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European Association of Euro-Pharmaceutical Companies

Medicines shortages in an overall stable PI market - a broader look at possible causes

Does pricing pressure on brand owners lead to more parallel trade ?

And why should there now be shortages in an overall stable PI market ?

Parallel trade/Distribution of medicines session

3rd annual Pharma Law Convention 2014

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EAEPC – who we are

- **Founded in 1998**
- **88 firms in 23 countries in the EEA - Direct members or national associations**
- **All products handled by EAEPC members have national or EU regulatory approval and are exlusively sourced from and sold to EEA markets**
- **Parallel distribution is regulated by both GDP and GMP rules: distributors who repackage are regulated like manufacturers and are holders of a manufacturing authorisation**
- **The number of parallel distributed medicines packages in Europe is estimated around 120-140 million packs p.a.**

PI retail market shares 2012

Area	% share	Trend	Comment
UK	**6**	→↑	Down from 17% after PPRS 2004/5, and 13% in 2007; currency impact strong
NL	**20**	↑	Identical reimbursement for brand and PI; sourcing from PI compensates pharmacy for margin loss owed to generics push
D	**9 – 11**	↘→	Specialty products driven; but Manufacturer discount and Discount Agreements of insurers limit expansion
DK	**16-19**	↗	Strong intra-PI competition, access to stocks limits expansion
SWE	**15-20**	↑↓	Policy driven – identical reimbursement; extra margin aimed at financing divesture of former monopoly retail pharmacies
IRL	**10**	↘↘	Low GBP facilitates sourcing, but austerity price cuts impact negatively. Reimbursement issues pending.
PL	**1**	↗	Has firmly established as reputed source of supply but mainly in OTC/non reimbursed market, as sensible reimbursement still missing; typical policy failure for newcomers to PI
FR	**< 1**	↑↑	Gradual introduction since ca 2007, achieved deal with reimbursement body at 5% below brand price, and offers extra margin to compensate pharmacy for lower sales price
IT	**< 1**	↑↑	Expanding in OTC, due to lack of sensible reimbursement system. First PI in reimbursed market now approved, but still no agreed method to ensure savings also reach payers.
BE	**< 1**	↑↑	Relatively new, but steadily expanding. Price differential goes to chain. Lack of method to ensure savings also reach the payer. Is extra discount to compensate pharmacy lawful?
CZ / BG	**0 – 1**	↗	Only a few lines currently available as PI. Potential exists, but likely to expand slowly. – In BG about to be launched, potential is there.

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No imports without exports

past

- **From South to North**
- **Limited range of products**

Status

Level of parallel trade in Europe stable over 5 yrs, ca. 4.5 Bln € import sales, less than 3% of pharma market.

present

- **Trade across the whole of Europe as price differentials become more diverse**
- **Fluctuations between markets, as currencies, prices and reimbursement may change**
- **Quota systems limit availability**
- **Parallel distributor will seek larger portfolio of products, and new source markets**

➔ Scrip: all products and all countries can be subject to import or export.

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Distribution today – some pointers

- **Most Member States have implemented some form of "public service obligation", following from Art. 81 of Dir 2001/83/EC**
- **Wholesalers can only make excess stock available for parallel distribution**
- **Supply quota management limits availability for wholesalers**
- **Wholesalers are structurally weak (in terms of comp law) – fear of DTP**
- **A price decrease does not impact national demand – no more prescriptions – same quota calculations - input volume remains stable**
- **Manufacturers actually exercise control over downstream volumes**

➢ **CONTRARY TO INTUITIVE BELIEF, AND GIVEN THE CONSTRAINTS OF PHARMACEUTICAL DISTRIBUTION: PRICE CUTS IN CERTAIN MARKETS DO NOT AUTOMATICALLY LEAD TO MORE "EXPORTS"**

EAEPC takes shortages very seriously – but do we know enough about the causes?

- Reports about shortage of crucial medicines in US or CH, where no parallel distribution exists
- Greece: No shortages in 2007/8 when export levels were >800 mio and double those of today, but now allegations of shortages appear
- Cost control – pricing pressures – margin squeeze in supply chain – reimbursement delays: many turn to export to keep up liquidity
- No more buffer stocks in the supply chain (cost of capital)
- Quality related medicine recalls lead to scarcity, locally or EU wide
- EMA reflection paper on shortages due to manufacturing issues (Nov 2011)
- Italy, UK: pharmacies point at quota systems limiting availability
- Too simplistic to put blame on trade !
- NEED FOR DATA AND INDEPENDENT RESEARCH

About birgli®

- Birgli is a management consulting platform of senior and well experienced independent executives from industry with a primary focus on the healthcare distribution market.
- Established January 2006, birgli is present in Europe and South East Asia and has a strong network in the United States and the Middle-East.
- Birgli provides consulting support in the areas of Healthcare Distribution, Mergers & Acquisitions, Finance, Management Support, Business Development, IT, and Healthcare Marketing & Sales.
- More information on birgli, our areas of expertise, and our team can be found at www.birgli.com

Summary : What did the report cover

- Focus
  - Shed light on causes of shortages and current actions to reduce them
- Coverage
  - France, Greece, Poland, Spain, and the UK
  - References and analogies from the US and other markets in Europe
- Data Collection
  - Challenging and limited
    - Concerns on sharing data
- Core principles
  - Patient rights
    - Enshrined in Article 81
  - Patient rights vs:
    - Commercial aspects
  - Patient rights vs:
    - Economic Capacity
      - Crisis & austerity impact access
    - Pro-activity
      - Regulations push MAH's to inform on mfg, shortages
    - Anticipation & Prevention
      - Shortages need to be anticpated and prevented
- Recurring themes
  - Lack of transparency
  - Limited sharing of data
  - Lack of communication between shareholders
  - Few true "cause-effect" studies
    - "everyone knows…"

Shortages in Europe : Economic Challenges & Austerity – public measures

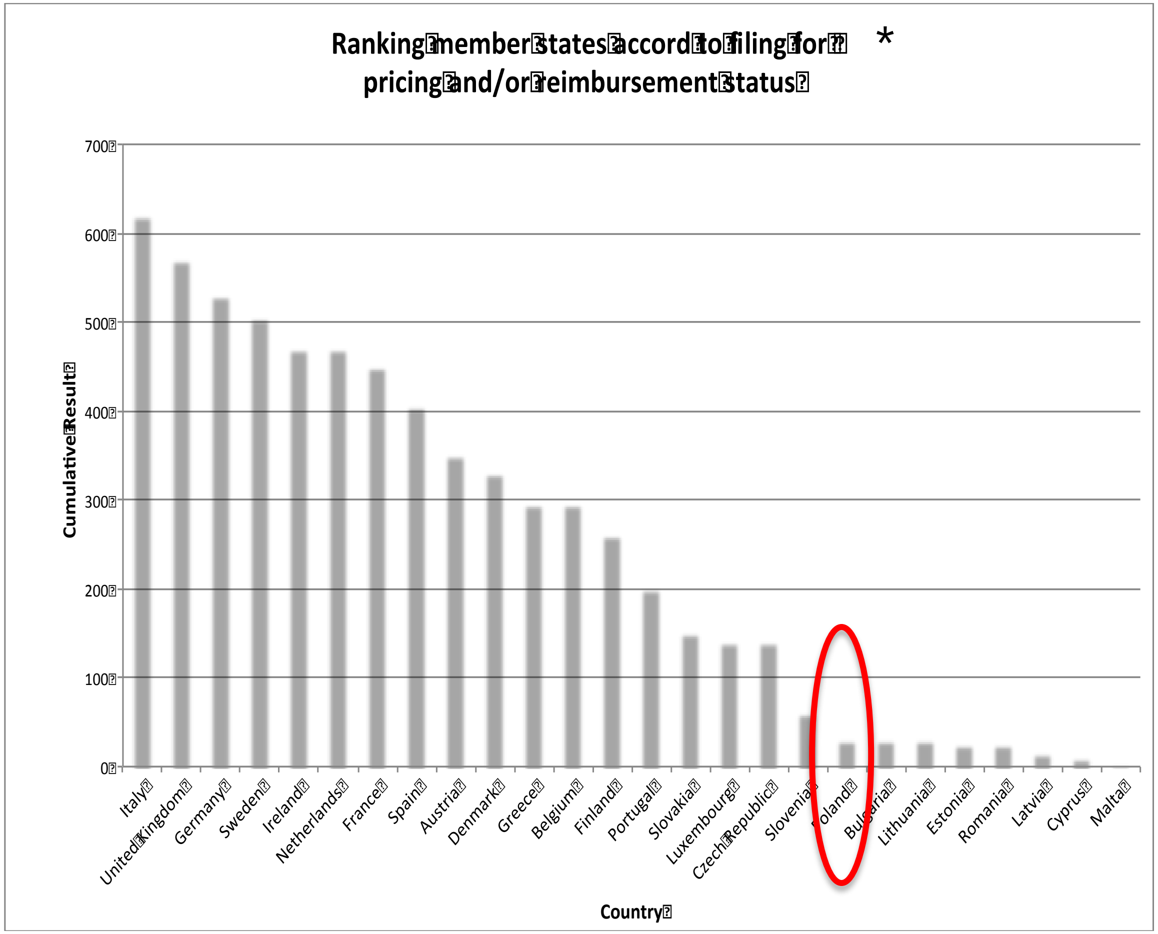
Pricing Policy Measures undertaken in EU countries in 2010 & 2011				
Price reductions	Discounts, rebates, clawbacks/paybacks and other arrangements	International Reference Pricing	Planned changes in distribution remuneration	Changes in VAT on medicines
Czech Republic Germany Greece Iceland Ireland Lithuania Malta Poland Portugal Spain Switzerland Turkey UK	Estonia Germany Italy Lithuania Poland Portugal Romania Spain	Germany Iceland Lithuania Malta Slovakia Spain Switzerland	Belgium Germany Greece Iceland Italy Latvia Lithuania Poland Portugal Spain Switzerland	Czech Republic ⇧ Finland ⇧ Greece ≈ Latvia ⇧ Poland ⇧ Portugal ⇧ UK ⇧

Country	Time	Price reduction
Greece	May 2010, July 2011	22% average price cut followed by across the board cuts of 10% respectively
Ireland	February 2010	40% price reduction on off patent medicines. More followed in 2012
Portugal	October 2010	6% deduction on maximum retail price and further cuts in July 2012, including a new basket of reference countries
Spain	May 2010	Price reductions ranging from 0-30% according to price level for all off patent medicines
Poland	2012	Price reductions at pharmacy level of an average of 5.7% (average prices are already 43% lower than other EU markets and 59% for innovative drugs)

- Delays in payment – Greece, Spain, and Portugal €15 billion overdue in 2/2012
- Tendering, especially generics
- Legislation supporting parallel distribution in particular Germany with the 5% ruling

Shortages in Europe : Measures taken by business impacting shortages (I)

- Tightening of payment terms
  - Commercial entities do not have unlimited financing capabilities, they need to generate cash=flow to run their businesses
  - Pharmacies & wholesalers impacted in particular in Greece, Portugal, and Spain as well as Poland
- Reduced product introductions and withdrawals (impact on lower priced markets)
  - 203 products withdrawn from Greece of which only 25 have a generic equivalent



*Also linked to market size & population

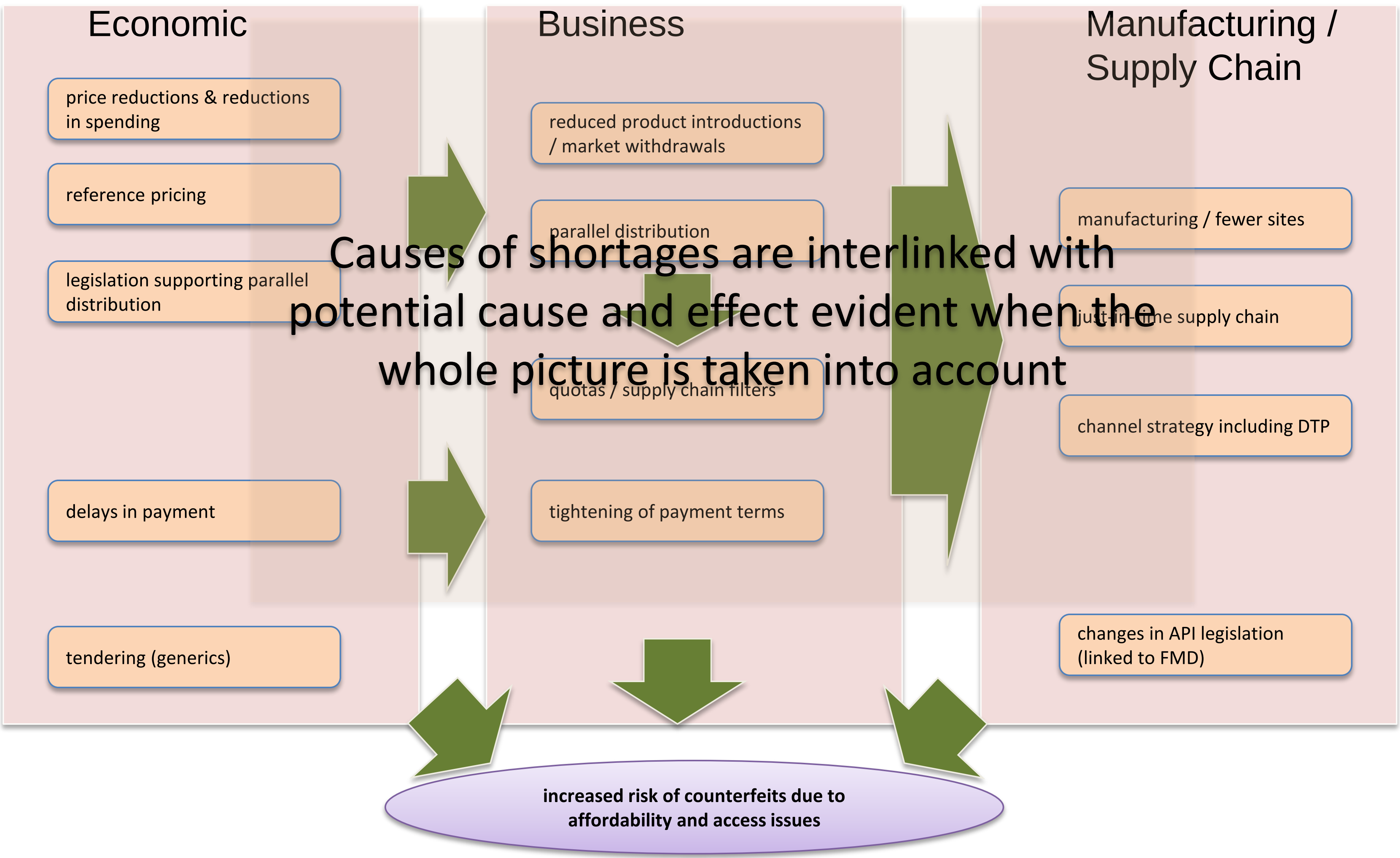
Shortages in Europe : Measures taken by business impacting shortages (II)

- Tender markets (especially generics)
  - Conditions too difficult to be commercially interesting.
- Parallel distribution
  - Public “support” (Germany and others)
    - Germany alone represents about €3 bln of parallel imports or 30-60% of the parallel distribution market. Pharmacies are obligated to purchase at least 5% of their needs via parallel distribution though the actual figure is estimated at 11.8% by EFPIA
    - An incentive to enter the market
  - Quotas
    - Implemented as a reaction to parallel distribution
    - A filter, product is usually still available in the market and delivered within 24-48 hours (is this a shortage?)

Shortages in Europe : Manufacturing & Supply Chain

- Manufacturing
  - Companies are reducing sites and focussing on products which provide an appropriate return.
  - In the US, of 168 products on shortage due to manufacturing issues, 56 had no supplier, 23 only 2 and 7 only one.
  - In the UK there were recently shortages for isosorbide mononitrate. The facility involved produces 1/3rd of the worlds supply
- Change in API regulation – July 2, 2013
  - To date not all major countries comply, though no major shortages appear to have occurred, it is still a risk
- Just-in time supply chain
  - Stock reductions by all stakeholders due to improved systems leads to risks of shortages as the case of the Icelandic volcano & Tsunami in Japan
  - Wholesalers hold as little as 1-2 weeks of stock
  - Pharmacies have limited shelf space
  - Few buffer stocks remain at national level
- Channel strategy including DTP
  - Impacts Public Service Obligations of wholesalers. Legislation needs to be adapted to ensure PSO to patient is maintained

An overview of the causes of shortages



Some recommendations by birgli

- **Centralised & Member State recommendations**
  - **Centralised reporting – use of the “Rapid Alert System”**
  - **Strengthen current legislation to rapidly move products to areas of shortages**
  - **Create a central unit of all stakeholders to review and develop solutions**
  - **Legal teeth**
  - **Include aspects of tracking in FMD serialisation effort**

- **Practical recommendations**
  - **Common set of “standard operating procedures” in the event of shortages**
    - **Incident management approach**
    - **CAPA (corrective and preventive action)**
  - **Exchange of information between commercial stake-holders about stock**
  - **Transfer(sale) of product to area of shortage including cross border if necessary (need strengthening of legislation) and…**

- **COMMUNICATION & TRANSPARENCY between stakeholders**

Conclusions & additional recommendations

- **Each stakeholder needs to be prepared to "give-up" certain elements of recourse when finding solutions**
- **There are many causes for shortages facing patients today with no single primary cause consistently emerging**
- **The impact of austerity and the current economic situation needs to be reviewed & considered**
- **Solutions need to be driven centrally and coordinated locally**
- **Dialogue between all stakeholders needs to take place without fear of legal or political reprisals – communication must improve**
- **Commercial stakeholders should consider finding solutions quickly before legislated solutions are imposed**

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Shortages – and the call for export restrictions

- UK: industry calls since 2010, when PI had decreased and PE increased
- SPAIN: RD/824; notification system, thanks to COM intervention reduced to 8-10 medicines
- SK: Notification system, all medicines, approval by agency not before 30 days, no criteria for shortage, agency requires batch number
- ESTONIA: notification system, all medicines, 30 days response time, no clear criteria, subject to approval by marketing authorisation holder – COM had intervened
- FRANCE: debate, critical comments by Competition Authority, information scheme under work
- CZ: Health committee held debate “how best to prevent (parallel) export of medicines”, but became aware of legal and factual obstacles
- ITALY: “exports causing shortages”: calls for dual-pricing, now strengthened PSO
- BG: industry proposes monitoring scheme for all medicines, alleges export are the one and only cause for shortages
- Call for more analytical and cooperative approach by stakeholders. EAEPC, PGEU, EFPIA, EGA and GIRP have just started this dialogue.

Some personal remarks on “access” issues

- Spending on newer medicines drives drug budgets up. Value for money?
- New does not always mean “truly innovative”, or fulfilling an unmet medical need
- Older but known meds sometimes withdrawn (also for cost of dossier maintenance); see also the shortages debate in some markets – question: who “owns” the drug, Mfct or society?
- Drug pricing: no correlation to disposable income (yet?)
- Existence of almost universal insurance coverage needs to be taken into account for “access” debate
- Differential pricing and some form of “controlled trade” for orphan meds ? Why not “controlled administration to the patients”?
- What is “orphan”? Gleevec started as one. Or see the Avastin/Lucentis debate.
- Re-nationalize the single market (for innovative drugs?) and stop all trade on public health grounds seems far beyond the exception clause of the Treaty.

Thank you.

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