Proposed extensions to ICAR ADE standards for UK Veterinary Treatment data

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# Introduction

Currently there exist no openly accessible standards for interchange of data regarding veterinary treatments given to food-producing animals in the UK. There is an emerging necessity for interchange of such data for the purpose of analysis and reporting in industry, academic research and regulatory contexts. Current challenges to these purposes, however, are the laborious and error-prone manual re-keying of data, datasets recorded using inaccessible technologies, conceptual mismatches between datasets, and extensive use of free-text data in lieu of standardised values. Many of these challenges may be addressed by widespread adoption of openly available data standards.

## Standards, Messages and APIs

For the purposes of this document, a data standard may be considered a set of rules regarding data describing a set of entities (physical, conceptual, temporal or legal). The specific medium by which these data are recorded is not specified, merely what information is required and the logical form thereof. Extending this concept to standards for data *exchange*, the standards specify the rules for what messages may be exchanged between parties and not the specific transport of these messages.

For automated exchange of messages between systems, Application Programming Interfaces (APIs) are commonly used. This specification does not cover implementation of such APIs but rather defines the rules by which an API may be judged compliant with the specification. Software tools exist for automatic generation of API implementations in a variety of programming languages from a suitable data specification, such that they are provably compliant with the specification.

## ICAR Animal Data Exchange standards

The International Committee for Animal Recording (ICAR) is an International Non-Governmental Organisation (INGO) and “strives to be the leading global provider of Guidelines, Standards and Certification for animal identification, animal recording and animal evaluation.” [1]. A number of working groups cover aspects of the organisation’s remit such as artificial insemination, milk recording, livestock genetics, and animal data exchange. The Animal Data Exchange (ADE) working group consists of representatives of companies and organisations from several countries whose business relates to the automated exchange of data regarding livestock animals [2]. This group have published a set of data standards which at the most recent revision (1.9) cover many aspects of livestock animal production but not that of veterinary treatments in the UK context.

Within the ICAR ADE working group, there is underway an initiative to produce a new set of ADE standards in a more open fashion, with a different technical format and design philosophy to the previously published standard [3]. Work from this group has also recently included standardised naming conventions and data dictionaries developed as part of the New Zealand Farm Data Standards programme. [4]

## Extensions to satisfy regulatory requirements

In this document are proposed a set of messages containing data pertinent to the recording of veterinary treatments given to food-producing animals as specified by Part 3 of the Veterinary Medicines Regulations 2013 [5] (henceforth, "the regulations").

The two events for which data are required to be recorded by the regulations are the administration of a licensed veterinary medicine to a food-producing animal (either by a veterinary surgeon or by other personnel on the holding), and the purchase/acquisition of a veterinary medicine for the purposes of administration to a food-producing animal. The proposed messages cover the attributes of these two events and supporting required data.

The administration event has been conceptualised at the "treatment course" level, with an awareness that this is a loosely defined concept that may take many forms. In the experience of the authors of examining records of treatments of food-producing animals from existing recording systems (both paper-based and electronic), the course concept is in use as an entity within such records and so any new data standards should seek to preserve this information, where present.

The acquisition/sale event has no such complexity of multiple forms within the existing datasets seen by the authors. Where attributes are referred to as “required” or otherwise, this is within the specific definition of what is required in the regulations, or for specific technical reasons. The non-required attributes are included due to their consideration as being important extra data for purposes beyond meeting regulatory requirements. The extensible nature of the ICAR ADE standards allows for additional attributes to be included where available.

# Message Specifications

## Administered Course and Dose

For the purposes of this specification, a Dose is considered a single act of administering a medicine to an animal, and a course is a set of these administrations considered to be part of a single treatment regimen. A message specification for a treatment course is given in Table 1. The primary forms of course recording that have been observed within existing datasets and conceptualised within the proposed specification are as follows:

1. Explicit multi-dose courses: A "course of treatment" of a single medicine administered to a single animal over one or many days consisting of multiple physical administrations (doses) of medicines for which the specific information of each is known.

2. Implicit multi-dose courses: A "course of treatment" of a single medicine administered to a single animal over one or many days consisting of multiple physical administrations (doses) of medicines for which only aggregate course-level information is known

3. Explicit single-dose courses: A "course of treatment" of a single medicine administered to a single animal as a single administration (dose) which is known to be the only administration of this course.

4. Implicit single-dose courses: A "course of treatment" of a single medicine administered to a single animal as a single administration (dose) where the number of doses within a course of treatment is unknown or the record system supports only dose-level recording.

The Course message must contain one or more Dose messages which contain attributes considered to be dose-level attributes (Table 2). Where only aggregate course-level information is recorded, these attributes may be encoded as a singular Dose message within the Course message.

The number of doses and their attributes may be inferred from the aggregate information in 2., and the presence of a course of treatment may be inferred from multiple single-dose "course" records in scenario 4., but this inference is left to the analysis of the data consumer. The purpose of these messages is to encode what data is known to be true at the time of recording and this only.

## Purchase

A minimal specification meeting the requirements of the regulations was developed for the sake of simplicity and avoidance of ambiguity.

## Medicine

The primary identifier for a veterinary medicine in the UK was considered to be the Marketing Authorisation (MA) number as issued by the Veterinary Medicines Directorate (VMD), sometimes known as the VM Number, since it is mandatory to display this number upon the package of a veterinary medicine [6]. It is also the primary identifier for a medicine within the VMD Product Information Database (PID) [7], the official listing of licensed veterinary medicines in the UK. The concept of a national authorisation number for veterinary medicines is common in many states and thus usage of the VM Number in this standard may support international acceptance of this standard. Other identifiers may be available in source systems and/or may be useful to data consumers (e.g. supplier codes or veterinary practice SKUs), but the presence of this information is not mandated by law and so cannot be relied upon. It is important to note that the MA/VM Number is used for identification of a specific medicine from a regulatory point of view. The change of certain attributes of a veterinary medicine, e.g. the name of the marketing authorisation holder, may trigger a change of VM Number by the VMD despite the fact that the quantitative and functional properties of this medicine are unchanged and thus the medicine may be considered unchanged by those tasked with using the medicine. For the purposes of accurate recording and analysis of medicine usage, it is important that a map of these changes is maintained and the authors believe this responsibility should lie with the VMD.

## Holding

The simplest means of identifying a holding of food-producing animals in the UK was considered to be the County Parish Holding Number, as issued by the Rural Payments Agency, since this is a mandatory identifier for areas of land used to keep livestock [8]. An alternative to defining a new message type for Holdings is to make use of the Location attribute of the ICAR Event message, from which the Purchase and Dose/Course messages are derived. Further study and discussion with the ICAR ADE Working Group is required to assess whether this can contain all necessary information, especially regarding the type of animals kept at a holding (i.e. is a “Beef” or “Sheep” holding).

|  |  |  |  |
| --- | --- | --- | --- |
| Attribute | Type | Required | Notes |
| Animal | icarAnimalIdentifierType [9] | x | Tuple (pairing) of identifying scheme and identifier (e.g. "APHA" + "UK123456 987654") |
| Holding | Holding |  | Holding where treatment took place; see "Holding" sheet. Alternatively, location attribute of icarEventCoreResource [10] from which this message is derived |
| Date | icarDateTimeType [11] | x | Date event happened Preferred ISO 8601:2004 format [12] (e.g. 2001-08-31T09:12:00Z) - allow truncation of time zone and/or time elements as per ISO 8601 standard. |
| ID | G/UUID [13] | x | Means of uniquely identifying this event |
| Metadata | icarMetaDataResource [14] |  | Source, Created/Modified datetime, Creator, Valid From/To, Description etc. |
| Start Date | icarDateTimeType [11] | x | Date/time first treatment happened |
| End Date | icarDateTimeType [11] | x | Date/time last treatment happened |
| Reason for Treatment | string | x | Free text in lieu of agreed standardised list |
| Total Quantity Administered | Tuple of decimal number + unit | x | Enumeration of standard units of measure (e.g. mg, ml, tubes, etc.) to be agreed based on Veterinary Medicines Directorate (VMD) Product Information Database (PID) |
| Medicine Administered | Medicine | x | See Table 3 |
| Doses Administered | Dose[] | x | Array of at least one dose (see Table 2) |
| Withdrawal End Dates | (icarDateTimeType [11], string)[] | - | Array of pairs (tuples) of **required** withdrawal end date/time and *optional* withdrawal time type (e.g. Beef - conventional, Milk - organic (OMSCO), etc.) |

|  |  |  |  |
| --- | --- | --- | --- |
| Attribute | Type | Required | Notes |
| Date | icarDateTimeType [11] | x | Date/time dose administered |
| Operator | string | x | Person administering the dose. Consideration should be given to data protection implications. |
| OperatorRole | string |  | Farm staff, veterinary surgeon, etc. |
| Batch/Expiry Dates | (string, icarDateTimeType [11])[] | x | Array of pairs of batch numbers and expiry dates |

## Message Definitions

Table 1: Administered Treatment Course Message

Table 2: Administered Treatment Dose Message

|  |  |  |  |
| --- | --- | --- | --- |
| Attribute | Type | Required | Notes |
| Date | icarDateTimeType [11] | x | Date sale event happened Preferred ISO 8601:2004 format [12] (e.g. 2001-08-31T09:12:00Z) - allow truncation of time zone and/or time elements as per ISO 8601 standard. |
| ID | G/UUID [13] | x | Means of uniquely identifying this event |
| Holding | Holding | x | Holding to which medicine was sold, see Table 4 |
| Metadata | icarMetaDataResource [14] |  | Source, Created/Modified datetime, Creator, Valid From/To, Description, etc. |
| Medicine | Medicine | x | see Medicine sheet |
| Quantity | Tuple of decimal number + unit | x | Enumeration of standard units (e.g. mg, ml, tubes, etc.) to be agreed based on VMD PID |
| Supplier | string | x | Name + address, standard format TBC |

Table 3: Medicine Sale/Acquisition Message

|  |  |  |  |
| --- | --- | --- | --- |
| Attribute | Type | Required | Notes |
| Scheme | string | x | "RPA" |
| ID | string | x | CPH Number [8] |
| Subholding | integer |  | Subholding, where applicable |
| Enterprise | string |  | Description of type of enterprise |

Table 4: Holding Identification Message

|  |  |  |  |
| --- | --- | --- | --- |
| Type | Type | Required | Notes |
| AuthorisationNumber | string | x | VMD MA Number/VMNo [6] |
| Name | string |  | Name of medicinal product |
| SKU | string |  | Source system product identifier |
| GTIN | string |  | Global Trade Item Number [15] of product |

Table 4: Medicine Identification Message

# Out of Scope Elements

A number of entities and attributes were considered out of scope of this proposed specification despite potentially containing information pertinent to the purposes outlined in the introduction to this document. The reasons for their exclusion were those of an aim for simplicity and pragmatism given some may require extensive consideration by a wide panel of domain experts. In many cases, attributes were defined as allowing free text entry rather than being limited to a specific set of reference values where definition of these reference values is beyond the scope and knowledge of the authors.

Examples of such out of scope elements are a standardised list of reasons for treatment, standardised descriptors of medicine withdrawal date, an identification scheme for veterinary practices or other vendors of veterinary medicines, and an identification scheme and set of roles for persons administering veterinary medicines to animals.

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