

Ingredient Fhir Resource Proposal

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Ingredient

Draft resource in build:

Owning work group name

BR&R

Committee Approval Date:

6th May 2019 (earlier approval as "MedicinalProductAuthorization" 13th September 2017)

Contributing or Reviewing Work Groups

- Pharmacy

FHIR Resource Development Project Insight ID

1367

Scope of coverage

This resource covers the detail of pharmaceutical ingredients, to a more detailed level than exists in the Medication resource.

Both regulatory and medication knowledge use cases need structured ingredient and strength information to fully represent drug composition.

This includes:

Substance (including as one or more "specified" substance aspects including the grade or process)

Strength expressed in different possible ways (presentation, concentration) and details of how that strength it is measured.

Strength expressed as a function of a second substance (reference strength substance), for example as equivalent of a certain amount of the "salt".

Manufacturer.

Resource appropriateness

There is an outstanding requirement to support the standardised exchange of detailed "Product" data, for regulatory and other use cases.

This resource does not intend to clash with the existing Medication resource, but complements it with an extra level of detail.

Drug manufacturers currently submit this data electronically to regulators, when products are registered or altered, or marketing situations change.

This resource has been designed in close consultation with Pharmacy WG - Medication knowledge bases also cover this level of detail and this resource is currently referenced within the MedicationKnowledge resource

Expected implementations

EMA and European drug manufacturers, who have a requirement to submit to EMA (and already do so in a proprietary format). The EU wide system is currently being redeveloped to use FHIR, and this data is directly in scope.

FDA for Drug Submission (currently using SPL, which is not likely to change in the near term, but have expressed an interest in FHIR).

FDA for Pharmaceutical Quality (HL7 PSS approved, based on this resource, June 2019).

Content sources

The core basis for the resource is information currently used by FDA (as SPL) and the EMA EU XEVMPD data base (and XEVPRM XML messages).

Also, information gained from early stage implementation of this resources at EMA (2018, 2019), and from many many received to EMA about the draft API specification from the European medicines regulatory network (<https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network>).

Example Scenarios

Pharma companies submit details of new products to regulators, and include ingredient details.

Pharmacies and prescribers can view and download this information for reference and integration with their systems.

Decision support systems can use ingredient substance information for allergy checking.

Specific use cases include:

Submission of products from drug companies and NCAs (National Competent Authorities - the national regulators) to regional regulators.

This is already implemented in Europe (by EMA and EU-wide stakeholders) with an earlier non-HL7 format (XEVPRM/XEVMPD). That scenario is currently being re-implemented, using this resource, as part of the EU wide SPOR project.

Resource Relationships

See diagram below.

Some notable resource references:

To a manufacturing organization. Incoming relationships from the pharmaceutical products that use the ingredient.

Also refer to the logical model which was used to clarify the resource relationships, at the request of FMG, in the preparation of this proposal (linked to the approved MedicationKnowledge proposal page): [MedicationKnowledge_FHIR_Resource_Proposal](#)

High level relationships of the main prescribing resources and the regulatory strata below:

Timelines

Draft content is modelled in the FHIR build (<http://build.fhir.org/regulatedauthorization.html>), with outline supporting documentation. Completion planned Q4 2019.

gForge Users

riksmithies

When Resource Proposal Is Complete

When you have completed your proposal, please send an email to FMGcontact@HL7.org

FMG Notes