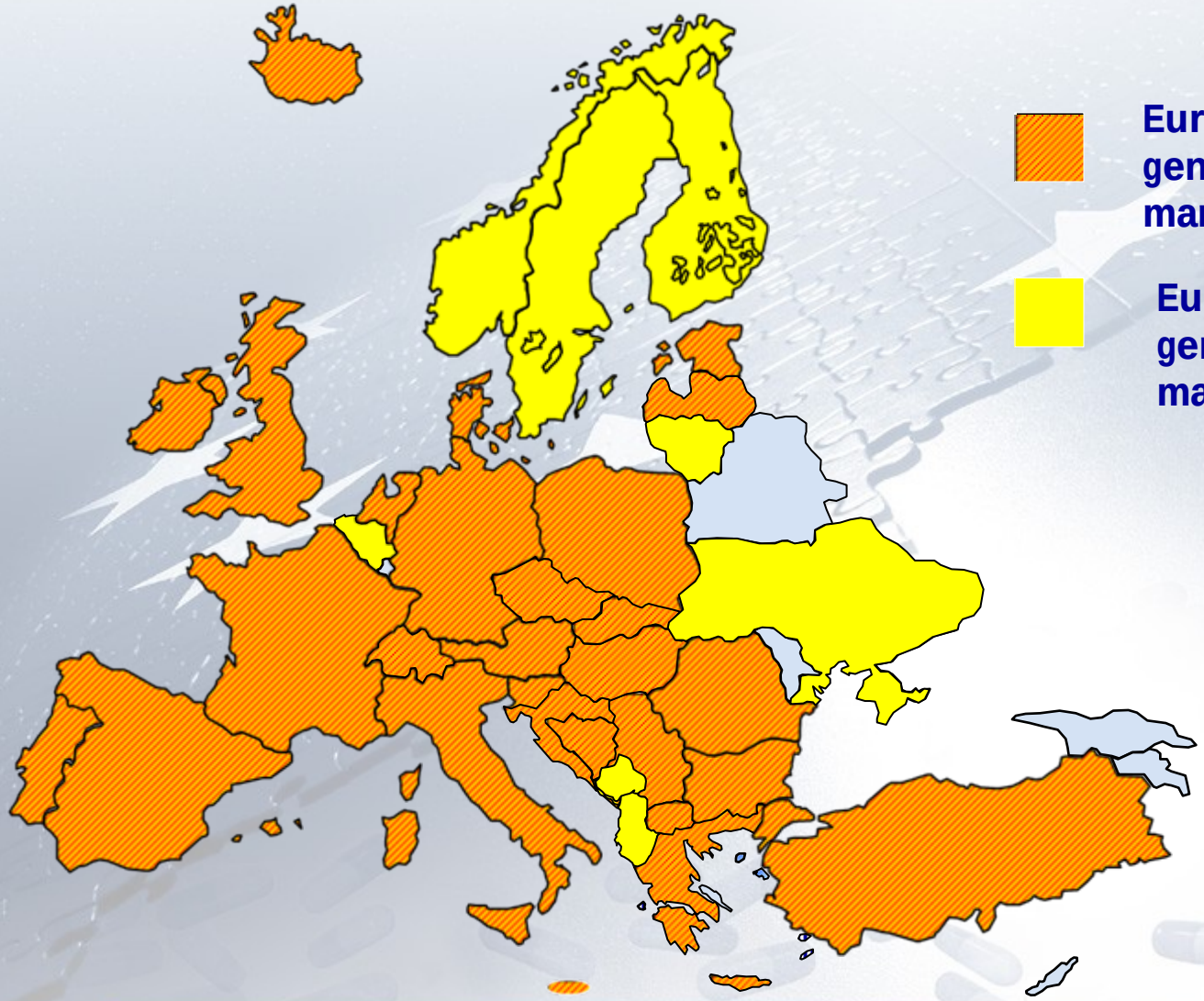
Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

EGA - introduction

- **Established in 1993. Based in Brussels**
- **Representing over 1000 companies**
  - Direct membership for both companies and national associations
- **Pan European (not only EU)**
  - Balkan generic medicines manufacturers: Hemofarm (Stada), Zdravlje (part of Actavis), Jadran, Alkaloid, PLIVA (TEVA), LEK (Sandoz)…

European Generic Medicines Development and Production



European countries with generic medicines R&D and manufacturing

European countries with generic medicines manufacturing

Source: EGA Internal survey 2010

Updated 201010

Key Role of Generic Medicines Manufacturers

- **Manufacturers from 12 new EU MS and Balkan countries as important contributors to the generic market**
  - Several major, quality, high-technology generic medicines companies
  - Major exporter to CIS
  - National Bolar provisions which have encouraged local production
- **EGA involved in CADREAC/ PERF dialogue**

EU Enlargement High on the EGA Agenda

- **EGA's own initiative to continue the regulatory dialogue with non-EU authorities**
  - six EGA Annual South East regulatory conferences
    - 6th SEE symposium in Serbia 29 Sept-1 Oct 2010
  - Discussion between the authorities and generic medicines industry from Albania, Bosnia and Herzegovina, Croatia, Kosovo (under UNSCR 1244), Macedonia, Montenegro, Serbia and Turkey to encourage co-operation and improve regulatory procedures in the region
  - The regular presence of authorities from new EU Member States (Slovenia, Hungary, Bulgaria and Romania)

Acquis Communautaires as a Fast-Running Train

- **Legislation has to be harmonised with the *EU Acquis* at the moment of accession**
  - Accession date not defined yet
- **What to do first?**
  - Assess the impact on local environment
  - Learn from others' experience!

Implementation of *Acquis* as a step by step process

Implementation of Acquis

- **Huge impact on the local national authorities, manufacturers and healthcare system**
- **Step by step approach to be agreed in the dialogue with the industry**
  - Upgrade to EU requirements very costly for both parties
  - Major capital investment in preparation for accession (e.g. 1 billion Euro in Poland).

Adapting to EU “additional ” requirements is adding to health costs

- **Average GDP per capita in Eastern European Countries is 5 times lower than EU average**
  - Generic medicines as a key component of sustainable healthcare
- **Introduction of patent extensions (SPCs)**
  - will have negative impact on healthcare delivery by delaying generic medicines e.g. in Poland it has cost health system an extra Euros 370 million p.a.
- **Data exclusivity**
  - If longer than 6 years, delivery of affordable generic medicines to patients is delayed; 8+2+ (1) at the moment of accession
- **Upgrade of dossier**
  - Withdrawal of products could create shortfall in medicines for patients.

Key areas for dialogue between industry and CA

- **To reach common understanding of the upgrade of MA dossiers and to prepare a long-term plan**
- **To follow latest legal developments and soft law (EU guidelines)**
  - Parallel, voluntary implementation in non-EU if the impact is anyway foreseen
    - For the internationally operating companies, the same medicinal products are authorised in the EU and non EU

Key areas for dialogue between industry and CA (1)

- **Revised Variations Regulation**
  - The same changes are relevant for both markets
  - Difference in the requirements causes an extra burden in preparation of documentation
  - Disharmony in the approval time causes a significant logistic problem for production
    - Necessity to wait for the last country or to stop production for less important markets (if still no approval)
- **Industry would welcome similar approach in the future in non-EU**
  - Same classification
  - Similar timelines and rules for implementation of variations in practice

Key areas for dialogue between industry and CA (2)

- **Pharmacovigilance**
  - Possible alignment of non-EU systems with EU developments
    - Pharmacovigilance System Master File
    - Case reporting
    - Literature search
    - New rules of PSURs for generic medicines

Key areas for dialogue between industry and CA (3)

- **Revised Bioequivalence guideline**
  - The same BEQ studies will be used to support both EU and non EU applications
- **Certain new requirements will make the studies quite different:**
  - Parent assessment. Metabolites not assayed
  - Truncated AUC
  - Scaling
  - Two stage design
  - BCS biowaiver

Key areas for dialogue between industry and CA (4)

- **The EGA advocated a Fast Track Procedure (FTP) for already authorised generic medicines**
  - MAH: quicker access to the market
  - NCA: quicker evaluation/ mutual recognition; availability of resources
  - Patients - affordability/ accessibility to generic medicines
  - Government - savings in healthcare budget

Possible scope

- **Main scope: medicinal products (MPs) authorised in the EU through CP, MRP or DCP;**
  - some authorities extended the scope: MPs authorised in the USA, Canada, Australia, Switzerland, Israel and Japan
- **Recognition of the assessment done by some SEE authorities:**
  - e.g. Montenegro' s cooperation with Croatia, Serbia

Fast Track National Procedure (FTP)

Conclusion from FTP Overview in 2009

YES	NO
Albania Croatia Kosovo Macedonia Montenegro	Bosnia and Herzegovina Serbia Turkey

2010 “picture”- Any change?

Conclusion

- **Implementation of *Acquis Communautaires* is a major challenge for both the authorities and the industry**
- **Step by step approach to be agreed in the dialogue with the industry to avoid "side effects"**
- **Experience from the 12 new MS to be used extensively to avoid mistakes**

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Thank you
See you in the Enlarged EU!