End to End Labeling process, Benefits of e-Labelling

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INTRODUCTIONS

Bas van Heijst

Regulatory Affairs

- From Netherlands
- More than 20 years industry experience
- Enjoy volleyball, skiing and my 2CV!

LEGAL DISCLAIMER

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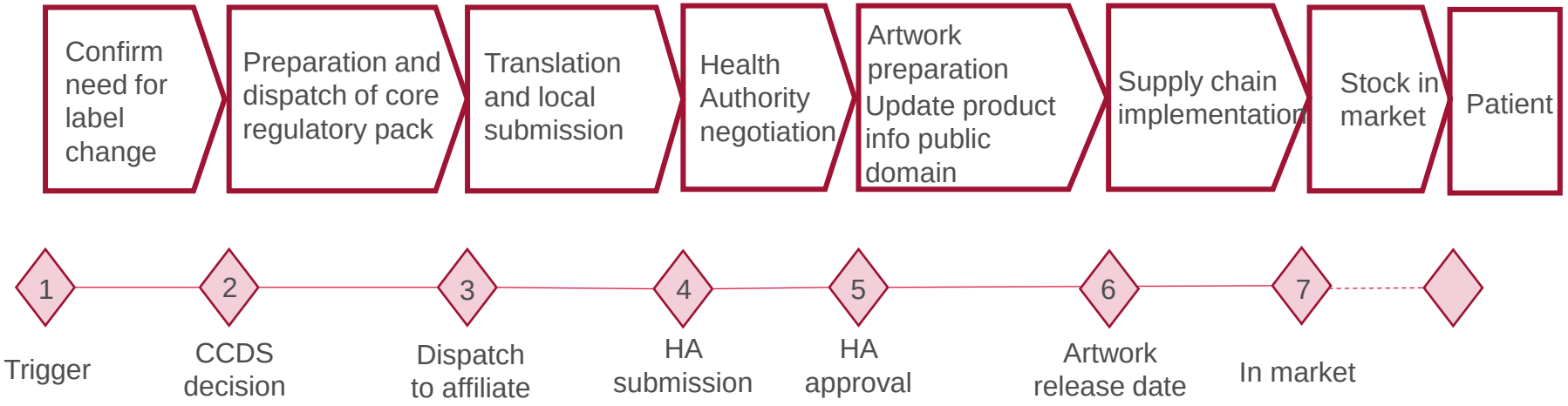
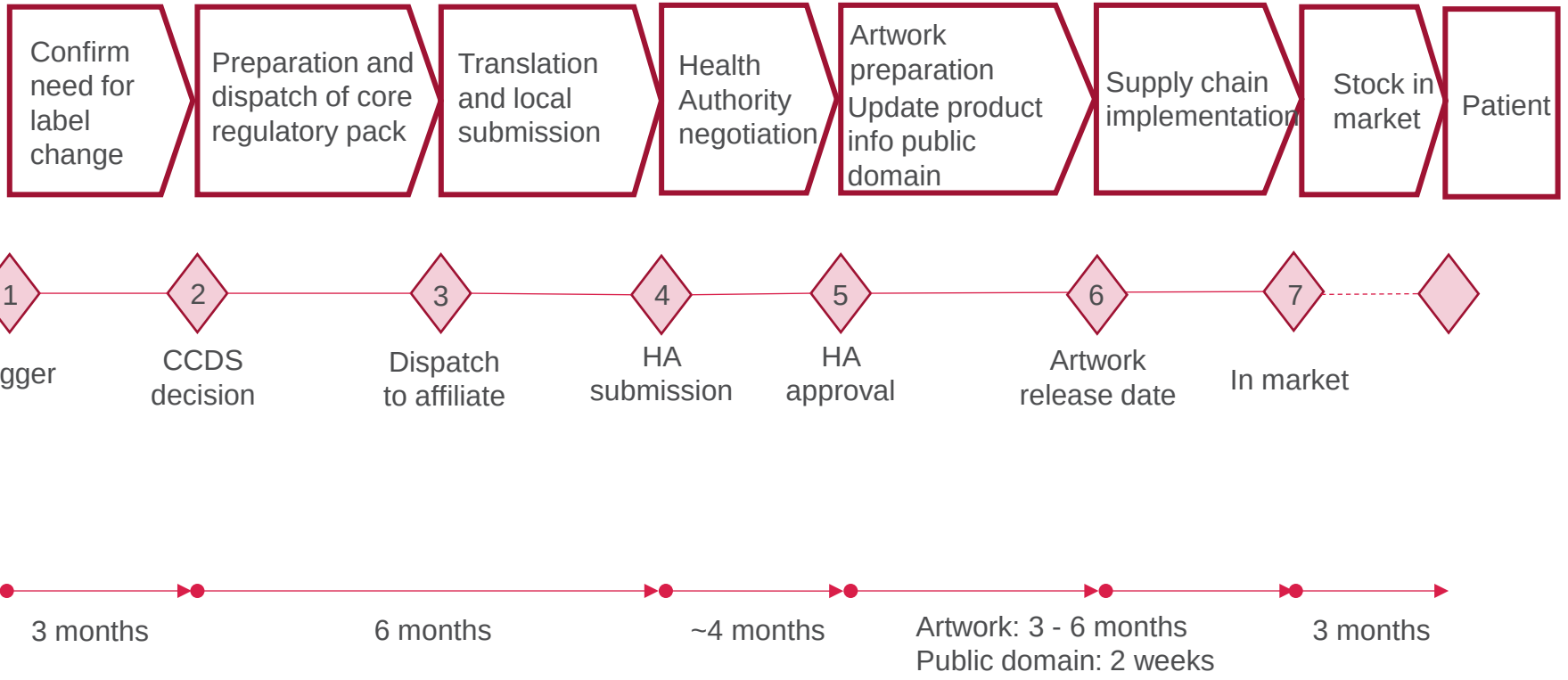
GENERAL END TO END LABELING PROCESS

KEY MILESTONES



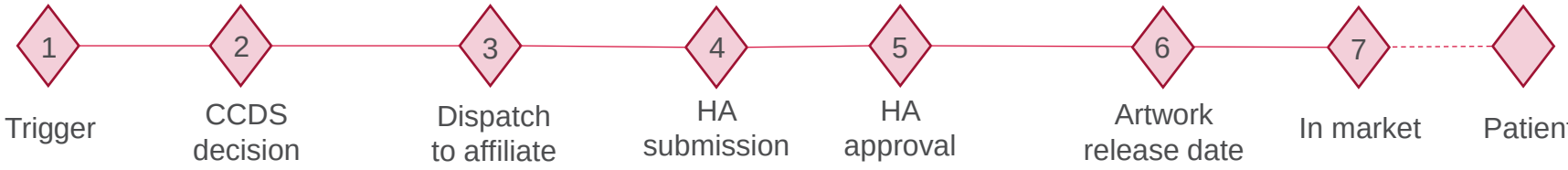
1 CCDS x 75 Markets x 2 SKU / Market = 150 tracking records

END TO END LABELING PROCESS ICH COUNTRIES



Total: 22 months

END TO END LABELING PROCESS NON-ICH COUNTRIES



Total: 37 months

DRIVERS FOR SHORTENING TIME TOWARDS PATIENTS

Patients wish this!!!

Quicker

More modern way (phone/apps)

SHORTENING DECISION/SUBMISSION TIMELINES!

GVP IX_Signal Management_Rev 1

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/10/WC500236408.pdf

IX.C.4.2. Variation of the terms of marketing authorisation

A marketing authorisation holder may conclude, based on their evaluation of a signal detected through the monitoring of EudraVigilance data, that the product information and/or the RMP should be updated through a variation. In such cases, the marketing authorisation holder should submit the variation application to the relevant competent authorities as soon as possible and no later than 3 months after completing the evaluation of the signal if it corresponds to an important risk, or within 6 months for adverse reactions or risks not considered important (see GVP Annex I).

ELECTRONIC LABELING

European Commission 22 March 2017

Commission report recommends improvements to package leaflets

The medicines we buy in the EU contain a package leaflet which should provide us - the user, with clear information on the medicines we are taking – name of the product and the manufacturer, therapeutic indications, dosage, shelf life, adverse reactions, and more. EU rules in place since 2001 ensure this.

Today, the Commission publishes a report to the European Parliament and the Council on current shortcomings in the summary of product characteristics and the package leaflets, and puts forward recommendations on how they could be improved to better meet the needs of patients and healthcare professionals.

Recommendations

Some examples of recommendations identified in the report are:

…

Making product information available in electronic in addition to paper form should be explored and key principles agreed upon.

…

http://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue.cfm?newsletter_service_id=327&newsletter_issue_id=2862&page=2&fullDate=Wed%2022%20Mar%202017&lang=default

15/11/2017

EMA to work with stakeholders to improve the product information for EU medicines

Stakeholder feedback sought on ongoing electronic initiatives

The European Medicines Agency (EMA) has published an action plan to improve the product information (PI) for EU medicines, an information package for patients and healthcare professionals that accompanies every single medicine authorised in the EU and explains how it should be used and prescribed. This action plan follows a report published by the European Commission in March 2017 which concluded that despite ongoing efforts to make the PI easy to read and useful, there is a need to improve how information on medicines is conveyed to patients and healthcare professionals.

One of the key areas of this plan is to explore how electronic or digital means can be used to improve accessibility to medicines' information by patients and healthcare professionals.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/11/news_detail_002853.jsp&mid=WC0b01ac058004d5c1

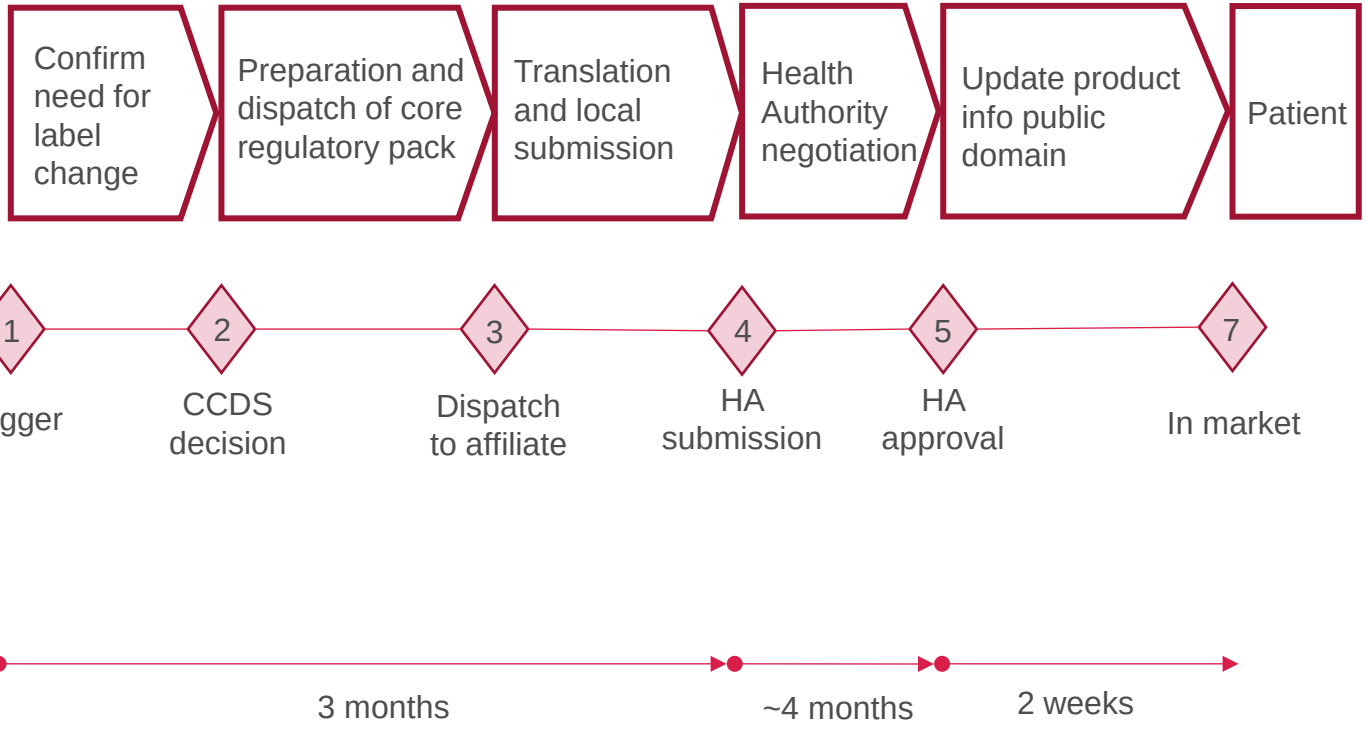
ELECTRONIC LABELING

Expect to:

Introduce electronic leaflets in parallel with traditional paper leaflets, for interim period

Then, abandon traditional paper leaflets, and continue with electronic leaflets only

END TO END LABELING PROCESS FUTURE?



Total: 7.5 months (!)

YOU MAY HAVE QUESTIONS! DO NOT HESITATE TO ASK!