



# The “Brussels Scene” Impacting Generic Medicines





*Making Medicines Affordable*

# EGA - Introduction

- **Established in 1993**
- **Based in Brussels**
  - **International non-profit organisation under Belgian law (AISBL).**
- **Pan European**
- **Around 60 direct members from both companies and national associations**





# Generic Medicines Cornerstone to Healthcare Sustainability

Every year generic medicines bring savings of **30€ BN** in the EU

Generic medicines account for **50%** of dispensed medicines and **18%** of pharmaceutical expenditure

One of the Most Competitive Sectors in Europe

**150,000** Employees in Europe

More than **1000** generic medicines companies in Europe

# Content

## ■ Policy Context

## ■ Current Issues

- Focus on the pharmaceutical package and transparency



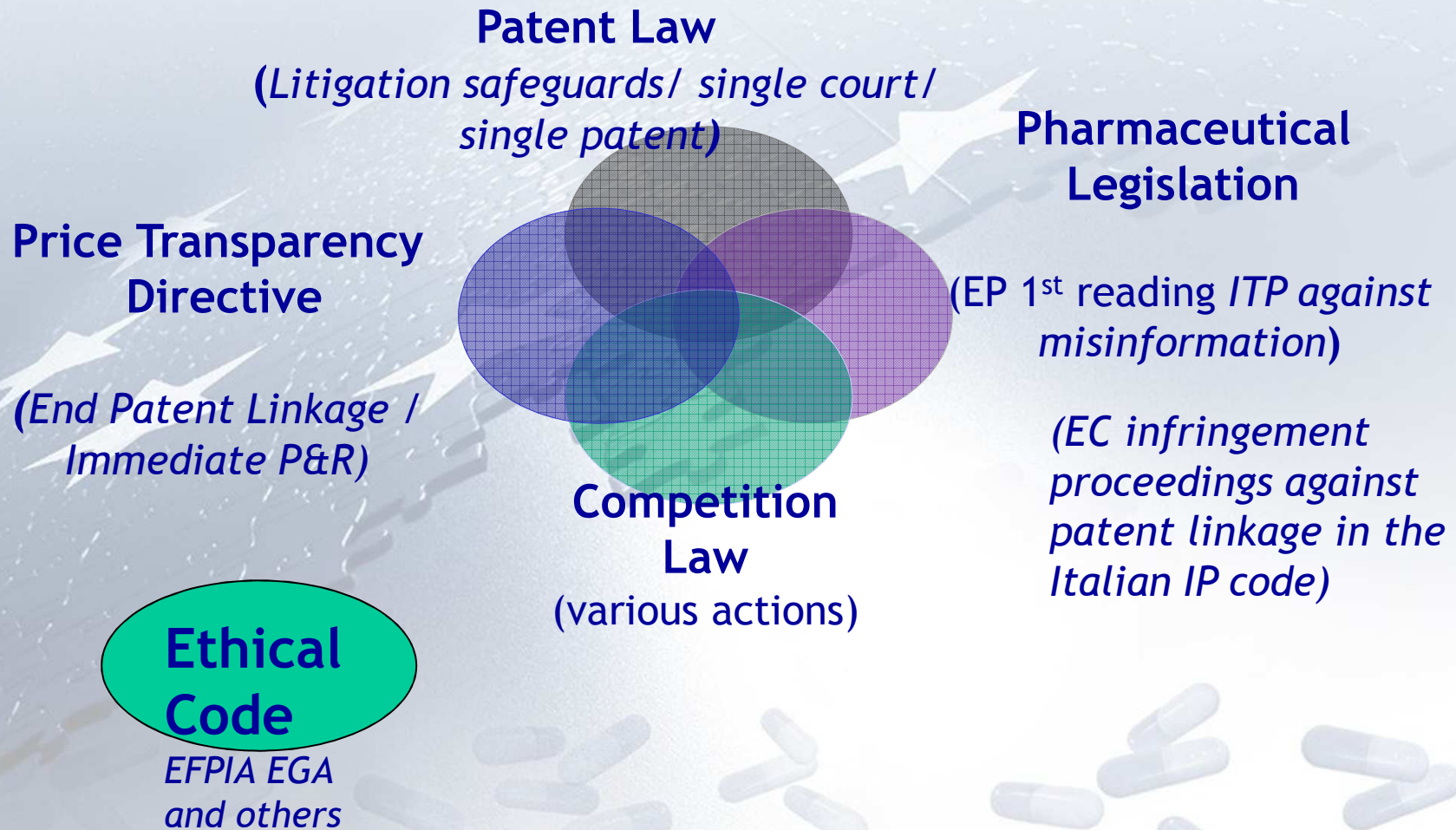
# “Europe 2020”



## ■ Three mutually reinforcing priorities:

- Smart growth: developing an economy based on **knowledge and innovation**.
- Sustainable growth: promoting a more resource efficient, greener and more **competitive economy**.
- Inclusive growth: fostering a **high-employment economy** delivering social and territorial cohesion.

# Following Up Sector Inquiry





# Better Regulation for all EU Policies

- Simple, reduce red tape and administrative costs/burdens
  - Assess impact on business and environment/ consultation of interested parties
  - Alternatives to laws should be considered
  - Actions proportionate to objectives
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# Brussels Scene - Legislation in the Spotlight

- **Pharmaceutical Package**
    - Pharmacovigilance
    - Falsified Medicines
    - Information to Patients
  - **Price Transparency Directive**
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# Brussels Scene - Legislation

- Patent Court currently in discussion at the EP
- Single Patent currently in discussion at the EP
- Customs Regulation Proposal currently in discussion at the EP
- Review of IP Enforcement Directive, public consultation closed
- Clinical Trials Directive, public consultation closed



# State of Play in the Legislative Process

## Pharmacovigilance

- Adopted in first reading (EP+Council)
- Implementation phase

## Falsified Medicines

- Adopted in first reading (EP+Council)
- Delegated act and implementation

## Information to Patient

- Adopted in first reading (EP)
- EC has issued a revised proposal

# Pharmacovigilance: key Measures Adopted

- No 'summary of essential information' in product information
- Electronic reporting of all adverse reactions by industry to central database Eudravigilance only
- No routine Periodic Safety Update Reports for generic medicinal products
- No traceability to patients of biologicals



# Pharmacovigilance: Implementation Phase

- **No savings as initially calculated by the EC:**
  - The resources gained via no routine PSURs for plain generics will be needed for the implementation of Risk Management plans
- **Reduce the burden on the generic industry in relation to the submission of information on all medicinal products to the EMA**



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# Falsified Medicines Directive

- Companies adopt a EU harmonised unique identifier which allows verification of authenticity and identification of individual packs
- Risk assessment based on five criteria, white list for prescription medicines
- Databases to be paid by manufacturing authorisation holders
- **Details now to be worked out in Delegated Act**



# Key Aspects of Delegated Act:

- The real problem of falsified medicines lies within the **illegal supply chain**;
- The EU should concentrate on the fact that the adaptation of the delegated act should be cost-effective:
  - Generic medicines are not target of counterfeiting, the delegated act should maximize the number of generic medicines on the white list to avoid compulsory safety feature
  - The safety and anti-tampering feature should be a 2D matrix barcode containing product and open serialisation code
  - The repository system can be national / regional systems. There is no need for a pan-European hub and this should not be made required by the delegated act.
- Continued smooth API import and limited administrative burden

# Information to Patients, the Revised Proposals:



- Ban advertising for all prescription medicines
- Allow information approved by competent authorities on officially registered websites
- Allow information through limited channels only :
  - Ban printed press as a channel of information
  - Allow marketing authorisation holders to provide printed material if explicitly requested by the general public

# A New Distinction is Introduced:

- The information shall not include comparisons between medicinal products
- Information that shall be made available by the industry

And

- Information that may be provided on a voluntary basis

# Review of the Transparency Directive

- Directive 89/105/EEC creates harmonised provisions to ensure the transparency of national pricing and reimbursement of medicinal products



- Why a review?

- Distortions of internal trade in medicines caused by national health expenditure controls
- One of the key recommendations of Sector Inquiry

# EGA Wish List:

- **Introduce immediate price & reimbursement approvals for generic medicines**
- **Stop patent linkage on price and reimbursement procedures**
- **Eradicate double bioequivalence assessment by price and reimbursement authorities**



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# Immediate Price & Reimbursement

- Reimbursement procedures for generic medicines should be automatic or reduced to a minimum
- Prevent information by price and reimbursement authorities to the originator further patent disclosure of our price and reimbursement request and potential launch date



# Stop patent linkage

- Practice of patent linkage is not part of EU pharmaceutical legislation
- Create dissuasive mechanism to stop any type of patent linkage



# Eradicate Double Bioequivalence Assessment

- **Strict assessment of bioequivalence data and the granting of the MA already done by the Competent Authorities**
- **No need to demonstrate equivalence again as this delays generic medicines market access**



# Next Steps...

- Interservice procedure currently on-going
- Proposal to be published by the end of the year





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**Thank you for your  
Attention**

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