e-VIS
e-Verifikation i Sverige

Workshop 16th June 2021:

Primary Pack Identifiers and National Alignment in Sweden

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Background

Some of the twenty-one Swedish Health Care Regions are starting to request identifiers on primary pack level for medicines. The driver for this request is the switch to new e-health records/systems where, among others, closed loop medication, bed side scanning and improved follow up of medicines will be possible. One of the health care regions added to their tender documents for procurements, with start date in Q3 2021, that labelling of primary packs will give an advantage in the procurement.

In the beginning of 2021, there was no clear owner for alignment of this topic. The Swedish authorities have neither expressed any clear directions for primary packs. The risks seen from the trade association for the research-based pharmaceutical industry in Sweden (Lif) were that a fragmented model could end up in several regional guidelines for how to identify primary pack and that these guidelines would cover (parts of) the Swedish market where in reality many medicines share pack across the Nordics. Alignment on this area was seen as crucial to create predictability on the market, both short and long term. Instead of one of the stakeholders in the supply chain taking lead on this Lif proposed to e-VIS Board that e-VIS would lead the coordination and alignment for primary pack identifiers.

"With the implementation of e-verification, there are technical solutions for handling codes on secondary packs and it should be possible to also handle codes on primary packs if the incentives exist."

e-VIS

e-VIS is the National Medicines Verification Organisation in Sweden in the scope of the Commission Delegated Regulation (EU) 2016/161. e-VIS is a non-profit organisation established in 2016 by the key stakeholders in the medicines supply chain in Sweden to manage the national medicines verification system for Sweden.

If e-VIS should be able to facilitate any project 'outside but close to FMD' all members need to be confident and supportive of it. e-VIS statues enable the association to collaborate in projects concerning topics of **common interest** and which are seen as important for the supply of medicines where the National System and e-VIS can be managed and used for purposes other than the EU directive on Falsified Medicines and its Delegated Regulation.

e-VIS Board supported the proposal from Lif that e-VIS will lead and coordinate the alignment on the Swedish market. The first activity was to arrange a Kick-off-Workshop in June 2021 gathering member associations, authorities, Health Care Region reps etc.

Purpose with workshop

- **Increase knowledge:**
  - Increase the general knowledge of the topic cross organisations in Sweden
- **Create engagement:**
  - Involve stakeholders and create a common picture of benefits and obstacles
  - illustrate the possibilities and how the benefits can be maximized
  - Identify hurdles and discuss how we can minimize these
- **Encourage action:**
  - Identify areas and topics that need to be investigated further
  - Identify concrete actions that can be carried out
  - Who needs to do what? Who will do what?
  - Align on next step and follow-up

Questions sent out prior to the workshop

- This is an issue for the entire pharmaceutical industry, for healthcare, pharmacies and authorities – how can we agree nationally?
- This is not a regional issue – how do we ensure Swedish and then Nordic coordination?
- Who should ensure that there is a code on the primary packaging?
- Are stickers attached to the secondary packaging a solution or should the code be affixed to the primary packaging?
- What should the code contain?
- How is this regulated?
- It is important to ensure that it is linked to the Swedish E-Health Agency's article register, how can this be achieved?
- How does it impact e-verification?
- What is important in the short- and long-term view?

Agenda workshop 16th June 2021

- Welcome – Kristina von Sydow, e-VIS
- Nordic guidelines – Hans Andersson, Lif
- Three cases:
  - Health Care Region Skåne – How can we use this in practice?
    Per Holmér, Christer Luthman, Berit Nilsson, Region Skåne
  - How is a pharmaceutical company impacted by the introduction of an identifier on primary pack?
    Maija Virtanen, Janssen, Finland
  - Denmark: How does the neighbours handle primary pack scanning?
    Ulla Bonnerup, Amgros
- Breakout sessions on challenges
- Next step – what questions need to be answered to create the possibility of primary pack identifiers and scanning?

Participating Organisations

Regional and National Level

- Health Care Region Skåne
- Health Care Region Stockholm
- Health Care Region Västra Götaland
- E-Health Agency
- Inera (IT service provider for Swedish Health Care Regions)
- The Swedish Medical Products Agency
- the National Board of Health and Welfare

Associations and Industry

- FGL: the Swedish Generic Medicines and Biosimilars Association
- GS1 Sweden
- LDF: the Swedish Association of Pharmaceutical Wholesalers
- Lif: the Swedish Trade Association for the research-based pharmaceutical industry
- The Swedish Association of Pharma Traders
- The Swedish Pharmacy Association
- e-VIS Secretariat

Summary from workshop 16th June 2021

- Increased identification of medicines bedside of the patient should provide a safer and more accurate use of medicines. Several participants in the workshop were pointing out that studies/evidence for this position would improve the incentives to add codes on primary pack.
- Possibilities for improved follow-up of usage as well of improved withdrawal and batch tracking would increase with more granular information on the inner pack.
- More granular information, however, requires, among other things, changes in the labelling of the packs, changes in the production, updates of national systems for article information and updates of the information systems and processes in Health Care. Many of the representatives from the industry expressed their concerns of having dynamic data (batch and/or expiry date) printed on inner pack. Having static data like product code on the primary level is more realistic to be achieved.
- There is a need to identify the products that should be prioritised for having identifier on primary pack since the switch for adding this to packs is a large-scale project for the industry that will take several years to fulfil. Some products might never be subject to this extra layer of information.
- The use of international standards is crucial. Standards facilitate, not only national solutions, but also solutions at Nordic and European level.
- During the workshop, many challenges were identified. The workshop concluded that to increase granularity of the identifiers on medicines are by no means impossible, but there is probably not 'one size fits all' solution, different solutions may be required for different products to move forward.
- Actions from the workshop was identified an added to the report for follow up purposes.
- Coordinated national dialogue should continue in the autumn of 2021 to follow up actions, create consensus and solve challenges. A following up workshop is scheduled for the autumn 2021.

The full report (in Swedish only) from the workshop can be found at e-VIS website:
https://e-vis.se/wp-content/uploads/2021/10/2021-09-Rapport-radslag-16-juni.pdf