



The New Medicines Legislation and Generic Medicines in the EU

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The Role of Generic Pharma Industry for Europe



- Increases access to pharmaceutical care for EU patients through more affordable medicines.
- Stimulates medical innovation through competition
- Provides budget headroom for financing genuine new innovations.
- Expands patient choice and value for money for OTC and co-payment prescription medicines.
- Develops for patients new formulations, methods of delivery and uses of well established medicines in both the prescription and OTC areas

The Role of the Generic Pharma Industry for Europe



- Increases Europe's share in the growing global generic pharmaceutical market and increases EU global competitiveness (Lisbon Agenda).
- Creates new sources of enterprise to generate employment and investment in Europe.
- Develop into future European innovative pharma and bio-tech companies.

The Generic Reality



- In the new EU 25 the generic pharmaceutical industry is becoming the principal supplier of medicines for EU citizens
 - 60-75% CEE (major exporter to non EU CEE)
 - 40-55% UK/D/DK/NL
 - 10-15% and expanding rapidly in PT/F
- The generic industry is the major user of MRP; will be the major user of the DCP and and will be new entrant into CP

On the Horizon Bio-Similar Products



Product	2001 Sales (\$bill)	global	Patent (EU)	expiry	Indication
EPO	6.4		2005		renal anaemia
insulin	4.0		2005		diabetes
G-CSF	2.1		2006		neutropenia
HGH	2.0		2002		growth deficiency
beta- interferon	1.9		2003		multiple sclerosis
alpha- interferon	1.7		2002		hepatitis C

Getting the Right Environment for Generic Competition?



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- Efficient regulatory system
 - Single Market
 - Intellectual property balance
 - National measures promoting generics



The New Legislation - a Better Environment for Generics?



- Creates a scientific definition of a generic medicine.
- Introduces a European Reference Product.
- Introduces an EU *Bolar* to encourage EU generic R&D.
- Creates a Global Marketing Authorisation which ensures no data exclusivity on line extensions, variations etc.
- Introduces prospective application of new 8+2+1 DE.

The New Legislation - a Better Environment for Generics?



- Creates the legal bases for SmPC harmonisation.
- Ensures that SmPC and usage patents are not in conflict
- Establishes an option to use either the Centralised Procedure and new Decentralised Procedure.
- Creates an EU legal framework for biosimilars (biogenerics).

However.....

The Devil is in the Detail



Potential Pitfalls 1



- Circumventing the global marketing Authorisation
- Extending Data Exclusivity beyond the intent of the law
- Limiting the Bolar provision and creating patent linkage
- Undermining the European Reference Product
- Not acting on SmPC harmonisation

Potential Pitfalls 2



- Making the bio-similar guidelines a barrier rather than a pathway for registration
- Failing to adapt the sunset clause to the market realities of generic medicines
- Not adjusting to realities of the usage patents
- Non-use of Centralised Procedure due to national usage patents, single name requirement and absence of reduced duplicate fee

Data Exclusivity and the GMA



- Global Market Authorisation (GMA)
 - Key to establishing Data Exclusivity.
 - GMA must not be circumvented.
 - GMA contains the initial authorisation and all variations, extensions, additional strengths, pharmaceutical forms, routes of administration or presentations authorised through separate procedures and/or under different name and/or based on different type of dossier.

Data Exclusivity and the +1

“Significant clinical benefit”

- Significant clinical benefit must be linked to a new indication, not to any change of product bringing a benefit.
- Justification must be supported by comparative clinical trials

Data Exclusivity and the +1

- Must not go beyond the intention of law consequently new therapeutic indication does not include treatment of new categories of patients or the improvement to the therapeutic use in existing categories of patients.
- SPC paediatric extension will cover paediatric population anyway and the Regulation almost certain to clearly prevent gaining both the +1 y DE and the 6 months SPC. (EP Amendment 52).

Bolar- Getting it Right



- Italian Patent Act Art. 68 Limitations to the Patent Right

1. *Whatever the subject of the invention is, the exclusive right granted by the patent does not extend to:*

a) acts performed privately and for non-commercial purposes, or for experimental purposes even if aimed at obtaining, in any country, an authorization to market a finished dosage form and at accomplishing the consequential practical requirements, including the preparation and the use of the active pharmaceutical ingredients which are strictly necessary thereto;

Bolar not Part of the Regulatory Approval Process



- Bolar covers a whole range of activities to enable in-patent development work and registration
- But must not be used as a backdoor to create patent-linkage in the EU. Under EU law
 - It is not the competence of national agencies or the EMEA to assess the patent status
 - A medicine's agency's role is the assessment of Quality Safety and Efficacy not of patents or any other considerations such as pricing.

European Reference Product



Approach to data exclusivity and share of information must be based on the intention of the law:

- Ensure the presence of a generic medicine in a national market where an originator has opted not to market its product on this market but only in parts of the EU – this is consistent with ensuring access to medicines for EU patients and promotion of the European single market.
- Facilitate the maintenance of generic medicines in New Member States as part of the upgrading requirements.

European Reference Product



- Application of data exclusivity must be based on DE of the generic applicant's Member State and not the reference product's Member State
- Information requested must be relevant for the evaluation of the generic medicine application and not additional data.
- Note: That EU Agencies have legal obligation to share information between one another.

Common Sense



Approach to the Sunset Clause

Must take into account the reality of the generic market i.e. take into account all the legal obstacles which prevent effective marketing of the generic product e.g

- Patents
- SPCs
- Data exclusivity
- Legal disputes
- Export only (Lisbon Agenda)

The Centralised Procedure and Single Name



- Requirement of a **single name** is inconsistent with national government requirements concerning generic naming and substitution.
 - INN+Company
 - INN only
 - Own Brand name
 - Special generic pre-fixes
- Solution must be found otherwise generic companies will not use the CP

The Centralised Procedure, SmPCs and Usage Patents



- “ The **SmPC** of a generic to a centrally authorized product has to be harmonized in the entire EU” (The minutes of the Pharmaceutical Committee November 2004)
- This is impossible if the CP originator product has different usage patents between Member States.
- If lowest common denominator is used this denies access to certain indications for EU patients
- Solution must be found , otherwise generic companies will not use CP.

Usage Patents and SmPCs In MRP and DCP



- The right approach!
- Applies the highest common denominator (best option for patients) at EU assessment.
- But allows the information covered by patent law to be omitted from the product information and patient leaflet for distribution at national level.
- Ensures consistency between originator and Generic medicines at least in countries with no use patents (thus no confusion for patients and health professionals) and respect for patent law (important for both originator and generic industry)

Bio-Similar Guidelines



- Must continue the pathway for bio-similar not create new barriers
- Not to be used by interest groups to obtain a commercial barrier to bio-similar which was not achieved in the legislation
- Should be based on the scientific approach so far used by European policy makers
- EGA had major concerns in the manner in which the planned public workshop has been operated. EMEA must ensure the independence of experts, academicians, patients association, clinicians and pharmacists commenting on these guidelines and on biosimilars

Partnership



- EGA will continue to work together with national agencies, Commission and EMEA to ensure the right environment for generic medicines in Europe.
- EGA appreciates the open and accessible dialogue with all parties during the implementation phase, especially with new CMD and EGA-EMEA working group.

Angels in the Outcome ?



Sweet NML

