e-Labelling

SAAPI Conference 2002

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Current challenges with labelling

- The approval process for label updates involves compiling information, review and approval by Health Authorities and implementing the changes in print.
- It is a long process that can take up to 1.5 years from data availability to approval and updated label accessible to patients.
- General health literacy is poor. Many users do not read or understand the label.
- Constant label revisions may impact stocks (stock-out or destruction), and hence may hinder patient access to medicines.

What is e-Labelling?

A Definition of eLabelling (or ePI)

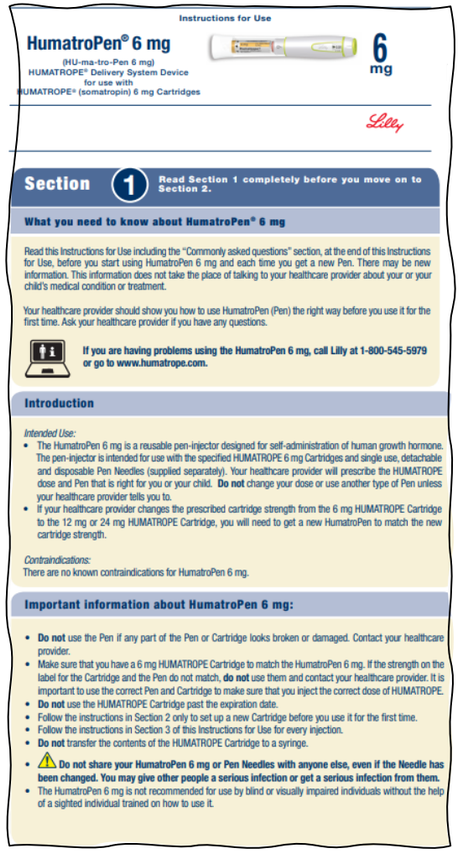
ePI is authorised, statutory product information for medicines … in a semi-structured format.

ePI is adapted for electronic handling and allows dissemination via the world wide web, e-platforms and print.

Unstructured formats such as PDF, Word or other free text files <u>are not</u> considered to be ePI

Electronic product information for human medicines in the EU: Key principles

The simple approach (unstructured)



Instructions for Use

HumatroPen® 6 mg

(HU-ma-tro-Pen 6 mg)
HUMATROPE® Delivery System Device
for use with
HUMATROPE® (somatropin) 6 mg Cartridges

6 mg

Lilly

Section 1 Read Section 1 completely before you move on to Section 2.

What you need to know about HumatroPen® 6 mg

Read this Instructions for Use including the "Commonly asked questions" section, at the end of this Instructions for Use, before you start using HumatroPen 6 mg and each time you get a new Pen. There may be new information. This information does not take the place of talking to your healthcare provider about your or your child's medical condition or treatment.

Your healthcare provider should show you how to use HumatroPen (Pen) the right way before you use it for the first time. Ask your healthcare provider if you have any questions.

If you are having problems using the HumatroPen 6 mg, call Lilly at 1-800-545-5979 or go to www.humatrope.com.

Introduction

Intended Use:

- The HumatroPen 6 mg is a reusable pen-injector designed for self-administration of human growth hormone. The pen-injector is intended for use with the specified HUMATROPE 6 mg Cartridges and single use, detachable and disposable Pen Needles (supplied separately). Your healthcare provider will prescribe the HUMATROPE dose and Pen that is right for you or your child. **Do not** change your dose or use another type of Pen unless your healthcare provider tells you to.
- If your healthcare provider changes the prescribed cartridge strength from the 6 mg HUMATROPE Cartridge to the 12 mg or 24 mg HUMATROPE Cartridge, you will need to get a new HumatroPen to match the new cartridge strength.

Contraindications:
There are no known contraindications for HumatroPen 6 mg.

Important information about HumatroPen 6 mg:

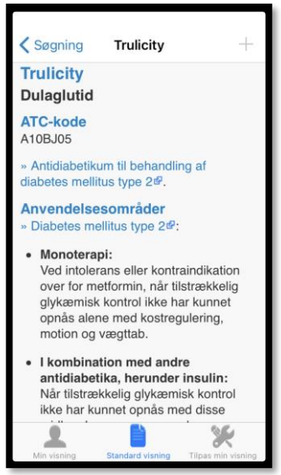
- **Do not** use the Pen if any part of the Pen or Cartridge looks broken or damaged. Contact your healthcare provider.
- Make sure that you have a 6 mg HUMATROPE Cartridge to match the HumatroPen 6 mg. If the strength on the label for the Cartridge and the Pen do not match, **do not** use them and contact your healthcare provider. It is important to use the correct Pen and Cartridge to make sure that you inject the correct dose of HUMATROPE.
- **Do not** use the HUMATROPE Cartridge past the expiration date.
- Follow the instructions in Section 2 only to set up a new Cartridge before you use it for the first time.
- Follow the instructions in Section 3 of this Instructions for Use for every injection.
- **Do not** transfer the contents of the HUMATROPE Cartridge to a syringe.
- ⚠ **Do not share your HumatroPen 6 mg or Pen Needles with anyone else, even if the Needle has been changed. You may give other people a serious infection or get a serious infection from them.**
- The HumatroPen 6 mg is not recommended for use by blind or visually impaired individuals without the help of a sighted individual trained on how to use it.

From print to printed paper online

The smart approach (semi-structured)

Structured Content Authoring (SCA)

API*

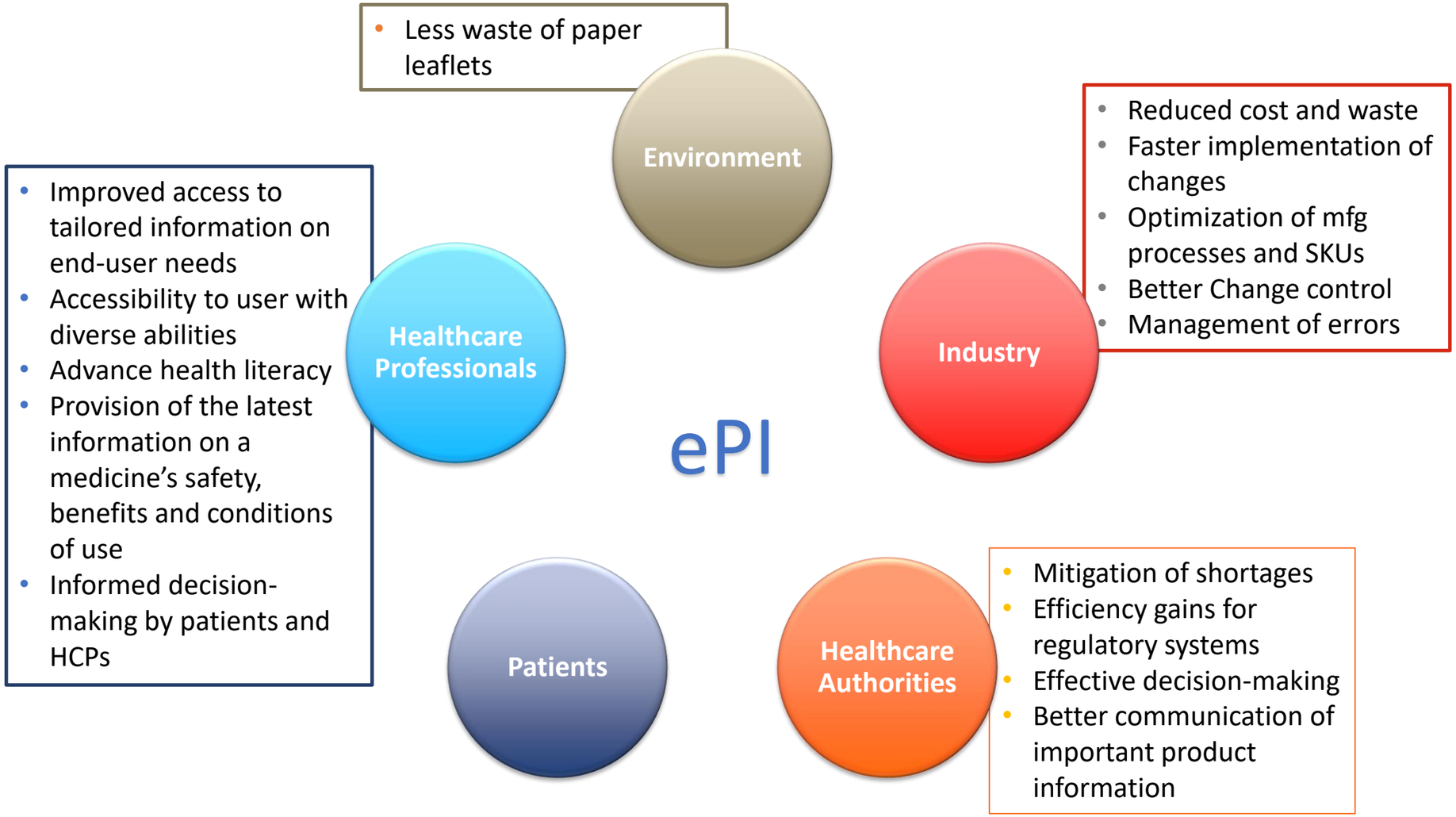


Semi-Structured Content (XML, HTML etc):

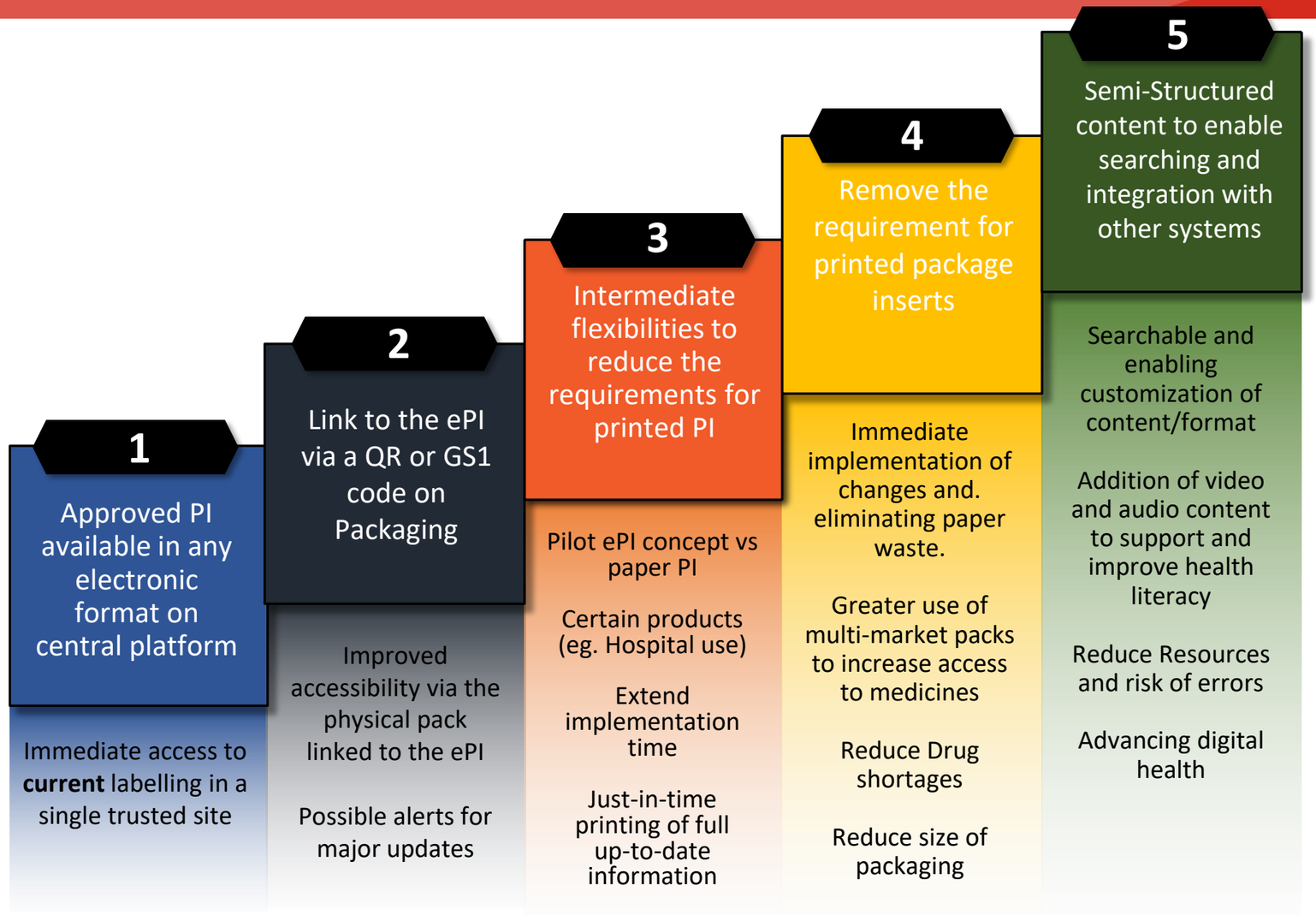
- It defines relationships between content.
- It provides a hierarchy to content and enforces a specific order.
- It makes the content portable and accessible because it is a standard that can be read by many different hardware and software platforms.
- It allows the content to be published to many different channels

API*: Application Programming Interface

Key Benefits of e-Labelling



Illustrative Roadmap Towards eLabelling



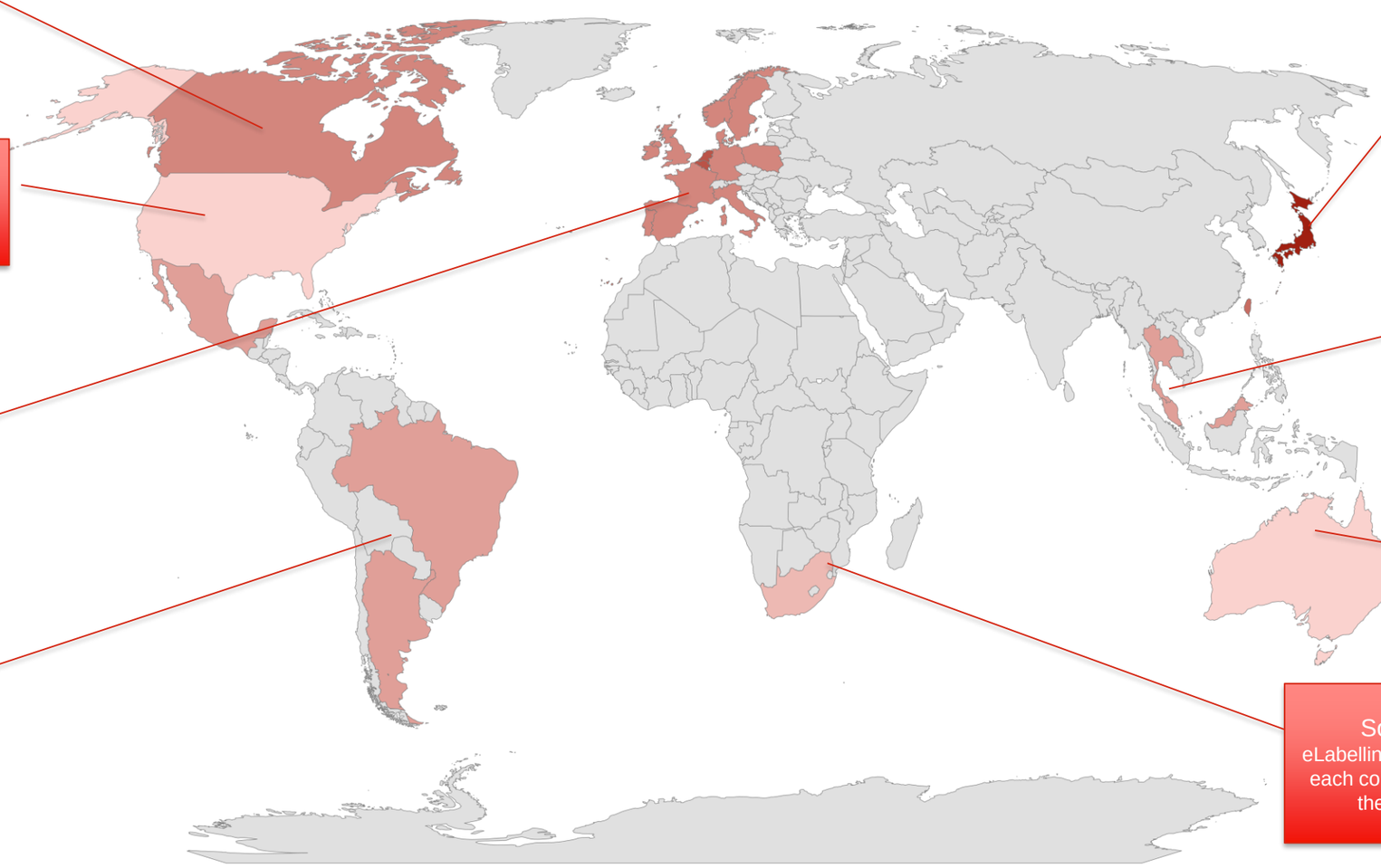
Regulatory Landscape

HCA:
Product Monograph transition to XML (HL7 standard) pilot ongoing

Structured labelling implemented, but regulations require paper PI

Europe:
EMA position paper
Multiple industry and NCA pilots and initiatives ongoing

LATAM:
Initiative ongoing to supplement PPM with e-labelling



Japan:
New legislation to enforce e-Labelling via PMDA website (HTML, XML) using a barcode on cartons

Taiwan, Malaysia, Thailand, Singapore:
Initiatives ongoing

Australia:
Structured Content allowed.
e-Labelling allowed except for injectables

South Africa:
eLabelling allowed, but up to each company how to host the digital labels

Challenges with eLabelling

- Regulators:
  - Decide on infrastructure, format and technical standards as well as ambitions: Integrated digital health platforms and mobile applications
  - Does regulation allow the removal of paper package inserts?
  - Develop/identify platform to host *up-to-date* labelling
  - Harmonise requirements with other countries to enable sharing of packs?
- Industry:
  - Openness to take part in pilots
  - Engage in facilitating harmonized standards. Many current initiatives are using the Health Level Seven/Fast Healthcare Interoperability Resources (HL7 FHIR)
  - Ability to host labelling if there is no government platform
  - Identify and enable means of getting paper leaflets to patients who don't have electronic means

Conclusion

eLabelling can

- Allow faster sharing of new information
- Enable digital transformation to e-prescribing and e-health records to deliver integrated healthcare solutions and tailored patient care
- Increase Patient Health Literacy
- Alleviate Drug Shortages
- Decrease use of paper
- Reduce package sizes

Further reading:

Electronic product information: From principles to actions; AESGP, EFPIA and Medicines for Europe reflections on EMA-HMA–EC Key principles for electronic product information

IFPMA Position Paper on: Improving Patient Safety and Health Systems Resilience Through the use of Electronic Labeling