IPSEN
Innovation for patient care

9th Pharma Packaging And Labeling Innovation Forum

Labeling & packaging improvement at Ipsen

Sylvie PUJOL
Senior Director Global Labeling
Global Regulatory Affairs

Christina MONTJOLY
Product Life Cycle Manager
Supply Chain

Introduction

Sylvie PUJOL- Head of Global Labeling - Ipsen

- 10 years at Sanofi France within Audit of EU Oncology phase 1-3 trials and Global Promotional Compliance for Diabetes
- 6 years at Sanofi-Aventis within Global Labeling for life cycle products & devices
- 6 years of strategic Labeling at GSK in the UK
- 1 year at UPSA France (BMS)
- 2,5 years at Ipsen France as Head of Global Labeling

Introduction

Christina MONTJOLY - Supply Chain Product Life Cycle Manager

- 7 years as a Graphic Designer
- 8 years experienced in packaging project management and process improvement within FMCG companies for cosmetic and food products (Unilever and Group Bel)
- 5,5 years at Ipsen as a Supply Chain Product Life Cycle Manager

Agenda

Summary of slide content

01 Presentation of the E2E Labeling process

02 Identified Pain points

03 Proposed Solutions

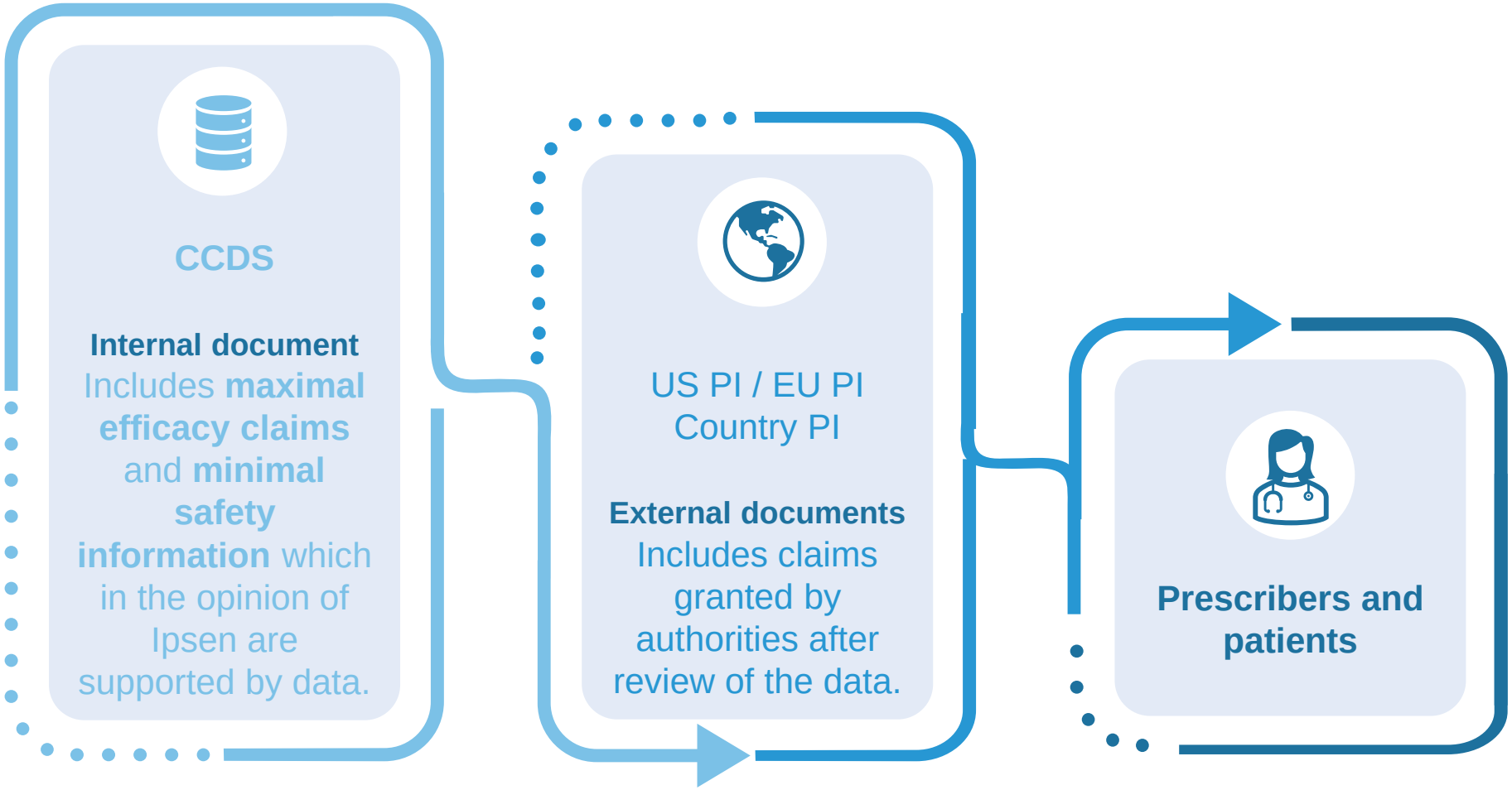
04 Conclusion

BRING
the full potential of our innovative medicines to patients

01 E2E labeling process at Ipsen

Labeling basis : Company Core Data Sheet

From Global to the patients worldwide



End-to-End Labeling Process

Regulatory framework

- EU Guideline on Good Pharmacovigilance Practices (GVP)[1] indicate that :

*« Marketing Autorisation Holder shall commit to **provide accurate and evidence-based product information** to healthcare professionals, regulatory authorities, and patients/consumers for **informing them in a timely manner on the safe and appropriate use** of our medicinal products »*

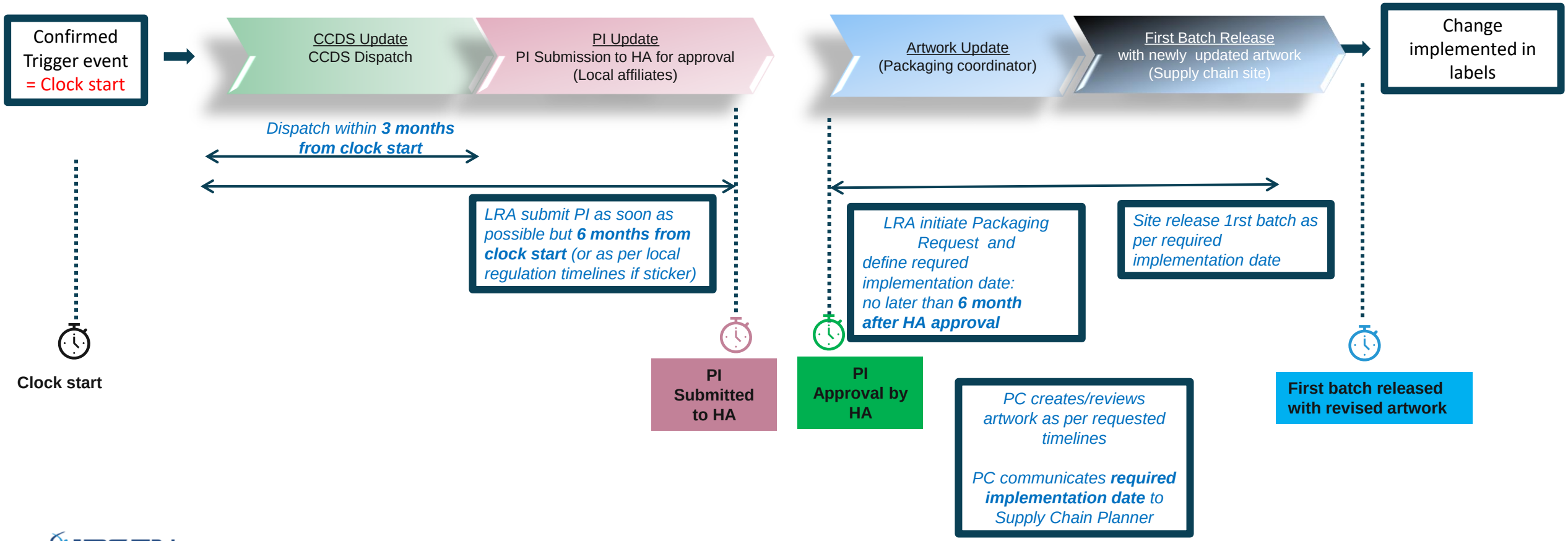
- MAH shall **submit safety updates to Health Authorities** after completing the assessment of the signal
  => **Clock start = signal confirmation :**

As per EU Guideline on Good Pharmacovigilance Practices (GVP) 1	Important risk	Adverse reactions or risks not considered important
	As soon as possible and no later than 3 months	Within 6 months

- **Global Labeling** function and the **Executive Labeling Committee** governance are in place in Ipsen

[1] Module XV-Safety Communication EMA/118465/2012 Rev 1. Also based on Directive 2001/83/EC on the code medicinal products in EU.

E2E Labelling Process Overview for Standard Safety Change



BUILD
a high-value
sustainable pipeline

02 Identified pain points

Managing labelling implementation complexity

Communication of labelling changes across the manufacturing network

Types of changes

Countries and SKUs impacted

Timing to implement

Local constraints and requirements

Product planning constraints

Low volume / infrequent packaging campaigns

Supplier leadtimes

Ensuring continuity of supply to patients

Complexity Managed by Supply Chain

Different sources of information

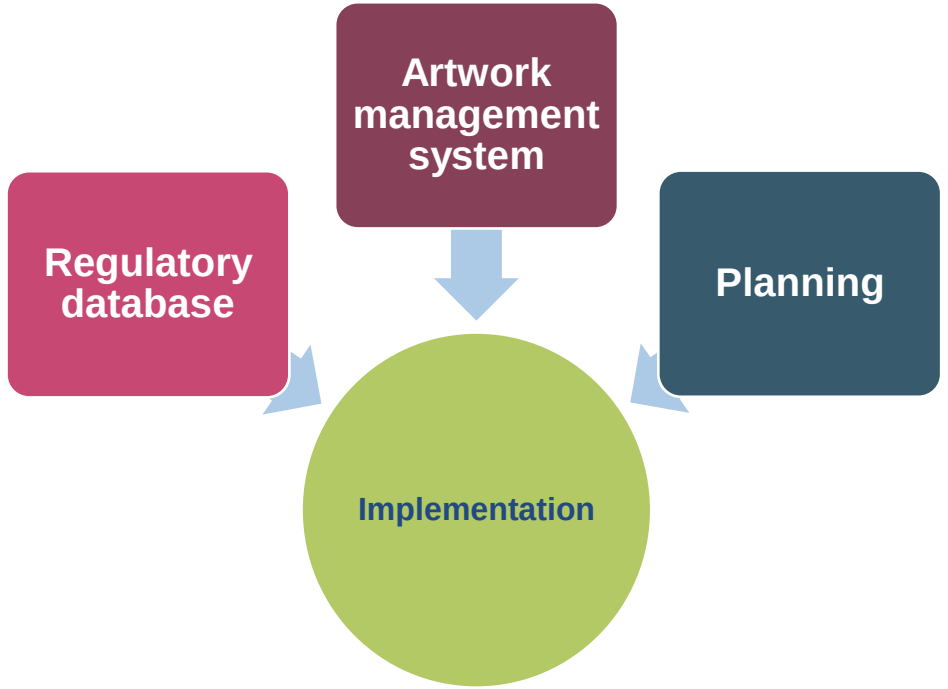
Labelling change info managed in 3 different systems

Lack of interoperability

Manual reconciliation

Data integrity

Exhaustivity & Accuracy issues



Complexity with processes and tools

DELIVER

efficiencies to enable
targeted investment & growth

Proposed Solutions

Improving E2E labelling communication

Product Artwork Oversight meetings

Governance

Have a clear governance to secure readiness & synchronization on artwork management E2E process with clear R&R

Regulatory Planning

Provide visibility of upcoming and ongoing variations impact printed packaging components

Provide input on Change classification

Supply Chain Planning & Packaging teams

Integrate into the 24 month horizon information regarding changes

Build Forecast of changes across the network

- ✓ **Escalate issues linked to implementation targets**
- ✓ **Prioritize artwork management and supply planning according to constraints**
- ✓ **First step to an artwork management control tower**

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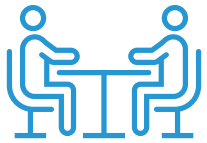
Improving E2E labelling visibility



- **Enhance communication and visibility across the network by sharing system data**

- **Manage End of Grace period local constraints**

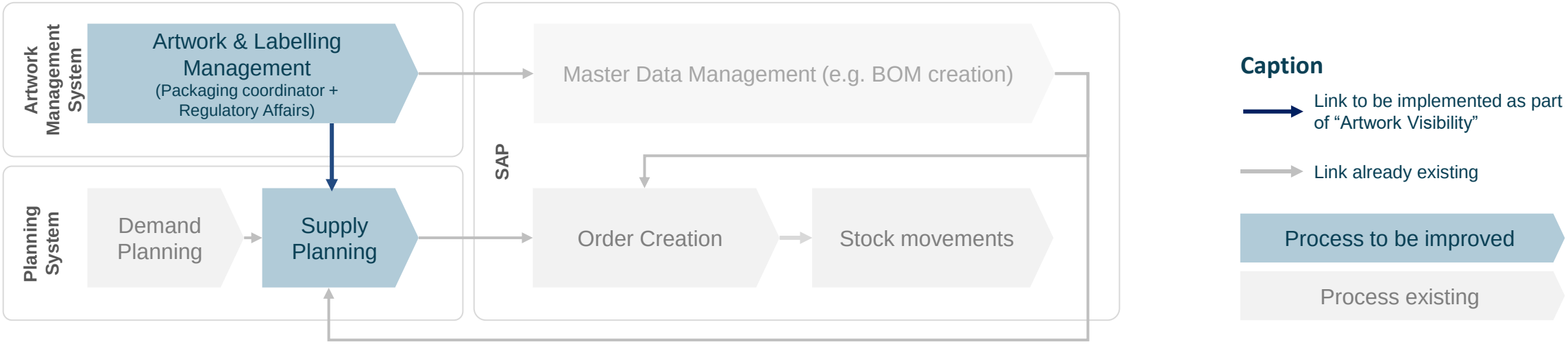
- **Artwork visibility: Integrating AMS and Planning**

Artwork Visibility Project

Increase visibility between country's regulatory constraints and supply planning

Objective: Connect supply planning & artwork management processes and systems to ensure that Finished Good batches distributed to countries respect regulatory requirements concerning artwork changes, i.e. changes of artwork need to be implemented within the time period defined by market authorities

Expected Benefits: Ensure compliance, increase visibility on upcoming artwork changes, reduce risk of write-off and manual workload associated with artwork changes



Integrating AMS data with planning

Expected Benefits of the Project

Supply Planners

- Consult planning tool reports to **manage the phase in/phase out** of artwork components
- **Manage stocks on hand**
- Ensure **products availability** to the different countries in time

Local Regulatory Affairs

- Receive planning tool reports to **monitor artwork implementation**
- Keep track of **planned date production with revised artwork and delivery**
- View the **actual production date with revised artwork and delivery and the batch number**

- ✓ Users will be able to **visualize the upcoming artwork changes** for a given country
- ✓ Reporting will **inform users on key milestones** regarding the artwork changes and end of grace period management

BOOST
a culture of collaboration
& excellence

04 Conclusion

Coming soon…

- Enhanced collaboration between Regulatory & Supply
- More interoperability between systems
- Better visibility of changes
- Ensuring updated product information is communicated to prescriber & patients

THANK YOU