EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Tourism, CSR, Consumer Goods and International Regulatory Agreements
Unit F5 Food and Healthcare Industries, Biotechnology

Access to Medicines in Europe

Meeting of the Project group on Biosimilars

Thursday, 3 March 2011 in Brussels

Minutes

1. PARTICIPANTS

[redacted] (AT), [redacted], [redacted], [redacted] (BE), [redacted] (CZ), [redacted], [redacted] (DK), [redacted], [redacted] (HU), [redacted] (IE), [redacted] (IT), [redacted], [redacted] (NL), [redacted] (NO), [redacted] (SE), [redacted] (AIM), [redacted], [redacted] (CPME), [redacted] (EPF), [redacted] (ESIP), [redacted] (HOPE), [redacted], [redacted] (EFPIA), [redacted], [redacted] (EGA), [redacted], [redacted] (EuropaBio), [redacted], [redacted], [redacted], [redacted] (EC)

2. EXCHANGE OF EXPERIENCES ON ACCESS AND UPTAKE OF BIOSIMILARS APPROVED SO FAR

Denmark, Italy and Hungary presented their experiences with the uptake of biosimilars so far (presentation attached). Austria briefly described its situation.

3. DISCUSSION ON PROJECT SCOPE

The group discussed the opportunity to enlarge the scope to the uptake of biologicals in general or all biologicals in the therapeutics areas where biosimilars have already been authorised.

It was agreed that the focus of the project should kept on biosimilars (as defined in EU law) but that all findings / conclusions / recommendations of the project that could be linked to them ore general issue of biologicals would be flagged as such to the Steering Group so that it could decide on the opportunity to adopt conclusions on biologicals.

Nevertheless, it was considered appropriate and useful to get a full picture of available biologicals in the therapeutic areas where biosimilars have already been authorised (see work plan "full therapeutic area" in work area B).

4. UPDATE OF TERMS OF REFERENCE

The chair agreed to take into account a number of additional comments even though the terms of reference had already been distributed to the Steering Group.

The following substantial changes were agreed (track changes attached):

– "Benefits and drawbacks" of the uptake of biosimilars was changed to the neutral term of "Effects and consequences" (point 3 and related references);

– Information to payers and purchasers was added as a mean of promotion; it was also made clear that any information initiative should be done without prejudice of EU and national legal frameworks (point 4 and related);

– Tendering and contracting were added as relevant procedures in addition to pricing and reimbursement for the uptake of biologicals in general and biosimilars in particular.

The terms of reference were adopted.

5. WORK PLAN

The work plan (attached) was amended in order to be consistent with the revised terms of reference.

The following tasks were allocated to the participants:

– Work Area A: Mapping exercise to know what information, e.g. reports and surveys, is already available in this area.

EFPIA and EGA to make a list of available fiches / Q&A material available in different national trade associations; Commission to contact Eminet for academic sources; Member States to inform on national sources if any.

– Work Area B:

  – Identification of biological medicinal products and their data protection expiry.

  Already available.

  – Identification of "the full therapeutic area".

  EGA / EFPIA / Europabio

  – Identification of authorised biosimilar medicinal products.

  Already available; Commission to produce template to be completed by Member States with reimbursement status.

– Clarification of legal status of the above-mentioned medicinal products (hospital-only medicines or primary sector medicines).

Member States on above template.

– Work Area C:

Examine if the Pharmaceutical Forum conclusions and recommendations on pricing and reimbursement also apply to biosimilar medicinal products.

Commission.

Results are expected to be presented during the next meeting.

6. NEXT STEPS

The next meeting will be held in Budapest on 4 May 2011.

The following is foreseen in Copenhagen on 24 October 2011.