



DATE: 21 September 2007  
EXCO/ES07/CET/1502

### **EXECUTIVE SUMMARY**

MEETING : EXCO Meeting in Seville, Spain

DATE OF MEETING: 4-7 November 2007

DRAWN UP BY : Francesco Paolo Vatti, CET Group 5

SUBJECT: The situation of generic biotech drugs in Europe – Executive summary

PURPOSE: For information

TABLED TO: All Attendees

After the elapse of patents, formerly patented drugs become available for any producer. Drugs identical to already authorised can have accelerated authorisation procedures in many Countries.

First patents about biotech drugs are now elapsing and new drugs are becoming available to any producer. So, the problem of the authorisation for marketing so-called “biogenerics” is arising.

The legal situation in Europe is quite difficult to understand. The authorisation of generics is usually connected to their similarity to original drugs. However, an essential similarity is very difficult to assess, due to the highly complicated structure of such drugs.

EMA provided no accelerated process for getting authorisation and a new trial is usually required.

Some biogenerics have already been submitted for authorisation in Europe: in particular Alpheon (recombinant human Interferon-alfa-2a, by BioPartners GmbH), Omnitrope (somatropin, By Sandoz GmbH) and Valtropin (somatropin, by BioPartners GmbH).

It is presently not clear which could be the interest of FICPI in this respect. A discussion on this point could be advisable.