possible values:

Table 2: Example from FIDIN Online Repertorium.

Data field	Value
Leverancier (Supplier)	'NL_Dechra'
EAN code	'8714225004218'
Farmaceutische vorm (Pharmaceutical form)	' Vloeistof'
Samenstelling (Composition)	'Per ml 1 ml of paraffine.'
Eigenschappen (Properties)	' Zie inleiding'
Doeldieren (Target species)	' Paard, hond, kat.'
Indicaties (Indications)	'Paard: obstipatie, in het bijzonder koliek. Hond, kat: obstipatie.'
Contra-indicaties (Contraindications)	''
Bijwerkingen (Side effects)	''
Toediening/dosering (Administration/Dose)	'Toediening: Oraal, evt. rectaal. Paard: 1e dag 2 à 3 maal daags 1 l, 2e en 3e dag telkens 1 l per dag. Hond: 5 - 30 ml enkele keren per dag. Kat: 2 - 5 ml enkele keren per dag.'
Wachttijdadvies (Waiting time recommendation)	'0 dagen.'
Waarschuwingen (Warnings)	''
Bewaarcondities/Houdbaarheid (Storage conditions/Shelf life)	'3 jaar, bij 15-25°C.'
Verpakking (Packaging)	'Flacon à 1 l. Can à 5 l.'
Registratienummer/Kanalisatiestatus (Registration number/Channelling status)	'REG NL 1858 VRIJ'

'EAN code' refers to the GTIN and is thus effectively reusable digitally. 'Registration Number/Channelling status' is a combination of the respective codes, which must be separated before they can be used. This lowers their digital reusability (risk of errors when separating). The 'Supplier' data field appears to be composed of a country code ('NL'), separated by an underscore with the name of a company. It is not convenient to put two types of information in one field because of the reusability factor. Furthermore, the country code is digitally reusable, but the company name – like the other data fields displayed – is not because it is, or appears to be, text based. Note that the consumer unit name does not appear in this list, only the EAN (GTIN). In addition, the search fields 'Active substance' and 'Form of administration' (see above) are also not included. Classifications of agricultural household and domestic animals could be used here.

4.1.8 Branchecodetable

The Branchecodetable (BCT) (Figure 15) contains information on veterinary medicine-consumer units (articles). The BCT contains approximately 4450 consumer units (reference date 12 July 2021). The data source contains all products from organisations affiliated with FIDIN, and in the field of antibiotics even *all* products, so also from non-FIDIN members. The data source is also fairly exhaustive for other products (non-antibiotics) [31].
Of all the products in BCT, 95-98% come from FIDIN members [33]. Successive versions of products - which always means a new GTIN - are not linked to each other in the BCT. Larger packages (trade units) are also other articles. No article numbers exist in the database at the pallet level (Figure 14).

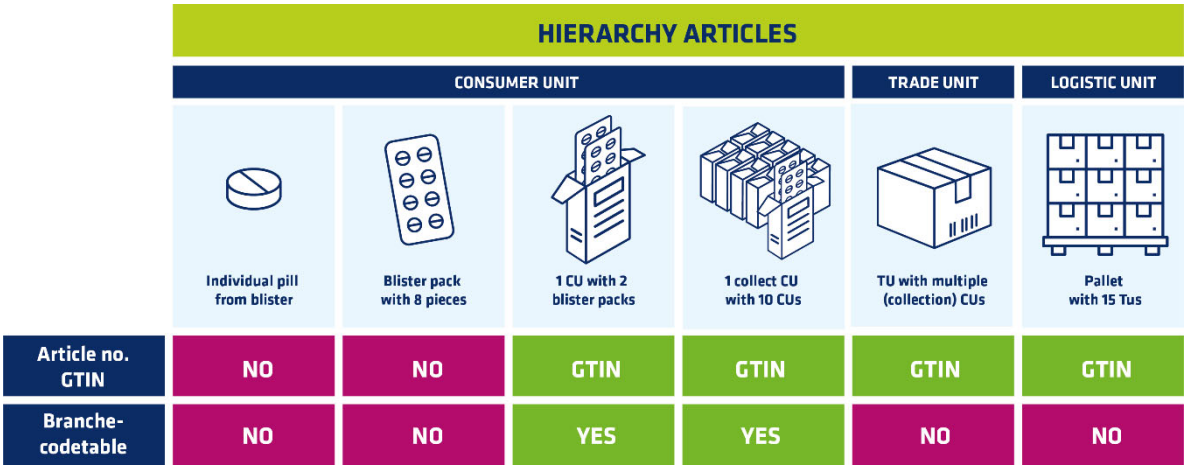

Figure 14: hierarchy of veterinary medicine article structure.

The veterinarian is required to record all antibiotic use and uses BCT in their PMS to do so. If an outside product is not listed, a veterinarian may ask FIDIN if it can include the product in BCT. This applies to all types of products, such as vaccines, for instance [33]. BCT is updated near daily. Changes are also visible immediately in the FIDIN Online Repertorium [32].
Digital systems can communicate with the BCT through an XML web service. An XML export can also be used (for table information only). The BCT, for which it serves as a source file, is available indirectly through the FIDIN Online Repertorium (previous section) via an initial version of an API. As a customer, access to the BCT can be requested through FIDIN (vetmessage@fidin.nl). There is also a so-called 'Brwijs-file' in which the article numbers used in the Netherlands are shown (https://adapter.vetmessage.nl/brwijs/).
In the table below, we show an excerpt of an Excel export from the BCT. This overview shows the basic data of the products (even if they are no longer on the market), such as EAN (GTIN), package size, channelling, etc., but also the method of administration, the active substance, the ATCvet-code, target animals, etc. The package insert texts are not included in this overview; these are found in the database for all registered veterinary medicines in the Netherlands. Package insert texts can be accessed via the Online Repertorium, to which the BCT is linked [31]. Each product has a number of lines in this export [32].

	EAN	Productnaam	REG NL	Master EAN	verp aantal	verp eenheid	Kanalisatie	Toedieningswijze	WS
24503	8713343001390	Program Injectie 40 10 injectoren	REG NL 9489	8713343001390	10	injector	UDA	subcutaan	
24504	8713343001390	Program Injectie 40 10 injectoren	REG NL 9489	8713343001390	10	injector	UDA		lufenuron
24505	8713343001390	Program Injectie 40 10 injectoren	REG NL 9489	8713343001390	10	injector	UDA		
24506	8713343001390	Program Injectie 40 10 injectoren	REG NL 9489	8713343001390	10	injector	UDA		
24507	8713343001406	Program Injectie 80 10 injectoren	REG NL 9498	8713343001406	10	injector	UDA	subcutaan	
24508	8713343001406	Program Injectie 80 10 injectoren	REG NL 9498	8713343001406	10	injector	UDA		lufenuron
24509	8713343001406	Program Injectie 80 10 injectoren	REG NL 9498	8713343001406	10	injector	UDA		
24510	8713343001406	Program Injectie 80 10 injectoren	REG NL 9498	8713343001406	10	injector	UDA		
24511	8713942400044	igressis 25 d 1 x 50 ml	REG NL 9819	8713942400044	25	dosis	UDD	intramusculair	
24512	8713942400044	Progressis 25 d 1 x 50 ml	REG NL 9819	8713942400044	25	dosis	UDD		porcine reprodu
24513	8713942400044	Progressis 25 d 1 x 50 ml	REG NL 9819	8713942400044	25	dosis	UDD		
24514	8713942400044	Progressis 25 d 1 x 50 ml	REG NL 9819	8713942400044	25	dosis	UDD		
24515	8713942400044	Progressis 25 dosis	REG NL 9819		25	dosis	UDD	intramusculair	
24516	8713942400044	Progressis 25 dosis	REG NL 9819		25	dosis	UDD		porcine reprodu
24517	8713942400044	Progressis 25 dosis	REG NL 9819		25	dosis	UDD		
24518	8713942400044	Progressis 25 dosis	REG NL 9819		25	dosis	UDD		
24519	8713942401126	Progressis 25 ds	REG NL 9819		25	dosis	UDD	intramusculair	
24520	8713942401126	Progressis 25 ds	REG NL 9819		25	dosis	UDD		porcine reprodu
24521	8713942401126	Progressis 25 ds	REG NL 9819		25	dosis	UDD		
24522	8713942401126	Progressis 25 ds	REG NL 9819		25	dosis	UDD		
24523	6111158911378	Progressis 25d	REG NL 120602//9819	6111158911378	25	dosis	UDD	intramusculair	
24524	6111158911378	Progressis 25d	REG NL 120602//9819	6111158911378	25	dosis	UDD		porcine reprodu
24525	6111158911378	Progressis 25d	REG NL 120602//9819	6111158911378	25	dosis	UDD		
24526	6111158911378	Progressis 25d	REG NL 120602//9819	6111158911378	25	dosis	UDD		
24527	3411112920747	Progressis 25ds	REG NL 9819	3411112920747	25	dosis	UDD	intramusculair	
24528	3411112920747	Progressis 25ds	REG NL 9819	3411112920747	25	dosis	UDD		porcine reprodu
24529	3411112920747	Progressis 25ds	REG NL 9819	3411112920747	25	dosis	UDD		

Figure 15: Excerpt of an export in Excel from the Branchecodetable.

The data fields in this table with their values can be described as follows:

Table 3: Example from the Branch Code Table.

	Value
EAN	'8713942400044'
Productnaam (Product name)	'Progressis 25 d 1 x 50 ml'
REG NL	'REG NL 9819'
Master EAN	'8713942400044'
verp aantal (packing number)	'25'
verp eenheid (packing unit)	'dosis'
Kanalisatie (Channelling)	'UDD'
Toedieningswijze (Method of administration)	'intramuscular'
WS (active substance)	'porcine reproductief en respiratoir syndroom virus (PRRS), geïnact.'
Hoeveelheid (Amount)	'0.0'
Per (per)	'mg'
DV	'dosis'
Indc	'QI09AA05'
Naam Indicatie (Name Indication)	'PRRS-virus, geïnact. - QI09AA05'
Diersoort (Animal species)	'Varken'
Doeldier (Target animal)	'Zeugen en geiten'
Stofnaam (Substance Name)	'lufenuron' (in another record)
hoeveelheid2 (amount2)	''
Per2	''
Min dos (Min dose)	'10' (in another record)
Max dos (Max dose)	'10' (in another record)
Rekendos (Calculation dose)	'10' (in another record)
DDF (daily dose factor)	'80.0' (in another record)
Ther.Duur (therapy duration)	'1' (in another record)
Duur GVP (Duration of GVP; minimum - and recommended - therapy duration)	'0' (in another record)
Diersoort2 (Animal Type2)	''
Doeldier2 (Target Animal2)	''
Soort Type (production)	'Melk' (in another record)
Dagen (Days; waiting time for consumption)	'3.5' (in another record)
Complex (waiting time complexity)	'*' (in another record)

In terms of code usage, the GTIN (EAN), REG NL, Channelling, Per (unit) and ATC-code (Indc) are easily digitally reusable. The product name refers to additional information relative to the GTIN. Other data fields refer to numbers (good digital reusability) and free text fields (digital reusability less effective) or proprietary standard lists (digital usage less wide).

4.1.9 IDMP

In the case of human medicines, the EU is developing Identification of Medicinal Products (IDMP)[10]. This data source is based on ISO standards related to internationally harmonised specifications for medicinal products (https://www.ema.europa.eu/en/human-regulatory/overview/data-medicines-iso-idmp-standards-overview). IDMP aims to become the basis for registration of human medicines in Europe.
Several data fields use databases that are part of SPOR, Substances Products Organisations Referentials. The 'Products' database contains all consumer units with their composition.
'Organisations' refers to the registration holders of the veterinary medicines. 'Referentials' refers to doses and other information.
Most products are developed for human applications, and then the product is considered for use on animals, with reference to the human reports. Active substances in the aforementioned EU SRS are described in a format of IDMP [4].

[10] https://www.nictiz.nl/standaarden/idmp

4.1.10 Comparison of the different data sources

The table below shows what data fields the various data sources have, where we give examples or descriptions of the values of the data fields, e.g. '8714225004218' and '8713942400044' for the GTIN data field in the FIDIN Online Repertorium and the Branchecodetable. These sample values relate to different products or articles and thus are not substantively comparable to each other. Thus, an empty cell (grayed out) means that the data source in question does not contain the specific data field.

Table 4: Comparison of the various data sources with example values.

Data field	Veterinary Medicines Information Bank	EMA Medicines database	VMRI Product Index	FIDIN Online Repertorium	Branch Code Table
GTIN				'8714225004218'	'8713942400044'
Master GTIN					'8713942400044'
Item name				'Paraffine vloeibaar 1 liter '	'Progressis 25 d 1 x 50 ml'
Packaging				'Flacon à 1 l. Can à 5 l.'	
Package number					'25'
Packaging unit					'dosis'
Registration number veterinary medicine [and channelling status]	'REG NL 102258'	'EMEA/V/C/000094'		'REG NL 1858 VRIJ'	'REG NL 9819'
Mutual recognition number			'IE/V/0504/001'		
RMS			'Ireland'		
Name of veterinary medicine	'Onsior 6 mg tabletten voor katten'	'Equilis Prequenza'	'Clavudale 40mg / 10mg Tablets for Cats and Dogs'		
International name		'Vaccine against equine influenza in horses'			
Local name of veterinary medicine			'Clavudal 40 mg/10 mg'		
Authorisation holder [and address]	'Elanco GmbH'	'Intervet International BV' (see also below)	'Dechra Regulatory B.V. Handelsweg 25 5531 AE Bladel The Netherlands'	'NL_Dechra'	
Address		'Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer The Netherlands'	See above		
Start date	'16 december 2018'	'08/07/2005'	'05.01.2012'		
Last modification date [with status]			'11.12.2020'		
Revision		'9'			
ATCvet-code [and name]	'QM01AH91 – Robenacoxib'	'QI05AA01'	'QJ01CR02 amoxicillin and enzyme inhibitor'		'QI09AA05'
Active substance [and concentration]	'ROBENACOXIB' and '6 mg/stuk'	'Equine influenza-virus strains: A/equine-2/South Africa/4/03, A/equine-2/Newmarket/2/93'	'moxicillin 40 g clavulanic acid 10 g'		'porcine reproductief en respiratoir syndroom virus (PRRS), geïnact.' and '0.0', 'mg', and 'dosis' for the 'Hoeveelheid', 'Per', and 'DV' data fields[11]
Daily dose factor					'80.0' (in another record)
Therapy duration					'1' (in another record)
Minimum (and recommended) duration of administration					'0' (in another record)
Indication					'PRRS-virus, geïnact. - QI09AA05'
Excipient and concentration	'CELLULOSE, MICROKRISTALLIJN (E 460)' and ''				
Target animal [and product type]		'Horses'	'Cats Non Food Dogs Non Food'	'Paard, hond, kat.'	'Varken' for the data field 'Animal Diersoort', and 'Ze'gen en geiten' for the data field 'Doeldier', which is a subdivision of it[12]
Type of Product					'Melk' (in another record)
Waiting time for consumption					'3.5' (in another record)

[11] There are duplicate fields (with sequence number 2 in the names) for one more substance with concentration, where the dose is divided into three fields: minimale dosis (minimum dose), maximale dosis (maximum dose), and rekendosis (calculation dose).

[12] There are duplicate fields (with sequence number 2 in the names) for diersoort (animal species) and doeldier (target animal).

Data field	Veterinary Medicines Information Bank	EMA Medicines database	VMRI Product Index	FIDIN Online Repertorium	Branch Code Table
Waiting time complexity					'*' (in another record)
Pharmaceutical form	'Tablet'		'Tablet'	'Vloeistof.'	
Form of administration [and dose]	'Oraal gebruik'		'Other Generic application'	'Toediening: Oraal, evt. rectaal. Paard: 1e dag 2 à 3 maal daags 1 l, 2e en 3e dag telkens 1 l per dag. Hond: 5 - 30 ml enkele keren per dag. Kat: 2 - 5 ml enkele keren per dag.'	'intramusculair'
Channelling	'Uitsluitend verkrijgbaar bij een dierenarts of op recept van een dierenarts bij een apotheek'				'UDD'
Composition				'Per ml 1 ml of paraffine.'	
Properties				'Zie inleiding.'	
Indications				'Paard: obstipatie, in het bijzonder koliek. Hond, kat: obstipatie.'	
Contraindications				''	
Side effects				''	
Waiting time recommendation				'0 dagen.'	
Warnings				''	
Storage conditions/ Shelf life				'3 jaar, bij 15-25°C.'	
PAR document			Link to a PDF plus a date in parentheses		
SPC document	Link to a PDF		Link to a PDF plus a date in parentheses		

Some data sources relate to veterinary medicine registrations, while others relate to *consumer units* (articles) of veterinary medicines. A link between the two is only established in the FIDIN Online Repertorium and the Branchecodetable. These data sources refer on the one hand to the registration number of a veterinary medicine and on the other hand to the GTIN of the consumer unit. Registration numbers from BD (national) and EMA (Europe) are used in the Veterinary Medicines Information Bank and the EMA Medicines database in addition to the above data sources. The VMRI Product Index works with the European Mutual Recognition Number (EMRN). Figure 16 provides an overview of data sources related to consumer units of human and veterinary medicines within the EU and NL. For human medicines, the G-Standaard (https://www.z-index.nl/g-standaard) exists in the Netherlands and a European system is being developed.

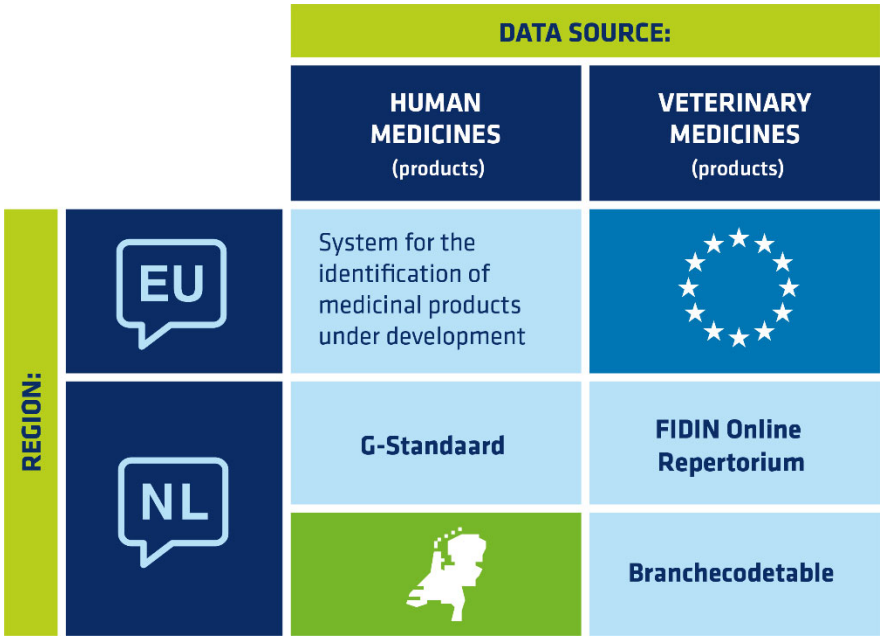

Figure 16: Data sources with consumer items of human and veterinary medicines.

A number of data fields in the various databases refer to standard codes, but many data fields are not digitally reusable or less so. Sometimes combinations of codes and (free) text are created within a single data field, which reduces the digital reusability of the code. There are routinely free text fields, or standard lists with limited use.

The source that does not provide the registration number of the product, VMRI Product Index, provides start and end dates for the product's registration. The other sources only provide the start date or no date at all, but this can be ascertained using the registration number in the Veterinary Medicines Information Bank.
The authorisation holder is given in all sources except the BCT. This is done in text form, so with lower digital reusability.
Only the FIDIN Online Repertorium uses a country code ('NL'), tacked with an underscore before the company name, which also lowers digital reusability.
The ATCvet-code only appears in the Veterinary Medicines Information Bank, the EMA Medicines database, the VMRI Product Index, and the Branchecodetable. Only the EMA Medicines database and the Branchecodetable use them without textual additions, making digital reusability the highest there.
The active substance and concentration also appear only in these four data sources, with the substance name and concentration appearing only separately in the Veterinary Medicines Information Bank and the Branchecodetable. In the other two sources, these are combined into one string, which lowers digital reusability.
The target animal, possibly combined with product type, are only shown by names in the EMA Medicines database, the VMRI Product Index, the FIDIN Online Repertorium, and the Branchecodetable.
The data fields have different names in the various data sources. The table below provides these names. If a cell is empty (grayed out for the overview), the data source does not contain the corresponding data field.

Table 5: Naming of fields in the various sources.

Data field	Veterinary Medicines Information Bank	EMA Medicines database	VMRI Product Index	FIDIN Online Repertorium	Branch Code Table
GTIN				'EAN code'	'EAN'
Master GTIN					'Master EAN'
Item name				Presumed artikelnaam	'Productnaam'
Packaging				'Verpakking'	
Package number					'verp aantal'
Packaging unit					'verp eenheid'
Registration number veterinary medicine [and channelling status]	'Registratienummer:'	'Agency product number'		'Registratienummer/Kanalisatiestatus'	'REG NL'
Mutual recognition number			'MR Number'		
RMS			'RMS'		
Name of veterinary medicine	'Productnaam'	'Name'	'Product Name in the RMS'		
International name		'International non-proprietary name (INN) or common name'			
Local name of veterinary medicine			'Domestic Product Name' (for each 'CMS Country', e.g. 'Belgium')		
Authorisation holder [and address]	'Handelsvergunning houder:'	'Marketing authorisation holder'	'MA Holder in the RMS'	'Leverancier'	
Address		'Contact address'			
Start date	'Datum inschrijving handelsvergunning:'	'Date of issue of marketing authorisation valid throughout the European Union'	'Date of outcome'		
Last modification date [with status]			'Date of last change'		
Revision		'Revision'			
ATCvet-code [and name]	'ATCvet code:'	'Anatomical therapeutic chemical veterinary (ATCvet) codes'	'ATC-Code'		'IndC'

Active substance [and concentration]	'Werkzame stof' (for each active substance 'Substantie' and 'Concentratie')	'Active substance'	'Active substances'		'WS', and 'Hoeveelheid 'Per', and 'DV'[13]
Daily dose factor					'DDF'
Therapy duration					'Ther.Duur'
Minimum (and recommended) duration of administration					'Duur GVP' (Good Veterinary Practice)
Indication					'Naam Indicatie'
Excipient and concentration	'Hulpstoffen' (voor elke hulpstof 'Substantie' en 'Concentratie')'Hulpstoffen' (for each excipient 'Substantie' and 'Concentratie')				
Target animal [and product type]		'Species'	'Species'	'Doeldieren'	'Diersoort'. The data field 'Doeldier' is in turn a subdivision of that[14]
Type of Product					'Soort'
Waiting time for consumption					'Dagen'
Waiting time complexity					'Complex'
Pharmaceutical form	'Farmaceutische vorm:'		'Form'	'Farmaceutische vorm'	
Form of administration [and dose]	'Toedieningsweg:'		'Application type level'	'Toediening/Dosering'	'Toedieningswijze'
Channelling	'Afleverstatus:'				'Kanalisatie'
Composition				'Samenstelling'	
Properties				'Eigenschappen'	
Indications				'Indicaties'	
Contraindications				'Contra-indicaties'	
Side effects				'Bijwerkingen'	
Waiting time recommendation				'Wachttijdadvies'	
Warnings				'Waarschuwingen'	
Storage conditions/ Shelf life				'Bewaarcondities/Houdbaarheid'	
PAR document			'PAR document'		
SPC document	'SPC, etiket en bijsluiter'		'FinalSPC document'		

4.2 Process data

Whereas master data on animal treatment products is organised in the same way for each sector, we see that this is certainly not the case for process data. We see that there are many different initiatives, interfaces and data files in each sector. Some of these are cross-sectoral, but the majority focus on one specific sector. Moreover, we see significant differences.
These differences arise mainly from the characteristic scale of livestock species. Pigs and chickens are mainly recorded at the group or stall level. In pigs, sows and piglets are again registered in a different way. Cattle and calves are mostly recorded at the individual animal level.
We also see major differences in registration, not only by sector, but also by group of veterinary medicines. Antibiotics and vaccines are subject to different laws and guidelines than other products. Furthermore, there is another difference in recording between the supply of veterinary medicines and their administration.
In this chapter, we look particularly at process data across sectors. In addition, the awareness meetings paid special attention to the organisation of process data in the pig and calf sectors. These are also discussed in this chapter.

4.2.1 Antibiotics

The current legislation on registration of the use of veterinary medicines dates back to 2008.
At the time, the link was made between livestock farming and the frequent occurrence of MRSA bacteria. It also revealed that sales of therapeutic veterinary antibiotics had risen sharply. In 2008,

[13] There are duplicate fields (with sequence number 2 in the names) for one more substance with concentration, where the dose is divided into three fields: minimale dosis (minimum dose), maximale dosis (maximum dose), and rekendosis (calculation dose).
[14] There are duplicate fields (with sequence number 2 in the names) for diersoort (animal species) and doeldier (target animal).

the Minister of Agriculture and various parties in the livestock industry entered into a covenant to significantly reduce the use of antibiotics in the livestock industry. The main tool used was the recording and benchmarking of antibiotic use. For this purpose, VetCIS was [34] created. This was a data hub through which veterinary medicine deliveries per livestock farm were forwarded to the sector databases for swine, veal calves, poultry and cattle by veterinary practices through their management systems. This allowed for the creation of an image of antibiotic use by sector [35].
The SDa (Netherlands Veterinary Medicines Institute) was established in March 2011. Starting in 2011, the SDa has annually received all veterinary medicine deliveries and animal numbers per farm from each livestock sector.
These numbers are the basis of the benchmark numbers that SDa calculates with the help of the DierGeneesmiddelen-standaard (DG-standaard): DDDAF (defined daily dose animal per farm) represents the number of animal daily doses per animal year per farm.
An overall national utilisation, the DDDANAT, is also calculated for the entire sector. This number indicates how many days per year an average animal in the industry was treated with antimicrobials. These numbers are published each year in the Nethmap /MARAN report [36]. This is a combined human/veterinary report on resistance development and use of antimicrobial products. The Dutch Working Party on Antibiotic Policy (Dutch acronym is SWAB) is responsible for Nethmap/MARAN reporting.
Because there is a real chance that microorganisms build up resistance to certain veterinary medicines [37], in the case of antibiotics, a distinction is made between first-choice, second-choice and third-choice products.
To protect human health, there must be a valid reason for using a second or even third-choice product in livestock production. The motivation should always be provided by the veterinarian [38]. The use of second-choice and particularly third-choice products has decreased dramatically since the start of registration and benchmarking [35].

4.2.2 Animal Daily Dose (DDD)

One tool for reducing antibiotic use in livestock production in particular is benchmarking. It allows livestock farmers to compare their use of animal treatment methods with those of similar farms. It also allows veterinarians to compare their use with that of others. An important number here is the Animal Daily Dose (DDD). Today, the SDa uses the term *'Defined Daily Dose Animal' per farm per year* (DDDAF) for this purpose in order to better align with international terminology. The DDDAF is calculated as the sum of the treatable kilos present on a farm over a year divided by the average number of kilos of animal present on a farm. This measure reflects usage at the farm level and is used to benchmark a farm company [39]
Because business practices in different sectors are not comparable, there are differences in the benchmark values at which an action is required by the livestock farmer or veterinarian.
These benchmark values are set by the SDa. A detailed description of how these numbers are calculated can be found in the SDa's 'Standard Operating Procedures'. [39]

4.2.3 Data sets

Within the field of animal treatment products, there are several places where data is collected or where information can be obtained. Online databases can be found for registration, general product information and administration and use of the veterinary medicines. Some sources are not public and are only accessible to suppliers of the data and authorised persons. In this chapter, we name interfaces and data collections that are in use in multiple chains. Here we do not pretend to have produced an exhaustive list. More specific data sets are discussed in the annexes.

4.2.3.1 Database of antibiotic use SDa

The Netherlands Veterinary Medicines Institute (SDa) is an independent institute that, among other things, sets standards for the responsible use of antibiotics in livestock production in the Netherlands. The SDa commissions, reports, and oversees the delivery of utilisation data and improvement processes. The SDa establishes benchmark indicators for antibiotic use in the livestock industry [21].

4.2.3.2 I&R RVO

In cases of animal diseases that pose threat to public health, swift action must be taken. Thus, there are legislation and regulations for the identification and registration (I&R) of animals (rvo.nl).
This regulation applies not only to commercially kept animals, but also, for instance, to dogs and horses. For cattle, pigs, sheep or goats and other animals kept on a commercial basis, the location where these animals are kept must also be registered with a so-called Unique Business Number (UBN) [40].

In cattle, calves receive two ear tags within 3 days of birth. The I&R database of the Rijksdienst voor Ondernemend Nederland (RVO) records which ear tag was delivered to which farm [40].

Pigs must be earmarked within one week of weaning or no later than 3 months after birth or earlier upon removal from the farm.
In addition to the regular ear tag, before a pig goes to slaughter it is given a so-called slaughter tag which shows the UBN of the last location the pig was at [41].

In dairy goats, earmarks must be applied within 7 days of birth. In sheep or other goats, this must be done within 6 months of birth. RVO's I&R database records which earmark is delivered to which farm[40].

For chickens, a KIP (Koppel Informatiesysteem Pluimvee) registration number is needed to register farm, housing data and type of livestock production. This number is administered by the designated poultry database AVINED [42].

Chamber of Commerce, BRS, UBN and their relationship
In the Netherlands, companies are registered with the Chamber of Commerce (KvK) with a KvK number. An agricultural company is also required to be registered with the Rijksdienst Voor Ondernemend Nederland (RVO) with a business relationship number (BRS number). This BRS number is linked to a KvK number.
An agricultural company with animals, must also be registered with the RVO as a livestock keeper. Livestock keepers are assigned a Unique Business Number (UBN) for each stall location. This UBN is again linked to both the BRS number and the KvK number.

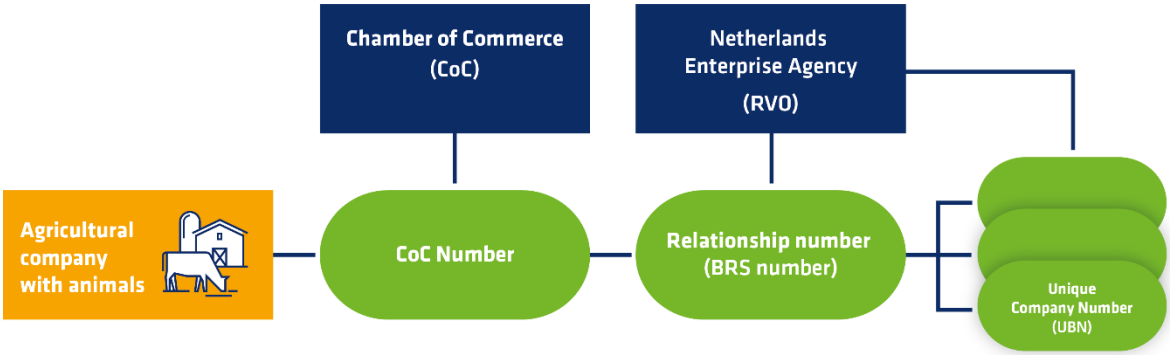

Figure 17: Relationship between of Chamber of Commerce, BRS and UBN.

Registration of animals and registration of animal movements are maintained per stall location (UBN). Animal registration in the Netherlands is required to be done through the Identification and Registration (I&R) system of RVO (for grazing animals) or through a database of manufacturer organisations (for poultry and pigs). Thus, agricultural companies with pigs and/or poultry must also be registered with a manufacturer organisation to keep their animal records.

4.2.3.3 ESVAC

The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project collects information on how antimicrobial products are used in animals throughout the European Union (EU) [43]. This type of information is required to identify conditions that may lead to the development and spread of antimicrobial resistance in animals. This database holding information on sold quantities of

antibiotics in Europe is accessible to anyone and can be downloaded as Excel files.
This registration was initially done on a voluntary basis by the various countries. This voluntary participation has increased from 9 to 31 member states since 2010 [43]. As of the new Veterinary Medicines Regulation, participation by all member states will be mandatory [44].

Figure 18: ESVAC database.

4.2.3.4 VetCIS

In response to the ESVAC project, the CBG exported the Veterinary Medicines Information Bank (antibiotics; approximately 400-500 medicines) for FIDIN. FIDIN then started working on this with suppliers. This is where VetCIS originated from [34]. This database contains article numbers. Vets use these article numbers, at the consumer unit level (packaging level) but not at the trade-item level. To update the database, they keep up to date with the official Government Gazette; new registrations are added manually by the producers through FIDIN. A batch of a veterinary medicine is always country-specific due to registration and the language on the label and package insert. EU legislation only requires a few data fields on a base unit package.
The VetCIS is now a data hub that supports and standardises digital information flows to and from the veterinarian. The data hub provides a central database for the prescription of and dispensing of data on veterinary medicines that enables the generation of benchmarks on veterinary medicine use for veterinarians as well as to aid reporting for scientific purposes and the government. (www.vetcis.nl)
The previously mentioned systems and databases use standards that are used for both veterinary and human medicines.

4.2.3.5 VETmessage

VETmessage is an independent industry-wide digital platform for sending and receiving electronic messages for veterinary medicine deliveries. It enables the purchaser of veterinary medicines and other veterinary products, to receive data from ordered consumer units electronically and process it directly into their practice management system. The system is now used to electronically send and receive packing slips (all information about the veterinary medicines delivered, including lot number, quantities and shelf life) [45]. The system will also be used to send and receive other information such as price tables and scales.

The Veterinary Medicines Regulation describes the generally applicable administrative obligations of veterinarians with respect to veterinary medicines [46]. The following must be reproducible in a simple manner with respect to each transaction and each package [47]:

- date of the transaction

- name and registration number of the veterinary medicine
- lot number
- quantity received or delivered/used
- name and address of the supplier or recipient
- identification of animals treated or to be treated
- expiry date

4.2.3.6 Food Chain Information (FCI)

By means of the so-called FCI form, livestock farmers can provide declarations about the health status of the animal or group of animals in question as well as information about the administration of veterinary medicines to the animal or group of animals to be slaughtered.
Since 1 January 2009, livestock farmers have been required under Regulation (EC) No. 853/2004 to deliver Food Chain Information (FCI) with the animals entering the slaughterhouse. In terms of veterinary medicines, all treatments administered within 35 days prior to slaughter must be listed. For antibiotic treatments, this is subject to a 60-day limit [48].

4.2.4 Information flows in the calf sector

The Dutch veal industry is characterised by a strong integration model within the chain: a limited number of large players control a large portion of the Dutch veal trade.
The white veal sector is highly integrated in the Netherlands. Partly because of this, this sector is able to be competitive in Europe. Integrations often stall calves on a fee basis with veal farmers. The veal farmer receives compensation for labour, stall space and also manure. Integration provides and retains ownership of the calves and the required feed, and takes care of the disposal of the calves ready for slaughter.
The pink veal sector has more free-ranging veal farmers, who keep the animals partly or fully at their own expense and risk. (1)

4.2.4.1 SKV (Stichting Kwaliteitsgarantie Vleeskalversector - Veal Calf Quality Foundation) database

This is a database into which veal processors enter slaughter data for herds of veal calves. Through the database, the SKV digitally delivers the required data to the veal processors on behalf of the veal farmer.

4.2.4.2 Guarantee System Tracing SKV - Veal calves (GTSKV)

This guarantee system includes a database in which the parties affiliated with SKV must report the transports of imported calves. It can take up to 5 days for transport data to be known when using the regular I&R scheme. However, with the GTSKV, this information is already known before transport [49].
SKV aims to also make GTSKV operational for domestic transports from calf collection centres to calf farmers.

4.2.4.3 InfoKalf database

Antibiotics are registered in InfoKalf. In this database, veterinarians can record which antibiotics have been prescribed to which veal calf farmer. This database has been designated by the government as a registry as referred to in the Animal Keepers Decree (Besluit houders van dieren). The veal calf farmer may authorise external parties, such as a veterinarian, to view these data [50] [49]. The InfoKalf website provides insight into such things as medicine deliveries, animal daily doses, FCI and ICM (Integrated Chain Management) statuses, antibiotic registration and veterinary medicine administration.

4.2.4.4 Calf Tracing System (CTS)

The CTS, developed on behalf of ZuivelNL, Vee&Logistiek Nederland and SBK, offers the possibility of registering every calf during transport from the dairy farmer to the calf farmer.
The Calf Tracing System (CTS) is a link in a chain registration system of newborn calves and is a contributing part of the certification system within the 'Vitaal gezond en duurzaam kalf' plan for livestock traders.

The CTS helps to improve compliance with existing quality requirements and the traceability of newborn calves. In addition, it offers opportunities to promote data exchange between the birthing farm and calf farm.

Traders and transporters immediately register every calf they load onto a transport at a dairy farm. In doing so, the animals should be assessed and monitored for age, weight and health. This calf transportation data is stored in a central database. Before the calves are unloaded at the collection centre, staff check that all animals to be unloaded are in the CTS [51]. The CTS is a database that allows a calf to be tracked from birth to slaughter, including transport movements. The data is not publicly available.

4.2.4.5 Vital Calf quality scheme

Vital Calf (Vitaal Kalf) is a new quality scheme set up by Stichting Brancheorganisatie Kalversector, covering the entire calf chain. In addition to veal farmers, other chain partners are participating in this scheme. In addition to revised ICM regulations, Vital Calf also includes new regulations (including reduction of antibiotic use, legally required monitoring of prohibited substances)
Vital Calf also forms the basis for future information exchange with the dairy industry. In doing so, SBK is anticipating developments within and outside the industry [51]. The so-called Animal Daily Dose (DDD) of each participant in the Vital Calf programme is also calculated. If the DDD falls above a standard set by the SDa, the veal calf farmer is required by the Vital Calf scheme to take measures to reduce use.

4.2.5 Information flows in the pig industry

In the Dutch pig industry we find a number of different farm types:

- Breeding farms: These farms only raise sows. Piglets are delivered to fattening pig farms after about 10 weeks.
- Fattening pig farms: On these farms, the piglets are fattened. Breeding farms deliver piglets at an average of 25 kg. When the piglets have reached a weight of about 110 kg, the fattening pigs go to a slaughterhouse.
- Closed farms: On closed farms, both breeding and fattening take place on the same farm.

Within the pig industry, we see large differences in the extent to which companies store use data of animal treatment methods. On larger and more automated farms, sows tend to have digital identifiers such as transponders, but piglets generally only have a traditional ear number. Registration of treatments of sows can often be recorded digitally with this system. In the case of piglets, this is done manually and at the group level.
However, there are already chains where piglets also have a digital transponder. However, the cost of these transponders is currently too high for this to be widely implemented.
The registrations can be made by the certifier (e.g. ICM) are checked annually.

A treatment plan is drawn up for a farm together with the veterinarian. Treatments are discussed with the veterinarian, but if pig farmers have taken the obligatory courses, they can administer the medication themselves. Only a limited amount of medication should be stocked on a farm. If a farm is affiliated with ICM, this stock information is maintained centrally at the ICM institution.
For most medicines, there are waiting periods before animals can enter the chain and treatments are not stored in a central database.
However, in the case of vaccinations and antibiotics, different rules apply and treatments must be recorded at the animal or group level, depending on the sector. Currently, the main reasons for

recording the use of veterinary medicines are to counteract bacterial resistance to certain essential antibiotics and to record the use of vaccines. [52]

4.2.5.1 IKB Varken

IKB Varken (ICM Pig) stands for Integrated Chain Management Pig. Each party in the production chain, from livestock farmer to butcher, can voluntarily participate in the ICM Pig scheme. This means that all participants in the entire chain conform to the quality requirements of ICM Pig.
It includes a register in which all ICM Pig-approved companies are registered. In addition to livestock producers, these include slaughterhouses, meat processing plants, and retail outlets [53].
ICM Pig is based on a positive list of veterinary medicines that includes the medicines permitted to be admitted to the ICM Varken scheme [54].

4.2.5.2 fTRACE

fTRACE is a German traceability solution. The system is based on the global GS1 standards, including EPCIS (Electronic Product Code Information Services) [55]. Partly because of this, all parties can exchange information within the supply chain [56]. (https://web.ftrace.com)

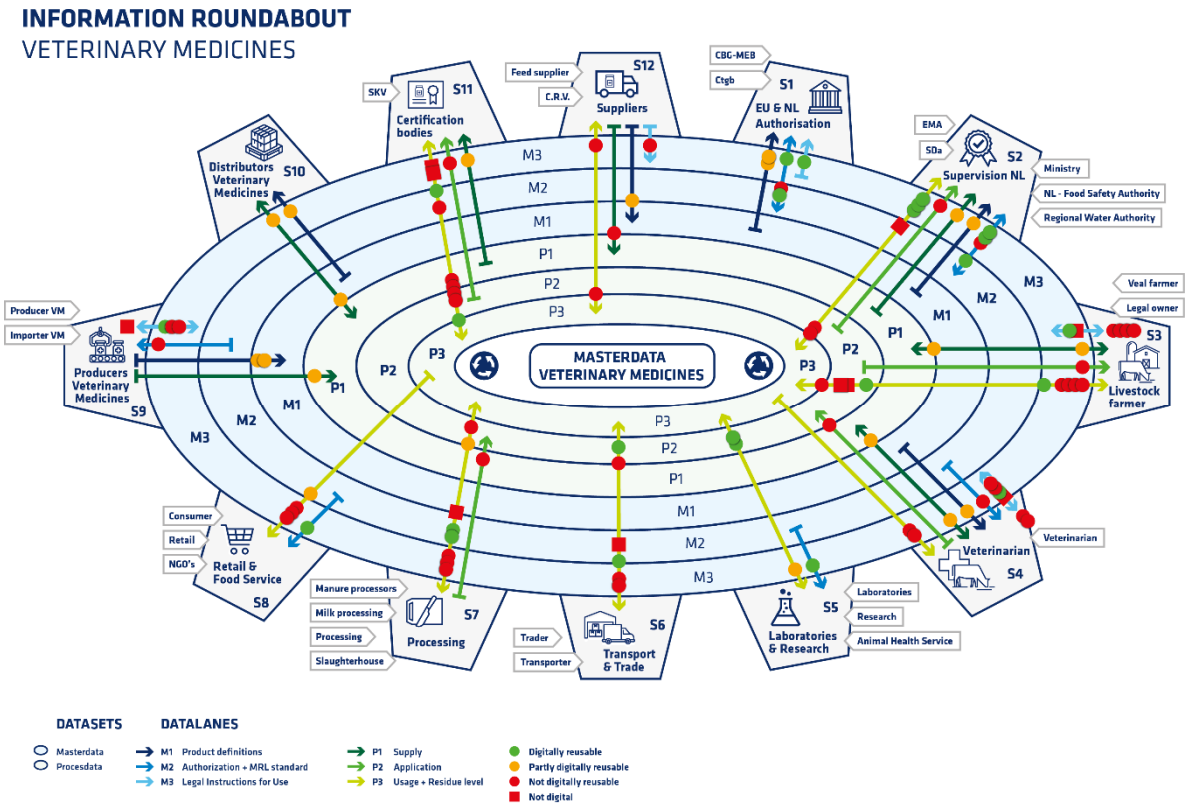

Figure 19: Information roundabout.

Table 6: Databases in which veterinary medicine use is recorded.

	Address	**Calves**	**Pigs**	**Cattle**
Database of antibiotic use SDa		X	X	X
ESVAC	esvacbi.ema.europa.eu/ analytics/saw.dll?PortalPages	X	X	X
Guarantee System Tracing SKV		X	-	-
I&R RVO		X	X	X
IKB Nederland	ikbnederland.nl	-	X	X
IKB Varken	ikbvarken.nl	-	X	-
Info Varken	infovarken.nl	-	X	-
Info Kalf	infokalf.nl	X	-	-
Calf Tracing System		X	-	-
MediRund	medirund.com	-	-	X
Vital Calf quality scheme	kalversector.nl/vitaal-kalf	X	-	-
Food Chain Information		X	X	X

5 Conclusion

5.1 Master data

This research shows that the data landscape in the field of veterinary medicines, especially in the European area, is very fragmented, with EMA Medicines database, EMA's veterinary medicine database, and Veterinary Mutual Recognition Information (VMRI) Product Index database. The latter two were merged into the Union Product Database on 28 January 2022. This is a good development. Next, it should be further investigated how the EMA Medicines database and the Dutch Veterinary Medicines Information Bank relate to this new database: where is the overlap, which standards are used, etc.?
Fragmentation is also evident in the fact that registered veterinary medicines and consumer units (articles, i.e. the packages of veterinary medicines) are in different databases. For instance, in the Dutch landscape, veterinary medicines are listed in the Veterinary Medicines Information Bank and consumer units in the Branchecodetable. Thus, the Veterinary Medicines Information Bank does not contain article numbers (GTINs), which would be desirable for other supply chain partners. The CBG, as a ZBO (Zelfstandig Bestuursorgaan - Independent Administrative Body), is legally responsible for the registration of medicines in the Netherlands. With that, however, information availability in this area is still too piecemeal. All data must be able to be retrieved centrally. Ideally, the different database types should be linked. In this manner, a system is obtained that contains veterinary medicine and consumer unit information. The FIDIN Online Repertorium and the Branchecodetable are existing initiatives in this area, but do not cover the entire Dutch market area: all antibiotics, but not all other types of products (non-antibiotics), yet are reasonably exhaustive. Of all the products in BCT, 95-98% come from FIDIN members. From the perspective of the chain partners, it is recommended to either broaden CBG's core task or to expand the FIDIN Online Repertorium and the Branchecodetable with the remaining portion of the articles available on the Dutch market.
For *human* medicine consumer units, the G-Standaard exists in the Netherlands and a European system is under development. For consumer units (veterinary medicine articles), as mentioned above, the FIDIN Online Repertorium and the Branchecodetable exist in the Netherlands, but no such initiative exists yet in the European area. It is advisable for veterinary medicine articles to join the European initiative for human medicine articles.
FIDIN Online Repertorium and Branchecodetable are used by many veterinarians in their PMSs. However, livestock producers' BMSs are not yet equipped to handle these data sources. Veterinarians act as intermediaries between industry and livestock farmers. Moreover, FIDIN's focus is very much on the Netherlands, for instance, in the area of data fields (e.g. Dutch Chamber of Commerce) and use of standards (currently more focused on the Netherlands rather than international standards and codes) and technical information for veterinarians. The system should be expanded for veterinary medicine logistics by adding data fields such as package dimensions (length, width, height) and materials.

Linkage and access issues are playing out in several areas:

- Linking of data to ensure there is no need for overlap in data sources. Instead of 'linkage', perhaps it would be better to speak of 'alignment'. Based on the data fields to be aligned, data sources can be combined.
- Digital access through an API, which provides information for automatic processing in a standardised form.
- The standardisation in its self: of data fields, (excerpts of) tables, (excerpts of) databases, forms, messages, etc. For the time being, this standardisation is mainly limited to data fields (e.g. a registration number) and messages (e.g. VETmessage messaging).

Apart from the sphere of linkage, there are also important steps to be taken in the technical area. For example, the CBG's Veterinary Medicines Information Bank, the EMA Medicines database, the EMA veterinary medicine database, and the HMA Veterinary Mutual Recognition Information (VMRI) Product Index database currently do not have an API (Application Programming Interface), as the Ctgb's MST database for crop protection products, biocides, and adjuvants does. However, for the sake of good digital information access to chain partners, an API is necessary [4]. The FIDIN Online Repertorium has recently introduced an initial API version, and with it the Branchecodetable indirectly, since that is the source file of the FIDIN Online Repertorium. Thus, the information exchange between the government (CBG) and customers (chain partners) is not yet fully digital in a two-way manner. Chain partners should on the one hand supply information digitally to the CBG, for example, in the field of adverse reactions to medicines, while on the other, the CBG does not yet supply this information digitally to its customers.
Another issue is that in CBG's Veterinary Medicines Information Bank, information from the EMA Medicines database is currently (manually) copied. This effectively copies the information, with the expected proneness to errors, delays, and maintenance problems that result. To avoid this, it is important to link the Veterinary Medicines Information Bank to the EMA Medicines database, eliminating the need for a secondary source.
Many data are not yet sufficiently standardised in existing data sources. People still often work with free text fields which lowers the digital reusability of information. This applies to almost all data fields, such as doses and modes of administration, among others. Only identification numbers are currently standardised to a significant degree. It is true, however, that there is still a gap between human medicines and veterinary medicines in this area. Human medicines have a different registration number than veterinary medicines, namely the RVG number versus the REG NL number. These numbers are not linked, making possible integration and identification of human medicine information and veterinary medicine information difficult. This is particularly problematic in light of antibiotic use for humans and animals, and bacterial resistance to antibiotics.

5.2 Process data

We see that in the context of antibiotic use, there is regulation and standardisation in terms of recording the administration of medicines. However, for other veterinary medicines, there is now a multitude of various initiatives. There is no shared vision of how to organise this in an efficient and effective way. We see overlap and missing standards which has increased the administrative burden, especially on the livestock farmer.
Finally, a point on the use of GLN (Global Location Number) by companies [57]. At present, it is not yet used in the registration of veterinary medicines by the Dutch government. One works instead with a company’s KvK number (Chamber of Commerce number). However, for better (international) traceability of products, it is important to use the GLN because the KvK number is only applicable nationally. For deliveries, one could then work with messages that are common in practice, as GLN is already widely used in international logistics. In addition, the KvK number is not scannable.

So, in summary, steps can be taken in linking data sources, providing APIs, and standardising information components. To achieve this, disparate bodies such as the EU, CBG, and FIDIN will need to start working together.
Lessons can be learned from the crop protection sector where retail parties have taken the reins of registration with supra-legal requirements that are less workable for growers. Proactive chain cooperation and standardisation of the registration of veterinary medicine use can prevent this from happening.

5.3 Recommendations

- An API needs to be built for CBG's Veterinary Medicines Information Bank.
- It is also important to develop an API for the EMA Medicines database.

- Link CBG's Veterinary Medicines Information Bank to the EMA Medicines database to avoid errors, delays and maintenance of this information in the former source.
- Deliver all information from the Veterinary Medicines Information Bank to customers digitally. This is for instance not yet the case for adverse reactions to veterinary medicines, which chain partners must submit digitally to the CBG.
- Expand the Veterinary Medicines Information Bank to include product article numbers, or expand the scope of the FIDIN Online Repertorium and the Branchecodetable to include the entire veterinary medicines market.
- Explore the possibilities of exchanging prescription-only veterinary medicines via a GS1 data pool, in addition to article master data for over-the-counter medicines.
- In the European field, a system is being developed for human medicine articles à la G-Standaard for the Netherlands. In the case of European veterinary medicine products, we advise joining this system.
- Link the different European veterinary medicine databases.
- Link the various veterinary medicine databases and veterinary medicine article databases (e.g., Veterinary Medicine Information Bank and Branchecodetable).
- A general recommendation is to use the GLN to identify production plants, for better (international) traceability of products. It is also important to use other standards such as GTIN and dispatch messages when trading the products.
- Branchecodetable, and thus FIDIN Online Repertorium, should be expanded for logistics of veterinary medicines by adding data fields such as packaging dimensions (length, width, height).
- Further standardisation is needed in the area of recording administration of veterinary medicines that is in line with the recording of antibiotic use.

6 Glossary

	Name
aCBG	Agentschap College ter Beoordeling van Geneesmiddelen (see CBG)
ATCvet	Anatomical Therapeutic Chemical classification system for veterinary medicinal products
BCT	Branchecodetable (FIDIN). All Dutch packages of veterinary medicines have a barcode and are accessible via one central database
BD	Medicines Evaluation Board (Bureau Diergeneesmiddelen)
BMS	Business Management System
BRS	Business Registration System. This is the relationship number of a company issued by RVO and previously a legal predecessor of RVO
CRV	Cooperative Beef Improvement (Coöperatie Rundveeverbetering)
CBG	Medicines Evaluation Board
CBG-MEB	College ter Beoordeling van Geneesmiddelen – Medicines Evaluation Board, official name of the CBG
CIBG	Implementing body of the Ministry of Health, Welfare and Sport
CMS	Concerned Member States
CP	Central Procedure
CPD	Collective of Practicing Veterinarians (Collectief Praktiserende Dierenartsen)
Ctgb	Board for authorisation of plant protection products and biocides
CVMP	Committee for Veterinary Medicinal Products
DBM	Animal Treatment Product (Dierbehandelingsmiddel)
DCP	Decentralised Procedure
DDB	Dutch Dairy Board
DDD	AnimalDailyDose (DierDagDosering)
DDDAF	Defined Daily Dose Animal per Farm
DDDANAT	Defined Daily Dose Animal National
DGB	De Groene Belangenbehartiger
DGM	Veterinary Medicine (Diergeneesmiddel)
EAN	European Article Number (currently GS1-13)
EER/ EEA	Europese Economische Ruimte / European Economic Area
EMA	European Medicines Agency
EMEA	European Medicines Evaluation Agency, former name EMA
EMRN	Europese Mutual Recognition Number
EPAR	European Public Assessment Report
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption.
EU	European Union
EU SRS	European Substance Reference System
FIDIN	Fabrikanten Importeurs Diergeneesmiddelen Nederland
GDP	Good Distribution Practice
Gemzu	Vereniging Gemeenschappelijk Zuivelsecretariaat
GLN	Global Location Number
GMP	Good Manufacturing Practice
GTSKV	Guarantee System Tracing SKV - Veal Calves (Garantiesysteem Tracering SKV- Vleeskalveren)
HMA	Heads of Medicines Agencies
I&R	Identification and Registration animals (Identificatie en Registratie dieren) (RVO). In the case of animal diseases that pose a threat to public health, it must be possible to act quickly. Thus, there are legislation and regulations for the identification and registration (I&R) of animals.
IDMP	Identification of Medicinal Products
IGJ	Health and Youth Care Inspectorate
IKB / ICM	IKB Varken (ICM Pig) is a chain quality system in the Dutch pig sector. It guarantees the production of safe pork throughout the chain, from pig farm to meat retail outlet.
KIP	Koppel Informatiesysteem Pluimvee

	Name
KNMvD	Royal Netherlands Veterinary Association
KvK	Chamber of Commerce
CTS	Calf Tracing System
L.o.E.	Lack of Efficacy
LNV	Ministry of Agriculture, Nature and Food Quality
LTO	Land- en Tuinbouw Nederland
MRL	Maximum Residual Limit
MRP	Mutual Recognition Procedure
NMV	Nederlandse Melkveehouders Vakbond (Dutch Dairy Farmers Union)
NVP	Nederlandse Vakbond Pluimveehouders (Dutch Poultry Farmers Union)
NVWA	Netherlands Food and Consumer Product Safety Authority (part of the Ministry of Agriculture, Nature and Food Quality)
NZO	Nederlandse Zuivel Organisatie (Dutch Dairy Organisation)
PMS	Practice Management System
POV	Producenten Organisatie Varkenshouderij (Producers Organisation Pig Breeding)
QS Food	QS Food is a German quality system and ensures quality throughout the food production chain; from farm to retail.
REG NL	Marketing authorisation number
RIVM	National Institute of Public Health and the Environment
RUP	Repeat Use Procedure
RVG	Register of Packaged Medicines (Register Verpakte Geneesmiddelen)
RVO	Rijksdienst voor Ondernemend Nederland (Netherlands Enterprise Agency)
SBK	Stichting Brancheorganisatie Kalversector (Veal Calf Quality Foundation)
SDa	Stichting Diergeneesmiddelen autoriteit
SKV	Stichting Kwaliteitsgarantie Vleeskalversector (Veal Calf Quality Foundation)
SPC / SmPC	Summary of Product Characteristics is a legal document approved as part of the marketing authorisation for each product and is the basis for information for health care providers about the use of the product. (https://www.ema.europa.eu/en/documents/presentation/presentation-summary-product-characteristics_en.pdf)
SPOR	Substances Products Organisations Referentials
SWAB	Stichting Werkgroep Antibioticabeleid (Antibiotic Policy Working Group Foundation)
UBN	Unique Business Number, a unique number for each location with cows, pigs, sheep or goats. A UBN is issued by the Rijksdienst voor Ondernemend Nederland (RVO) (Netherlands Enterprise Agency)
UDN	The Unique Veterinarian Number (Uniek Dierenarts Nummer) is a unique number for the veterinarian issued by the KNMVD. It is used in: Retraining or continuing education, Geborgde Dierenarts, Gezondheidsdienst voor Dieren
UPD	Union Product Database
FCI	Food Chain Information
VMRI	Veterinary Mutual Recognition Information
ZuivelNL	Dairy chain organisation

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Annex 1 Actors and data sources

Actors Veterinary medicinal products

	Name	Functie	Type of Organization	Web	Contact
	Vertrouwensloket Welzijn Landbouwhuisdieren	Committed to the prevention of animal neglect.		www.vertrouwensloketwelzijnlandbouwhuisdieren.nl	06 22 43 57 57
	Diergeneesmiddelen.info	Website with collection of package leaflets of veterinary medicinal products for the information of pet owners. The site is a private independent initiative		diergeneesmiddelen.info	Adorfer Str. 20 49828 GEORGSDORF Duitsland info@diergeneesmiddelen.info
Animal Health Europe		Animal Health Europe is the association representing producers of animal medicines, vaccines and other animal health products in Europe.	Trade association	www.animalhealtheurope.eu	168 Avenue de Tervueren Box 8, 5th floor 1150 BRUSSELS, Belgium +32 2 543 75 60 info@animalhealtheurope.eu
AVINED		Cooperation between the organizations: LTO/NOP, NVP, COBK, NEPLUVI and ANEVEI. Foundation AVINED manages a number of databases for the benefit of the Dutch poultry sector	Trade association	www.avined.nl	Postbus 2703 3430 GC NIEUWEGEIN 088 - 998 43 40 info@avined.nl
CBG (BD)	Bureau Diergeneesmiddelen	The CBG (Agentschap College ter Beoordeling van Geneesmiddelen), Bureau Diergeneesmiddelen (BD) handles the processing and evaluation of applications and issues of production, distribution and marketing authorisations for veterinary medicinal products.	Government	www.cbg-meb.nl/dieren www.diergeneesmiddeleninformatiebank.nl	Graadt van Roggenweg 500 3531 AH UTRECHT 088 224 8000
COV	Centrale Organisatie voor de Vleessector	COV is an organisation that represents the collective interests of employers in the Dutch meat sector, both nationally and internationally. The members of the COV are jointly responsible for approximately 90% of the total Dutch turnover of meat.	Trade association	www.cov.nl	Louis Braillelaan 80 2719 EK ZOETERMEER 079 3634900 info@cov.nl
Coviva	Coalitie Vitale Varkenshouderij	Chain-wide cooperation of parties in the entire pig chain: Producenten Organisatie Varkenshouderij (POV), Rabobank, Vion, Agrifirm, ForFarmers, Topigs Norsvin and the Dutch Ministry of Agriculture, Nature and Food Quality.	Trade association	www.vitalevarkenshouderij.nl	Nieuwe Kazernelaan 2-D42 6711 JC EDE 088 888 66 05 info@vitalevarkenshouderij.nl
CPD	Collectief Praktiserende Dierenartsen	The CPD is the association of and for practicing veterinarians	Trade association	www.cpd-online.nl	Postbus 9528, 1006 GA AMSTERDAM 06 1372 74 72 info@cpd-online.nl
CRV	Coöperatie Rundveeverbetering	This cooperative originated at the beginning of 2017 from the merger of the cooperative CR Delta u.a. in the Netherlands and the Vlaamse Rundveeteelt Vereniging VRV vzw in Flanders.	Trade association	www.crv4all.nl	Wassenaarweg 20 6843 NW ARNHEM 026-38 98 800
CVMP	Committee for Veterinary Medicinal Products	European Medicines Agency's (EMA) committee responsible for veterinary medicines	Government	www.ema.europa.eu/en/committees/committee-veterinary-medicinal-products-cvmp	European Medicines Agency Domenico Scarlattilaan 6 1083 HS AMSTERDAM 088 781 6000

DDB	Dutch Dairymen Board	The aim of the DDB is to improve the milk price and the position of dairy farmers in relation to the other links in the dairy chain, to realise market power for the dairy farming sector and to achieve control over the farmer's milk price.	Trade association		Ged. Schuinesloot 3 7776 PD SLAGHAREN 06 30 10 58 90 info@ddb.nu
EMA	European Medicines Agency	The Agency is responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU.	Government	www.ema.europa.eu www.ema.europa.eu/en/medicines	Spark building (operational) Orlyplein 24 1043 DP AMSTERDAM Domenico Scarlattilaan 6 (official) 1083 HS AMSTERDAM 088 781 6000
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption	ESVAC project collects information on how antimicrobial medicines are used in animals across the European Union	Government	www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption-esvac	European Medicines Agency Domenico Scarlattilaan 6 1083 HS AMSTERDAM 088 781 6000
FIDIN	Fabrikanten Importeurs Diergeneesmiddelen Nederland	Trade association of veterinary pharmacy in the Netherlands, with its members, is the representative organization of the veterinary medicine industry in the Netherlands	Trade association	www.fidin.nl	Hogeweg 16 Postbus 80523 2508 GM DEN HAAG fidin@fidin.nl 070 750 31 16
FVE	Federation of Veterinarians of Europe	FVE is the European representation for the veterinary professions in Europe	Trade association	www.fve.org	Avenue de Tervueren 12, B-1040 BRUSSELS +32 2533 70 20 info@fve.org
GD	Gezondheidsdienst voor Dieren	GD works on the health of farm animals and companion animals, together with animal farmers, veterinary practices, governments and the business community.	Government	www.gddiergezondheid.nl	Arnsbergstraat 7 7418 DEVENTER 0900 1770
Gemzu	Vereniging Gemeenschappelijk Zuivelsecretariaat	Trade association for the dairy wholesale trade	Trade association	www.gemzu.nl/	Van Stolkweg 31 2585 JN DEN HAAG 070-4131910 info@gemzu.nl
GS1 Nederland		As an independent not-for-profit organization, develops international uniform standards for the identification, recording and sharing of data.	Standardization	www.gs1.nl	Amsterdamseweg 206 1182 HL AMSTELVEEN info@gs1.nl 020 511 38 20
Health for Animals	Glabal animal medicines association	Global representative of producers of veterinary medicinal products and aims to achieve a harmonised, scientifically based regulatory framework	Trade association	www.healthforanimals.org	168 Avenue de Tervueren, Box 8 1150, BRUSSELS, Belgium Tel: +32 2 541-0111 info@healthforanimals.org
IGJ	Inspectie Gezondheidszorg en Jeugd	Supervises the quality and safety of health care and youth care in the Netherlands. Working with other European countries to monitor the international market for medicines and medical devices	Government	www.igj.nl	Stadsplateau 1 3521 AZ UTRECHT 088-120 50 00 meldpunt@igj.nl
KNMvD	Koninklijke Nederlandse Maatschappij voor Diergeneeskunde	The professional organization for veterinarians in the Netherlands. The KNMvD promotes the professional development of the veterinarian in the field of animal welfare, animal health, public health and food safety.	Trade association	www.knmvd.nl	De Molen 77 3995 AW HOUTEN +31 30 6348 900
Nevedi	Nederlandse Vereniging Diervoederindustrie	Nevedi represents the interests, contributing to a favorable economic development and social position of affiliated feed companies in the Netherlands	Trade association	www.nevedi.nl	Braillelaan 9

					2289 CL RIJSWIJK 085 77 319 77 info@nevedi.nl
LTO	Land- en Tuinbouw Organisatie Nederland	Entrepreneurs' and employers' organisation for the agricultural and horticultural sector. Partnership of LTO Noord, ZLTO and LLTB. Represents nearly 50,000 agricultural entrepreneurs.	Trade association	www.lto.nl	Bezuidenhoutseweg 105-113 2594 AC DEN HAAG 070 - 338 2700
NMV	Nederlandse Melkveehouders Vakbond		Trade association	nmv.nu	Krachtighuizerweg 28 3881 PD PUTTEN 06 213 22 313 info@nmv.nu
NVP	Nederlandse Vakbond Pluimveehouders		Trade association	www.nvpluimveehouders.nl	Postbus 800 7600 AV ALMELO 0342 465 008 info@vnpluimveehouders.nl
NVWA	Nederlandse Voedsel en Waren Autoriteit	The NVWA checks whether veterinarians, traders and livestock farmers comply with the rules for veterinary medicines. Illegal trade is also detected.	Control	www.nvwa.nl/onderwerpen/diergeneesmiddelen	Catharijnesingel 59 3511 GG UTRECHT 088 223 33 33
NZO	Nederlandse Zuivel Organisatie	The Dutch Dairy Organisation (NZO) is the trade association of the Dutch dairy industry..	Trade association	www.nzo.nl	Benoordenhoutseweg 46 2596 BC DEN HAAG 070 – 2191700 info@nzo.n
OECD	Organisation for Economic Co-operation and Development.		Government	www.oecd.org	2, Rue André Pascal 75775 PARIS Cedex 16 France +33 1 45 24 82 00
OIE	World Organisation for Animal Health	The World Organization for Animal Health or OIE was founded in 1924 by 28 countries, after rinderpest broke out in Belgium by importing cattle from India. The organization is engaged in the collection, analysis and dissemination of scientific veterinary information	Government	www.oie.int	12, Rue de Prony 75017 PARIS, France +33 1 44 15 18 88 oie@oie.int
Overheid	Overheid.nl	Legislation in the Netherlands on veterinary medicines	Government	wetten.overheid.nl/BWBR0032386/2018-08-01 wetten.overheid.nl/BWBR0032626/2018-07-07 wetten.overheid.nl/BWBR0032386/2015-01-01 wetten.overheid.nl/BWBR0030250/2018-07-01#Hoofdstuk2_Paragraaf3	
POV	Producenten Organisatie Varkenshouderij	POV represents the interests of the collective pig farming sector and is the springboard for strengthening the market position, revenue models and chain cooperation..	Trade association	www.pov.nl	Postbus 240 8000 AE ZWOLLE 088 888 66 05 info@pov.nl
SBK	Stichting Brancheorganisatie Kalversector	SBK represents the interests of many parties within the veal sector, but is also committed to monitoring and promoting transparency.	Trade association	www.kalversector.nl	Nevelgaarde 20d 3436 ZZ NIEUWEGEIN 088 998 4325 info@kalversector.nl
SDa	Autoriteit Diergeneesmiddelen	The independent institute For Veterinary Medicinal Products Authority strives for the responsible use of		www.autoriteitdiergeneesmiddelen.nl	Yalelaan 114

		antimicrobials in Dutch animal husbandry in the interest of public health and with due regard for the safeguarding of animal welfare..			3584 CM UTRECHT 088 - 03 07 222 info@autoriteitdiergeneesmiddelen.nl
SKV	Stichting Kwaliteitsgarantie Vleeskalversector	Promotes the quality of veal, Guarantees that veal is produced without the use of unwanted growth promoters	Trade association	skv.info	Nevelgaarde 20d 3436 ZZ NIEUWEGEIN 030-6941910 skv@skv.info
Stichting VETmessage		Foundation VETmessage is the independent industry-wide platform of the veterinary industry for sending and receiving electronic messages for both suppliers and buyers of veterinary products.	Trade association	fidin.nl/beleid/distributie/vetmessage	vetmessage@fidin.nl
SWAB	Stichting Werkgroep Antibioticabeleid	Aims to optimise the quality of antibiotic use in the Netherlands in order to contribute to the control of resistance development and to limiting the costs and other negative effects of antibiotic use.			Albinusdreef 2 2333 ZA LEIDEN
UECBV	European Livestock and Meat Trades Union	The UECBV is the European spokesperson for the national organisations representing the livestock markets, cattle traders, meat traders and slaughterhouses..	Trade association	www.uecbv.eu	81A, Rue de la Loi (box 9) - 4th floor 1040 BRUSSELS, Belgium +32 2 230 46 03 info@uecbv.eu
V&LN	Vee&Logistiek Nederland	Vee&Logistiek Nederland is the representative of the interests of entrepreneurs in the cattle trade and livestock transport, entrepreneurs with cattle collection centres and importers and exporters of live cattle.	Trade association	www.vee-logistiek.nl	Benoordenhoutseweg 46-5 2596 BC DEN HAAG +31 70 219 30 00 info@vee-logistiek.nl
VDDN	Vereniging Diervoederspecialiteiten en Diergezondheidsproducten Nederland	Previously Dufagro, Fagrovet and Nefato	Trade association	www.vddn.nl	Postbus 5100 5800 GC VENRAY +31 478 579221 info@vddn.nl
WBR	Wageningen Bioveterinary Research	Researches animal health and (infectious) diseases. Among other, through (pre)clinical studies, animal models, epidemiology and risk management.	Research	www.wur.nl/nl/Onderzoek-Resultaten/Onderzoeksinstituten/Bioveterinary-Research.htm	Houtribweg 39, 8221 RA LELYSTAD info.bvr@wur.nl +31 320 238 007
WHO	World Health Organization	The World Health Organization is a specialized agency of the United Nations based in Geneva with the aim of mapping global aspects of health care, coordinating health care activities and promoting the health of the world's population.		www.who.int	Avenue Appia 20 1202 GENEVE Switzerland +41 22 7912 111
WTO	World Trade Organization	The World Trade Organisation is an intergovernmental organisation that monitors compliance with agreements on trade between countries. Many of these agreements are important for international business	Government	www.wto.org	Rue de Lausanne, 154 Case postale 1211 GENEVE 2 Switzerland
ZuivelNL	ZuivelNL	Ketenorganisatie of the dairy sector	Trade association	www.zuivelnl.org	Benoordenhoutseweg 46 2596 BC DEN HAAG 070 219 1600

Data Sources

	Naam	URL	Definition
NL	**Diergeneesmiddeleninformatiebank**	www.diergeneesmiddeleninformatiebank.nl/nl	Veterinary medicines information bank of the college for the assessment of medicinal products which also include veterinary medicinal products. This list is updated weekly with a response time of 2 weeks.
	Fink-Gremmels Repertorium	www.fg-repertorium.nl	The Fink-Gremmels Repertorium contains the information on veterinary medicinal products and veterinary care products offered in the Netherlands by members of the FIDIN. This site offers, among other things, online leaflets as a reference work. The initiator of this site is FIDIN and is maintained by Prof. dr. J. Fink-Gremmels of the Department of Pharmacology, Pharmacy and Toxicology (VFFT) of the Faculty of Veterinary Medicine in Utrecht and his staff. You can also search by barcode.
EN	**European Medicines Agency**	www.ema.europa.eu/ema	The website and database of the European Medicines Agency. This site also offers an Excel export. The content does not give confidence in proper maintenance of this data source.
	RIVM	www.rivm.nl/rvs/Databases	
NL	**VetCIS**	www.vetcis.nl	Central veterinary information system (VetCIS), to which the practice management systems (PMS) of veterinarians, livestock farmers and veterinary medicine suppliers can be connected and they can exchange data electronically.
EN	**Eudralex**	ec.europa.eu/health/documents/eudralex_en	Database for EU regulations for (animal) medicines
EN	**ESVAC**	https://bi.ema.europa.eu/analyticsSOAP/saw.dll?PortalPages	European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)

FIDIN Members

FIDIN is the trade association of veterinary pharmacy in the Netherlands, with its members is a representative organization of the veterinary medicine industry in the Netherlands. Within FIDIN, producers and importers of veterinary medicines are united.

Name	Address	Website	Telephone	Email
Aesculaap	Mijlstraat 35 5281 LJ BOXTEL	www.aesculaap.nl	+31 411 67 59 15	info@aesculaap.nl
Alfasan	Kuipersweg 9, 3449 JA WOERDEN	www.alfasan.com	+31 348 41 69 45	info@alfasan.nl
ASTfarma BV	Wilgenweg 7 3421 TV OUDEWATER	www.astfarma.nl	+31 348 56 34 34	info@astfarma.nl
Bayer HealthCare	Energieweg 1 3641 RT MIJDRECHT	www.bayer.nl	+31 297 28 06 66	ah.nl@bayerhealthcare.com
Boehringer Ingelheim	Comeniusstraat 6 1817 MS ALKMAAR	www.boehringer-ingelheim.nl/animal-health	+31 72 566 24 11	vetmedica.nl@boehringer-ingelheim.com
Ceva Santé Animale	Tiendweg 8c 2671 SB NAALDWIJK	www.ceva.nl	+31 174 64 39 30	info@ceva.nl
Dechra	Pettelaarpark 38 5216 PD 'S-HERTOGENBOSCH	www.dechra-eu.com	+31 497 544 300	
Dopharma	Zalmweg 24 4941 VX RAAMSDONKSVEER	www.dopharma.com	+31 162 58 2000	pr@dopharma.com
ECOstyle	Ecomunitypark 1 8431 SM OOSTERWOLDE	www.ecostyle.nl	+31 516 432122	agrovet@ecostyle.nl
Elanco	Papendorpseweg 83 3528 BJ UTRECHT	www.elanco.com	+31 30 602 59 52	
Emax	Compagnieweg 2 3771 NH BARNEVELD	www.emax.nl	+31 342 427171	info@emax.nl
Henry Schein Animal Health	Beversestraat 23, 5431 SL CUIJK	www.henryscheinvet.nl	+31 485 33 55 55	info.vet@henryschein.nl
Huvepharma	Uitbreidingstraat 80 B-2600 ANTWERPEN	www.huvepharma.com	+32 3 288 18 49	

Name	Address	Website	Telephone	Email
	België			
IDT Biologika	Ceresstraat 13 4811 CA BREDA	www.idt-biologika.de		Benelux@idt-biologika.com
MSD Animal Health	Wim de Körverstraat 35 5831 AN BOXMEER	www.msd-animal-health.nl	+31 485 58 76 52	IntervetNederland@Intervet.com
Vétoquinol	Postbus 3191 5203 DD 'S-HERTOGENBOSCH	www.vetoquinol.nl	+31 10 498 00 79	info.nl@vetoquinol.com
Virbac	Hermesweg 15 3771 ND BARNEVELD	www.virbac.nl	+31 342 427 127	info@virbac.nl
Zoetis	Rivium Westlaan 74 2909 LD CAPELLE A/D IJSSEL	www.zoetis.nl	+31 10 714 00 00	info.nl@zoetis.com

Animal Health Europe Members

Bayer	
Boehringer Ingelheim	
Ceva	
Dopharma	
Elanco	
Huvepharma	
IDT	
MSD Animal Health	
Orion	
Vetoquinal	
Virbac	
Zoetis	
Pharma.be	Belgium
CSAVPC – CSAVFS	Czech & Slovak Republics
VINORDIC	Denmark & Sweden
FVPA	Finland
SIMV	France
BfT	Germany
Havepharm	Greece
HAIVPM	Hungary
APHA	Ireland
AISA	Italy
FIDIN	Netherlands, The
LMI	Norway

POLPROWET	Poland
Apifarma	Portugal
Veterindustria	Spain
ScienceIndustries	Switzerland
NOAH	United Kingdom
EBA	Ukraine

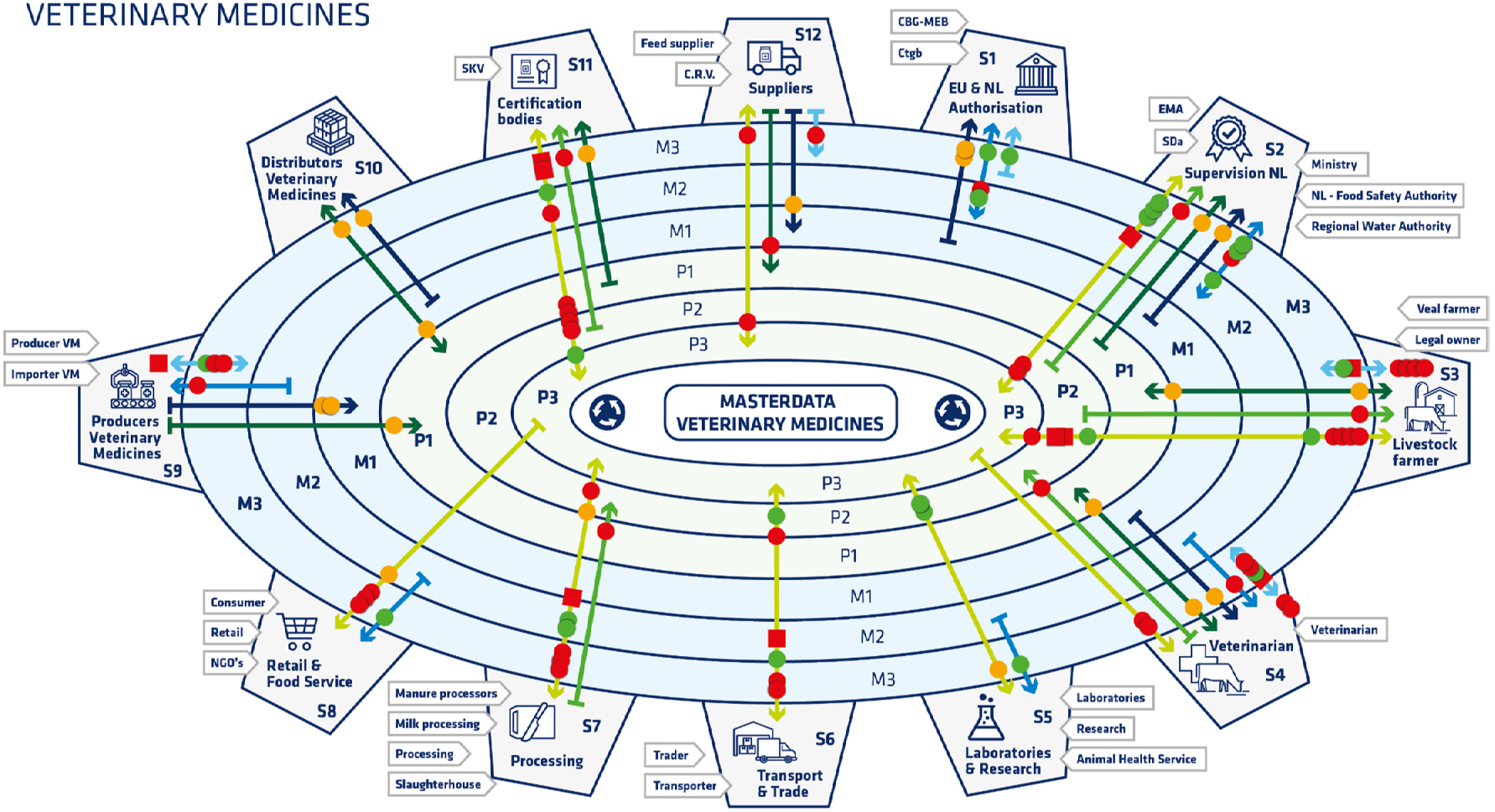
Awareness Workshops

To collect information about the use and availability of data for this domain exploration, various so-called 'awareness workshops' were held with a constantly changing representation from the calf and pig chain. During these workshops, an attempt was made to paint as complete a picture as possible of the data-supplying and data-demanding actors within the sectors.
The aim of these meetings was twofold: to gather information and to bring together various actors from the chain in order to get to know each other's situation and to map out the information flows within the sector.

Figure 20: the result of an awareness workshop.

In the information roundabout and matrix below, the actors and information flows that emerged from these sessions are brought together. In addition, it is also indicated as much as possible what the key fields are with which information can be traced back.

INFORMATION ROUNDABOUT
VETERINARY MEDICINES



DATASETS

- Masterdata
- Procesdata

DATALANES

- M1 Product definitions
- M2 Authorization + MRL standard
- M3 Legal Instructions for Use
- P1 Supply
- P2 Application
- P3 Usage + Residue level

- Digitally reusable
- Partly digitally reusable
- Not digitally reusable
- Not digital

Figure 21: Information matrix.

The colors indicate which type information it concerns (Mx = master data, Px = Process data). The arrows indicate where the information comes from and who the buyers are.

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The mission of Wageningen University & Research is "To explore the potential of nature to improve the quality of life". Under the banner Wageningen University & Research, Wageningen University and the specialised research institutes of the Wageningen Research Foundation have joined forces in contributing to finding solutions to important questions in the domain of healthy food and living environment. With its roughly 30 branches, 6,800 employees (6,000 fte) and 12,900 students, Wageningen University & Research is one of the leading organisations in its domain. The unique Wageningen approach lies in its integrated approach to issues and the collaboration between different disciplines.