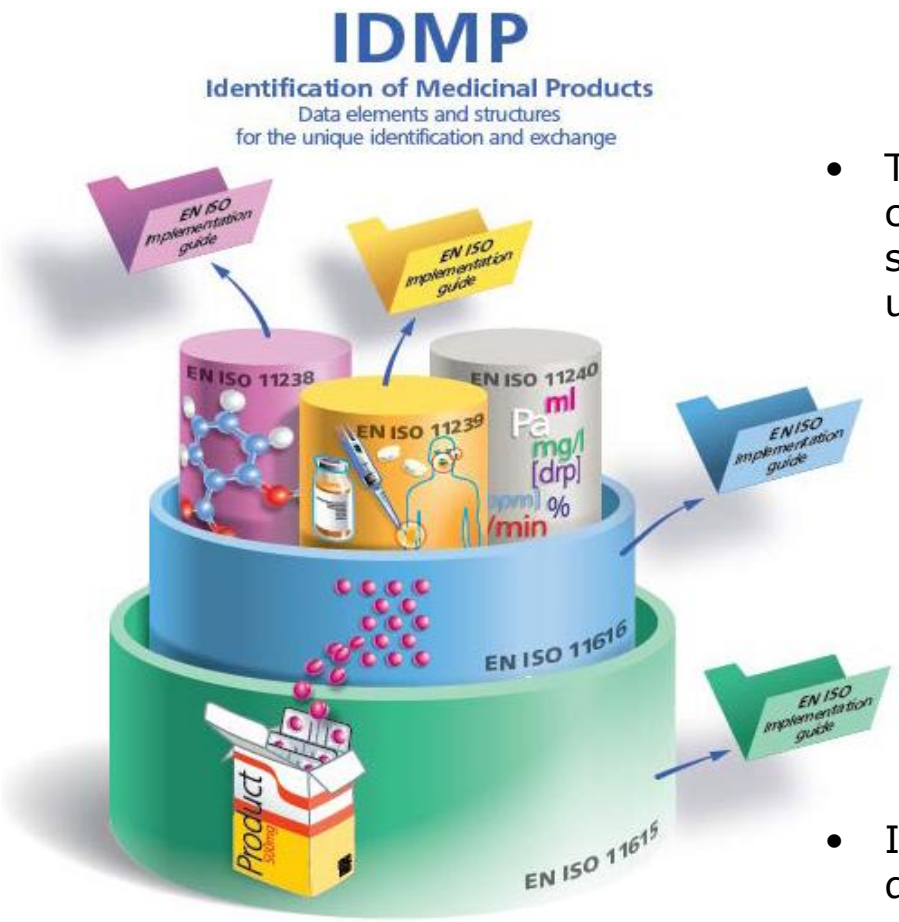
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Outcome of the ISO Plenary meeting held on 2-6 May 2016 (Amsterdam)

Presented by **Paolo Alcini** on 29 June 2016
Head of Data Standardisation and Analytics Service



- The ISO IDMP standards establish definitions and concepts and describe data elements and their structural relationships that are required for the unique identification of:
  - Medicinal product information (MPID/PCID) - ISO 11615
  - Pharmaceutical product information (PhPID) - ISO 11616
  - Substances (Substance ID) - ISO 11238
  - Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239
  - Units of measurement (UCUM) - ISO 11240
- ISO IDMP standards apply to both authorised and developmental medicinal products for Human use

Resolutions:

1. **prEN ISO/FDIS 17523** Health informatics- Requirements for electronic prescriptions:
   - Project lead: Frits Elferink
   - Status report:
     - The FDIS ballot comments are presented in which technical comments are not allowed. All editorial comments have been accepted. The FDIS ballot is approved with one negative vote received from Germany. The latter is based on the clause 6.6 concerning the authentication of the electronic prescription by e.g. an electronic signature. The German delegation is of opinion that this clause and requirement is much too ambitious for implementation.
   - Decision: WG6 agrees with proceeding to publication and Christian Hay congratulates the WG6 with the publication of this standard.

Resolutions:

2. **prEN ISO/DTS 19293** Requirements for the record of dispense medicinal products:
   - Project lead: José Costa Teixeira
   - Scope:
     - This TS shall determine the data set for the dispensation of medicinal products systems which are compliant to this TS, support the interoperability between the EHR systems, the decision-making processes, reconciliation of medication lists, track & trace dispensed medicinal products as well as document their authentication.
     - The discussions make clear that there are links with other work items, e.g. ISO/TS 19256 (MPD) or EN ISO 17523 (electronic prescription).
   - Decision: WG6 decides to request for an extension of 1 year for this work item and issue a call for experts.

Resolutions:

3. **prCEN ISO/DTS 19844:2016** Health informatics –Implementation guide for ISO 11238:
   - DTS ballot reconciliation:
     - Herman Diederik lists the improvements made throughout the document since the 2015 publication and the draft sent to ballot. The different models are presented which provide a view of part of a specific model.
     - The 2016 iteration is ready for publication; latest stage of the specification will be sent to WG6 members so that they can review consistency of the changes made.
     - Members can comment the main body in the context of the 2017 iteration, and are invited to keep these comments aside until the draft 2017 document is provided.
   - Decision:
     - WG6 decides to proceed to publication of the 2016 iteration, after having a review period until the end of May. The final document for publication will be submitted for publication by 15 June 2016.

Resolutions:

4. **Review of prEN ISO 11238** Health informatics - Data Elements and Structures for the Unique Identification and Exchange of Regulated Information on Substances:
   - Status:
     - WG6 agrees to schedule the item for the next meeting for which the first draft of the revision will be provided by 30 September.
     - Depending on the proposed changes in the standard, WG6 will decide in Lillehammer if the next stage is proceeding to DIS or FDIS ballot.

Resolutions:

5. **prEN ISO/DTS 20443&20451** Health informatics and Review of **prEN ISO 11615&11616** Health informatics:
   - Project Lead: Vada Perkins and Paolo Alcini
   - Discussion points:
     - Initially, the implementation guides 20443 and 20451 should be published after Amsterdam meeting while the standards, they are meant for, are in revision and are proceeding to DIS or FDIS ballot:
       - The industry wishes to proceed to publication as they are awaiting to use the implementation guides as soon as possible.
       - From the ISO process point of view, we run the risk to proceed to publication of the implementation guides, whilst changes might be recommended coming from the ballots for the standards 11615 and 11616.
       - During a period of time, the implementation guides will refer to a standard which is not available (since still in DIS ballot).
   - Decision:
     - WG6 agrees that for ISO/DTS 20443 & 20451 no decision is needed in this meeting and depending the revision of 11615 and 11616, WG6 will take the necessary decision (publication) in Lillehammer.
     - WG6 agrees to proceed to 20 weeks DIS ballot for the revision of prEN ISO 11615 &11616 and having the DIS ballot documents ready by 30 May.

Resolutions:

6. **ISO/DTR 14872** Core principles for maintenance of identifiers and terms:
   - Project Lead: Vada Perkins
   - Status report:
     - Vada Perkins provides a short report on where the discussions are with the different organisations who have maintenance competences throughout the world.
     - The International Pharma Regulatory Forum is also interested in these discussions. It's not foreseen which impact this interest can have.
   - Actions:
     - The DTR ballot decision will be prepared for discussion at the Lillehammer meeting (objective is to move this to ballot).

Outcome of the Amsterdam meeting

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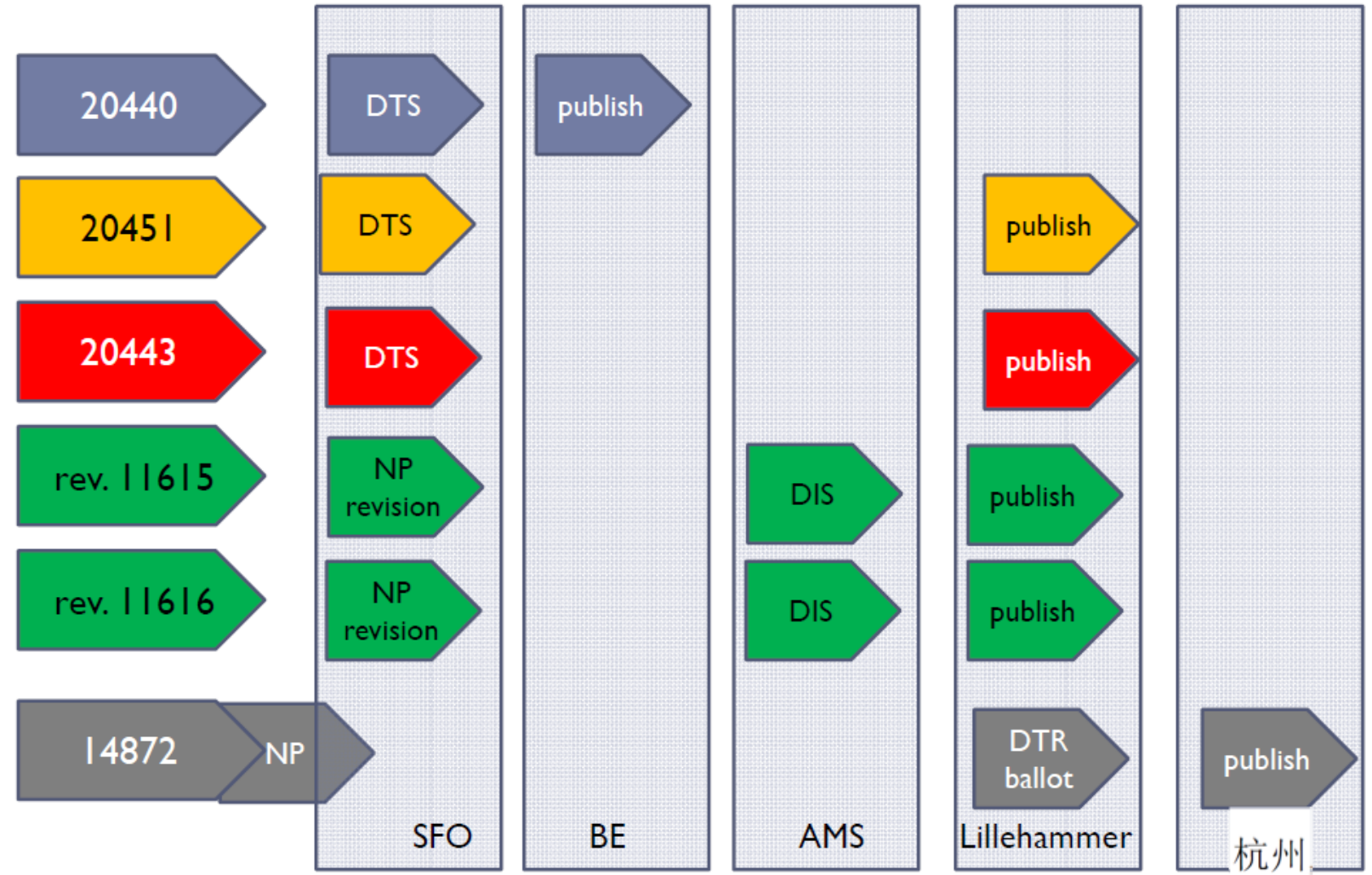
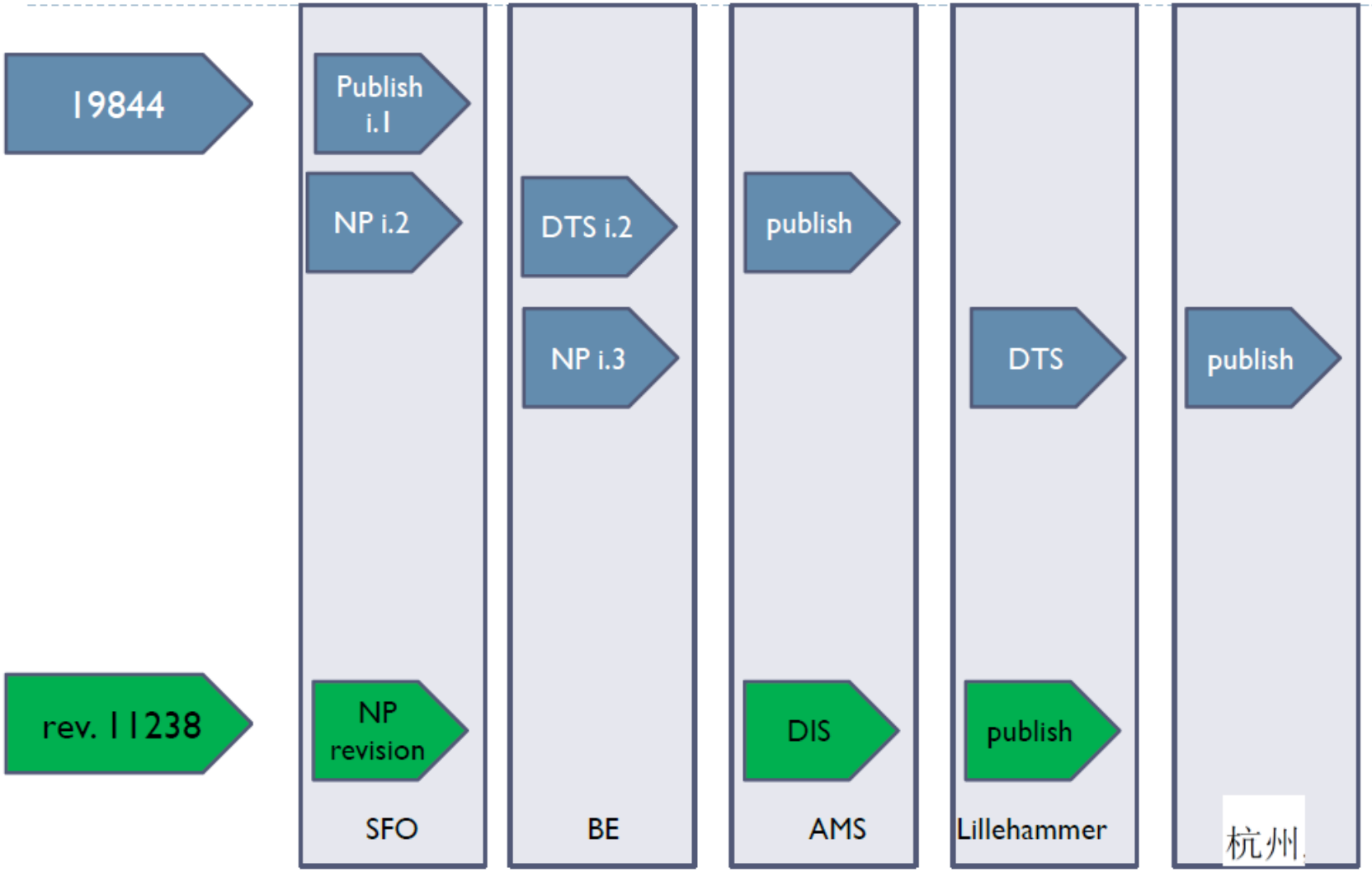
IDMP roadmap



IDMP roadmap



Points to note:

1. Publication process: There should be a conversation with ISO/CS about selling the IDMP standards and implementation guides together in a bundle and not selling these documents separately.
   - Action on Christian Hay to take up this to ISO Management and report latest on in the Lillehammer meetings.
2. The question is raised if it's allowed to re-use the content of one of the implementation guides, into, for example, the website or web tool of regulatory agencies. This is allowed as long the user is adding value to the content of the implementation guide. It's not allowed to copy the entire content of a standard into a website. Christian Hay compares the copyright of standards with authorship in general (e.g. books) where referencing to the source is very important.
   - Action on Christian Hay: The discussion is concluded with the action that it's important that we receive confirmation from ISO/CS in regard to the copyright as the IDMP implementation guides will be re-used into the databases / tooling / training materials by regulatory agencies.

ISO Brochure on Copyrights

Thank you for your attention

Further information

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