

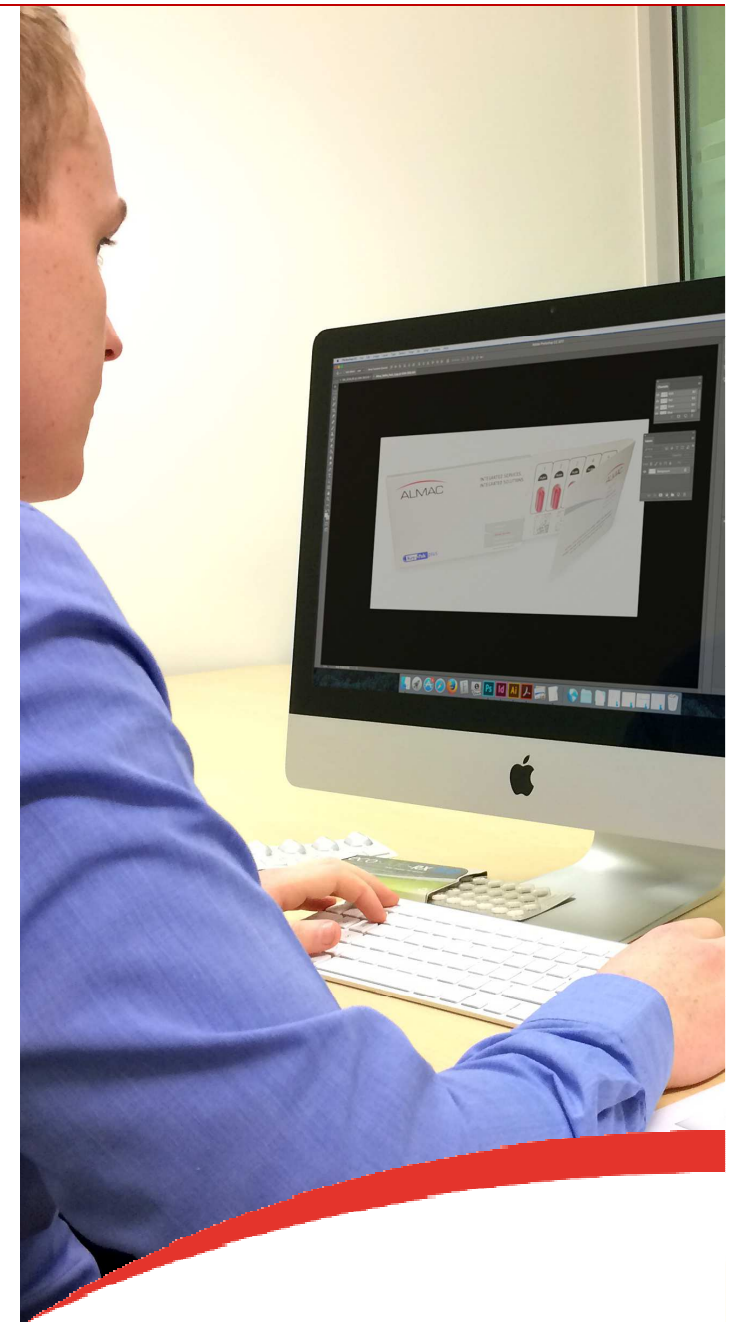
# Key Packaging Considerations

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# Agenda

- US vs EU
- Considerations for Pack Design
- Overview of Regionalisation



## US Factors

Factor	US
Countries	1
Recognised Languages	1
Regulatory Bodies	1
Languages per pack	1
Typical Leaflet Size	250 x 353 mm



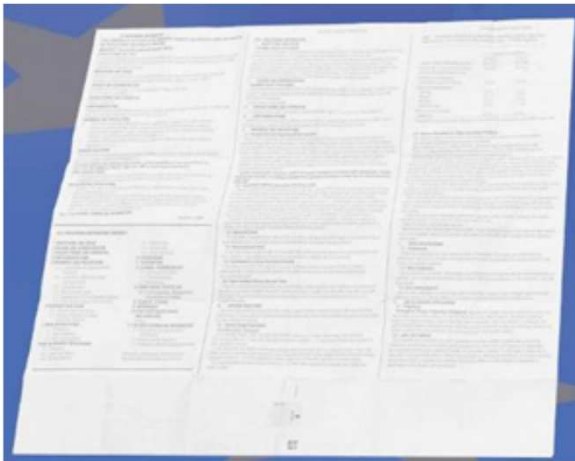
## US vs EU Factors

Factor	US	EU
Countries	1	28
Recognised Languages	1	24
Regulatory Bodies	1	31
Languages per pack	1	1-5
Typical Leaflet Size	250 x 353 mm	500 x 700 mm



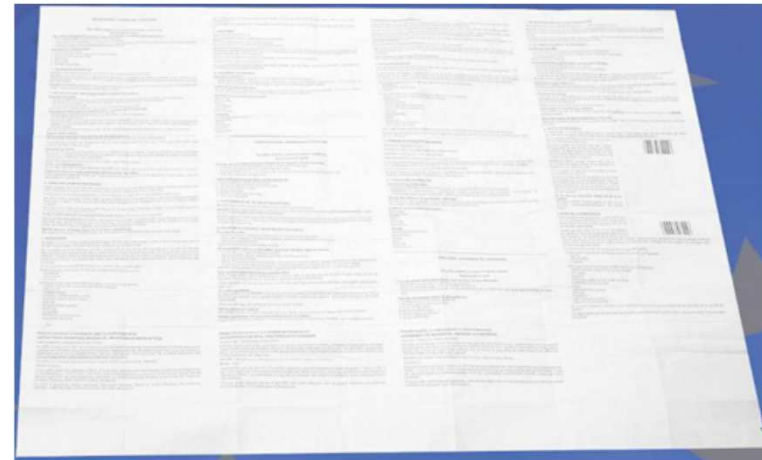
## PIL Comparison: EU vs US

US



Single Language,  
1 Sided

EU



4 Languages,  
Double Sided

# Considerations for Pack Design

## Target Population

Regulatory

## Processability

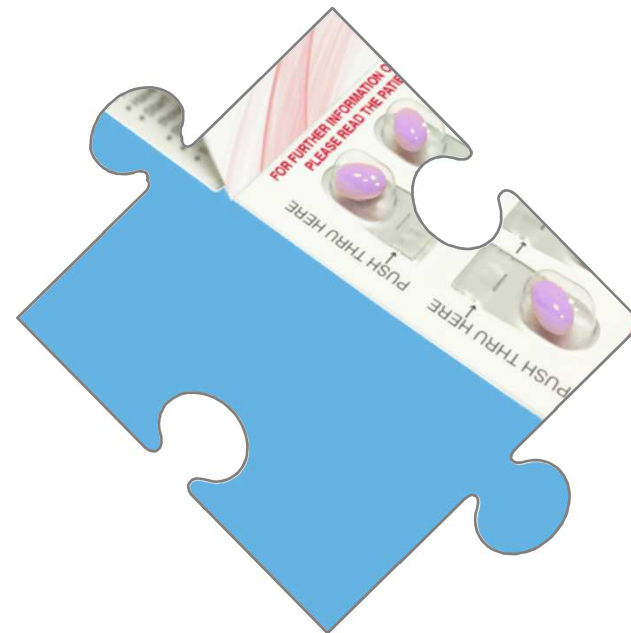
## Commercial & Marketing



# Considerations for Pack Design

- Treatment Environment
- Dosage Form
- Child Resistance
- Senior Friendly
- Dosing Regime

## Target Population



# Considerations for Pack Design

- Cost of Goods
- Automated or Manual Process
- Equipment/Tooling
- Availability of Materials
- Lead Times

## Processability



# Considerations for Pack Design

- USP
- Brand Identity
- Anti-counterfeit

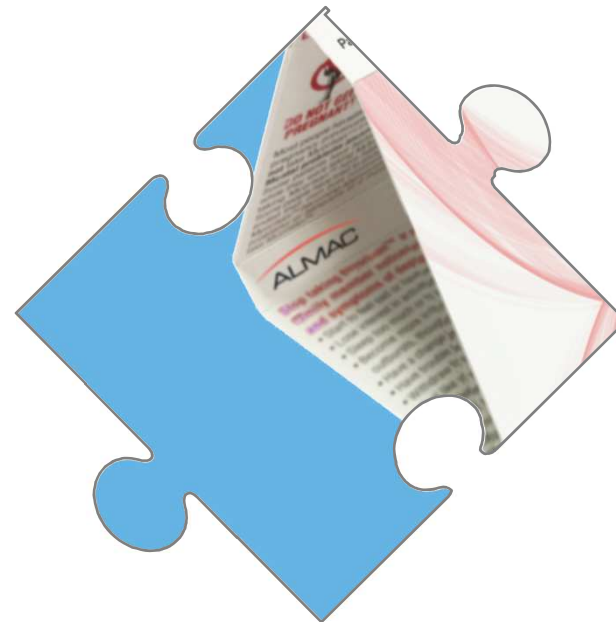
## Commercial & Marketing



# Considerations for Pack Design

- Font Size
- Readability
- Serialisation
- Braille
- Required Text & Symbols

## Regulatory



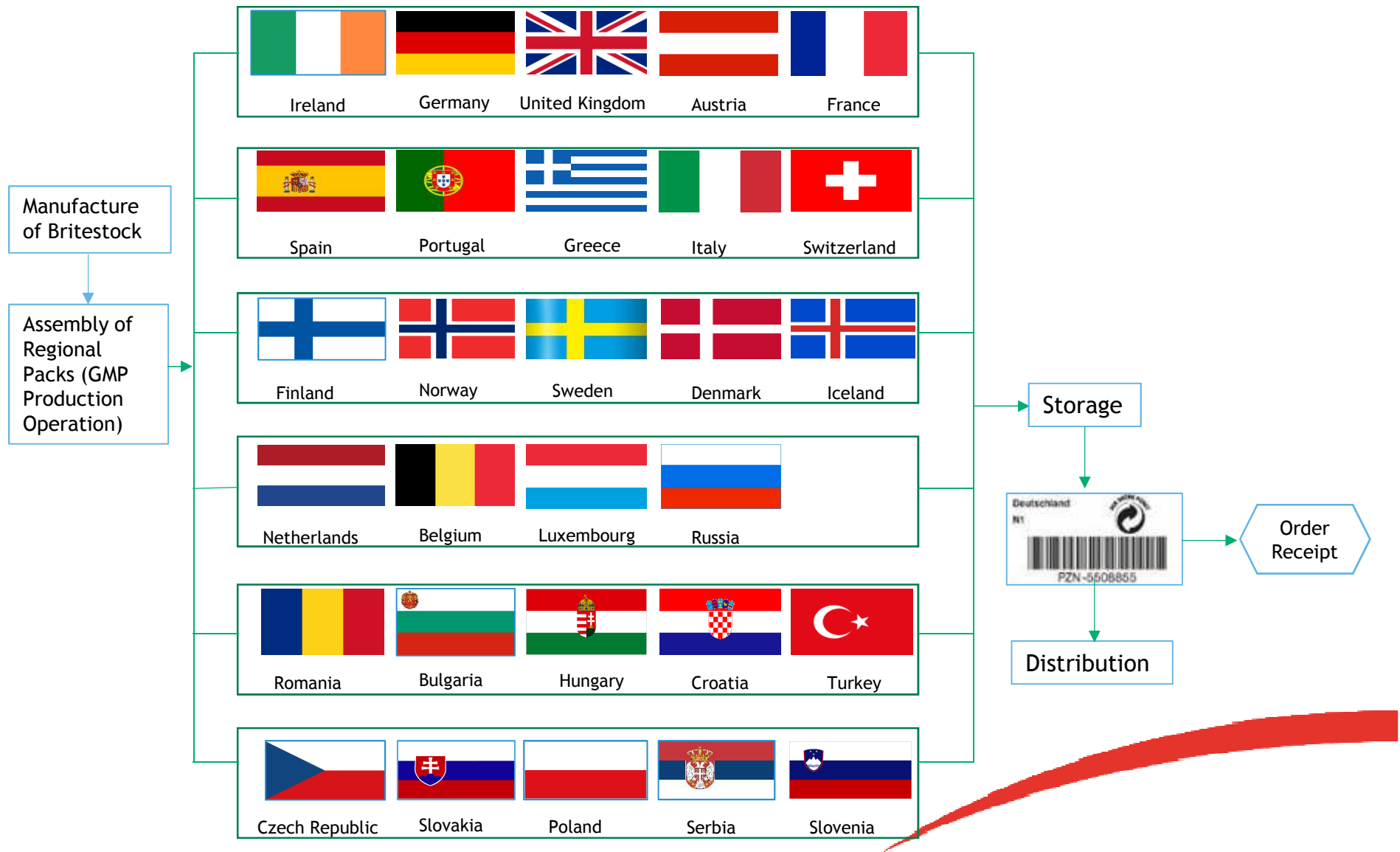
# Overview of Traditional Secondary Packaging Process



# Overview of Historic Packaging



# Overview of Regionalisation



# What is Blue Box?

Country specific information which is presented in the official language(s) of the Member State concerned, to make the pack Market Specific



# Benefits of Regionalisation

- Reduced Handling
- Reduced Stock Holding
- Reduced Lead-times
- Reduced Cost of Goods
- Reduced Sampling
- Increased Flexibility



# Considerations for Regional Groupings

- Keylines Size/Capacity
- Target Markets
- Cultural Precedents
- Common Languages
- Serialisation Requirements
- Parallel Importation

