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DG HEALTH AND FOOD SAFETY
DG COMMUNICATIONS NETWORKS, CONTENT AND TECHNOLOGY

eHealth-units

20TH EHEALTH NETWORK 8 NOVEMBER 2021, BRUSSELS, BELGIUM

COVER NOTE

4.1 eHealth Network ePrescription Guidelines revision

1. Issue at stake

The ePrescription guideline has been published in its Version 2 in 2016. A lot of work has been ongoing on ePrescription definition and the ISO IDMP standards have well evolved. In the eHealth Network meeting in spring 2021 it was agreed that the Subgroup on Semantics should investigate the revision of the ePrescription guideline and report back to the eHealth Network in its fall meeting.

In multiple sessions the Subgroup on Semantics discussed the current state of the ePrescription guideline. A small task force was installed to look into details. A great number of comments was received through the UNICOM project, from EMA, and from members of the Subgroup. Not all of them have been adressed fully up till now. The UNICOM project has prepared a change proposal for eHDSI, which has to be considered by the Subgroup for the ePrescription guideline as well.

In this meeting, the Subgroup is asking for advice and confirmation on the general revision direction. The Subgroup on Semantics will then continue the revision and present a draft version to the eHealth Network in the beginning of 2022 for commenting. The aim is to have a final draft for approval in the spring meeting of eHealth Network in 2022.

2. Summary

There are ongoing reflections and discussion on the ePrescription guideline. This process requires additional time to mature, as well as needs eHealth Network guidance regarding the findings encountered so far:

- The ePrescription guideline and the Patient Summary guideline need alignment. Content, scope and dataset need to be harmonised, to the extent possible, as the two guidelines should not contradict or deviate from each other. The larger scope of the Patient summary guideline and its character as being a guiding principle for all kind of similar implementations should be reflected in the ePrescription guideline as well.

- The scope of the ePrescription guideline needs clarification. In the guideline Version 2 it is stated that medical devices are out of scope whereas at another article they are declared to be in scope. It is not clear if "*Magistral/extemporaneous medicinal product*" should remain in scope. In discussions, the question was raised if prescription of food supplements/additives are in scope.

- **Guidance from the eHealth Network is needed regarding what is in the scope of the guideline and if the elements out of scope need to be addressed in another guideline as well.**
  In order to not overburden the eHDSI implementation the subgroup recommends to keep the scope of the ePrescription guideline limited to authorised medicinal products and to work on a separate guideline for ePrescription of additional elements that are not authorised medicinal products (medical devices, nutraceuticals and maybe magistral/extemporaneous medicinal products), even though they are part of the Article 1 (19) of Directive 2001/83/EC and are included in the Comission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems (2008/594/EC).

- Alignment with other initiatives: it was discussed that it would be helpful to align the ePrescription guideline at least in overlapping fields with the project on the electronic Product Information activities (ePI) from EMA as added value might be harvested from linking ePI to ePrescription in digital applications. The Subgroup on Semantics recommends in addition to work on a possible alignment with the ePI initiative of the EMA and to harmonise both initiatives, if possible, to foster joined use.

- ISO IDMP family of standards are great candidates for the preferred vocabularies. However, the implementation of some of these standards is not widespread, as well as some of the identifiers are not fully specified yet.

  - **Guidance from eHealth Network is needed regarding if a strategic (long term) implementation of the ISO IDMP family of standards is envisioned for not only regulatory but as well clinical use cases.**

3. Format of procedure in the meeting

For discussion.

The chair of the Subgroup on Semantics presents the results of the revision so far and asks guidance of the eHealth Network on:

- Scope of the ePrescription guideline for the further revision
- Harmonisation of work with UNICOM, ePI work of EMA and the Patient Summary guideline 3 (inclusion of planned care and possible other use cases that might arise in the future)
- Use of the full ISO IDMP implementation beyond the regulatory use case towards the clinical use case