Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

Introducing EGA

- EGA was formed in 1993 and is the official representative body of the European generic pharmaceutical industry.
- We represent over 600 companies and their subsidiaries throughout Europe, employing over 100,000 people in our industry.
- Generic medicines companies provide almost half of the prescription medicines dispensed in Europe, bringing savings of €18-20 billion annually in the EU 27.

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Development of Off-patent Medicines for Paediatric Use: Generic Industry Perspective

Information Day on PUMA and the EU 7th Framework Programme for Research

EMEA, 6 June 2007

Michael Banks, Teva Europe

Off-patent sector key!

- The majority of the medicines children need are off-patent

  In addition to this …
- With the initial deluge of applications, Paediatric Committee are unlikely to be able to assess all before they come off-patent – meaning it will possibly be the FP7 funding, not the patent-extension provisions which result in the development of childrens medicine

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Generic medicines industry key!

- The generic industry will proabably be the key partner in the development of those medicines most needed by children – the off-patent ones!

Moreover

ESF key for situations

- Where paediatric populations are small (insufficient market return likely)
- Where only requirement is SmPC change
- Where trials could show should not be used in children (negative outcome)
- Where multi-drug therapy or multi-therapy research needed …

Generic Industry concerns:

1. **How will the Regulation impact our MAs for adult indications?**
   - e.g. We will be obliged to take the child indication into our product information (SPC/PIL) – which is no small undertaking (Type 2 variation)
   - We will have to include the child symbol on our packaging
   - New avenues for confusion
   - May affect our adult product pricing and reimbursement applications

Generic Industry concerns (ii):

2. Will the Regulation really benefit children?

- since it came at the high cost to us of delaying our market entry by 6 months for many adult products – fairly broad/open interpretations

Opportunities for (combined with concerns of) the Generic Industry:

"PUMA"

Paediatric Use Marketing Authorisation

- Only effective if product is differentiated – so cannot be substituted by adult products already on the market (an already-established practice)
- No guarantees re substitution and reimbursement status – which is Member State competence

Opportunities for (combined with concerns) **the Generic Industry** (ii):

2. FP7 funding to help with research and development costs

- Development of new formulations is costly
- Child clinical trials are costly

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Exciting but scary!

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Not easy pickings, nonetheless

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Are generic companies interested?

- Some expressions of interest
- Many have not yet focussed on

- Generic medicines companies will make ideal partners for FP7 funding applications and we invite other parties interested in researching off-patent medicines to contact the EGA!

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Thank you!

EGA

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