EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

Pharmaceutical Pricing Policies in Europe: Challenges and Solutions

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Dr. Alexander Natz

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European Confederation of Pharmaceutical Entrepreneurs AISBL

I. Overview and Objectives

EUCOPE: the mid-sized companies perspective (at national + EU level)

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EUCOPE represents

- **900+ mid-sized innovative companies** via the associations EMIG, BPI, BioDeutschland, SwedenBio, IML, PEF, BIO (USA) **at the EU Institutions and in Member States**
- Founded in 2010 in Brussels
- Companies represented: Achillion, Actelion, Alcon, Alexion, Ariad, B. Braun, Biogen, BioMarin, Biotest, Celgene, CSL Behring, Ferring, Grifols, Intercept, Medac, Miltenyi, MSD, Norgine, PTC, Raptor, Sarepta, SOBI, Vertex, ZealandPharma, Zogenix
- **Recognized stakeholder by EMA, HMA, European Commission and the European Parliament**
- **Innovative, mid-sized, often family owned or biotech companies**

EUCOPE Positions

- http://www.eucope.org/en/positions/

Primary focus is on market access

- **EUCOPE regularly informs members about changes regarding P&R in key Member States (EU 5) next to the legislation on the EU level**

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EUCOPE Members (extract)

Biogen
ACTELION
Biotest
From Nature for Life
Celgene
FERRING
PHARMACEUTICALS
BIOMARIN
medac
ALEXION
GRIFOLS
CSL Behring
Intercept pharmaceuticals
B BRAUN
SHARING EXPERTISE
NORGINE
VERTEX

EUCOPE Members: Orphan dedicated & mid-sized companies

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SMEs and Midcap companies

SOTIO
ADDMEDICA
SHIRE
BIOTEST
CTRS
APOTEX
ORPHAN EUROPE
IPSEN
ACTELION
IDM PHARMA
GRIFOLS
ADIENNE
NORGINE PHARMA
OTSUKA NOVEL PRODUCTS
CELGENE
BIOMARIN
SWEDISH ORPHAN BIOVITRUM
CSL BERHING
EISAI
BIOCODEX
VERTEX PHARMACEUTICALS
MILTENYI BIOTECH
CHIESI FARMACEUTICI
MEDAC GMBH
LFB
OCTAPHARMA
CRUCELL SWEDEN
EPICEPT GMBH
ARIAD
ALEXION
PIERRE FABRE
CEPHALON
BIOGEN
HRA PHARMA
INTERCEPT
ALLERGAN
DOMPÉ
SAREPTA
ACHILLION

Large companies

BAYER
PFIZER
AMGEN
BAXTER
ABBOTT
NOVARTIS
ASTRAZENECA
JANSSEN CILAG
MERCK SERONO
GENZYME-SANOFI
GLAXOSMITHKLINE
BRISTOL-MYERS SQUIBB

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EUCOPE P&R topics for 2016 (in red)

- **Incentives and reimbursement** for orphan drugs, advanced therapies and personalized medicines and fixed dose combinations
- **Foster innovation by coordination on HTA:** avoiding national re-assessments / different comparators / participation in EUnetHTA / parallel advice
- **HTA and rare diseases:** No “one size-fits-all” approach
- **No promotion of off-label use for cost containment purposes induced by law:** Respect the authorized indication
- **Restrict tendering** to non-innovative products and non-biologics
- **Joint Procurement / Joint Negotiations:** Only under specific circumstances, voluntary – not suitable for OMPs
- **EMA Transparency Policy:** Clear rules to protect CCI / trade secrets (CJEU intervention, EMA and NCA practice on FOI requests, TTIP)
- **New Clinical Trial Legislation:** implementation and database
- **Serialization and Coding:** pragmatic, cost-effective approach needed
- **EMA Early Access: PRIME + Adaptive Pathways**
- **EU Funding:** Horizon 2020 healthcare calls, IMI 2
- **IRP has to reflect patient access as main objective**

Key objective 2016 I: MS shall allow for Differential Pricing and keep rebates confidential

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EXPLANATORY MEMORANDUM

Pharmaceutical Prices: Why are there differences between Member States?

Summary

- Prices of pharmaceuticals differ across Member States due to factors which are beyond responsibilities of pharmaceutical companies (**different wholesale / pharmacy margins, different VAT rates, different pack sizes and distribution channels, exchange rate fluctuations, and most importantly, different price-settings by authorities, but also differences in national health and pharmaceutical policies and priorities**).
- **Price-setting is a competence of Member States** and reflects the different national healthcare policy priorities and purchasing power.
- Comparisons of pharmaceutical prices among Member States must be performed with great caution taking

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Key objective 2016 II: Economic off-label use: Common approach at EU Level in favour of predictability and patient safety

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EuropaBio
The European Association for Bioindustries

efpia
European Federation of Pharmaceutical Industries and Associations

January 2015

NON-COMPLIANCE OF ITALIAN RULES ON OFF-LABEL USE OF MEDICINES WITH THE UNION *ACQUIS*

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COMPLAINT IN THE CONTEXT OF ARTICLE 258 TFEU

Key objective 2016 III: Strict conditions for Joint Procurement allowing for reward for innovation

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Date: 29 June 2015

EUCOPE Position on Joint Price Negotiations for Medicines

A. Background & Initiatives:

During the last months, several Member States have bilaterally engaged in discussions on joint price negotiations for innovative medicines. Recently, **Belgium and the Netherlands announced their intention to jointly negotiate the price for orphan drugs and other medicines of high value or with a high budgetary impact/a high cost per patient with individual pharmaceutical companies in a pilot project** expected for early 2016. Besides price negotiation, cooperation on other aspects like horizon scanning, shared registers or moving towards harmonized value assessment methods, is also envisaged.

Key objective 2016 IV: Restrict tendering to non-innovative products and non-biologics

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Date: 18 February 2015

EUCOPE Position Paper on Biosimilars

Summary

Biologic medicines today account for 27% of the pharmaceutical sales in Europe and are growing at 5.5% vs. total market growth of 1.9% in value sales between 2012 and 2013. With many of Europe's top selling biologic molecules facing patent expiration before 2020 expectations are high from payers looking to generate savings as these products face direct competition for the first time from biosimilars.[1]

"*A biosimilar is a biological medicinal product that contains a version of the active substance of an already authorised original biological medicinal product (reference medicinal product.*"[2].
"*Biosimilars are not the same as generics, which have simpler chemical structures and are considered to be identical to their reference medicines […]. When approved, its variability and any differences between it and its reference medicine will have been shown not to affect safety and effectiveness.*"[3].

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Key objective 2016 V: HTA and rare diseases
No "one size-fits-all" approach

Country	Orphan Benefits
Germany	Assumed added value up to 50m EUR , but negotiation of price
France	ATU pre –approval, no benefits, conceptual support
England	No
Italy	No
Spain	No
Sweden	Potentially higher ICER
Finland	None officially
Austria	None officially
Scotland	Orphan Modifiers (potentially higher ICER, but…)
Ireland	None officially, but…
Portugal & Greece	None

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Key objective 2016 VI: Incentives and reimbursement for OMPs, ATMPs, personalized medicines & fixed dose combinations

THE PRESIDENT OF THE FIRST CHAMBER OF THE GENERAL COURT

hereby orders:

1. **The European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Confederation of Pharmaceutical Entrepreneurs (Eucope) are granted leave to intervene in Case T-547/12 in support of the form of order sought by the European Medicines Agency (EMA).**

2. **The Registrar shall send to EFPIA and Eucope a copy of the procedural documents served on the parties.**

3. **A period shall be prescribed within which EFPIA may submit a statement in intervention.**

4. **A period shall be prescribed within which Eucope may submit a statement in intervention.**

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Thank you for your attention!

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