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## FICPI INFORMATION DOCUMENT

### 29 AUGUST 2013

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#### CET INFORMATION DOCUMENT

<p>TITLE: <i>Report of FICPI meeting with the World Health Organisation (WHO) 29 August 2013, Geneva, Switzerland</i></p> <p>DRAWN UP BY: <i>Bastiaan Koster, FICPI President</i></p> <p>PURPOSE: For information and publication in the library section of FICPI's website</p>	
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A FICPI delegation consisting of Bastiaan Koster (President), Eric Le Forestier (President of CET) and Roberto Pistolesi (Sub-Chair of CET 5, Life Science) visited the WHO on 29 August 2013. It was the second visit to the WHO after a FICPI delegation visited the WHO in 2012 for the first time. At the 2012 meeting the WHO was represented by Mr Zafar Mirza, the coordinator of the WHO department of Public Health, Innovation and Intellectual Property. At the 2013 meeting, the FICPI delegation was met by Dr. Peter Beyer, as Mr Zafar Mirza was on leave. Dr Beyer is the senior advisor to the Department of Public Health on Innovation and Intellectual Property.

### PATENTS AND HEALTH

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Dr Beyer said that there is very close cooperation between WHO, WTO and WIPO. There was for example in August a workshop in South Africa arranged by the 3 organisations to look at IP and related issues including health.

Dr Beyer indicated that according to the WHO 46% of essential medicines are available in public hospitals in developing countries and 78% in private hospitals, and most of them are patent-free. Antiretroviral drugs are, as a general rule, not a problem but cancer drugs are not always available in developing countries. Dr Beyer also indicated that in many cases prices are believed to be too high even for developed countries. Developing countries will change their laws to deal with high prices, while developed countries may change the reimbursement by medical schemes on such high price drugs. During the 2012 meeting the issue of public funding in respect of health areas which are not market driven was discussed. Dr Beyer says that it is still a problem to get publicly funded research going for problematic diseases which are not market driven. The Research for Health strategy is intended to address this inter alia.

### DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

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This matter was only touched on and will be discussed during the WTO meeting.

### COMPULSORY LICENSES

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Dr Beyer indicated that many African countries have indicated that they do not have issues with patents preventing drugs from being available in their countries. Licence agreements are in place in respect of HIV related drugs and cancer drugs may follow. Some of the patented cancer drugs are selling at very high prices which is not feasible in developing countries.



HIV drugs in Africa are, as a general rule, at rock bottom prices in view of licence arrangements. In South American countries, this is not always the case as many of these countries are not part of existing licence arrangements.

FICPI will send Dr Beyer all our position papers and resolutions on compulsory licence issues.

## TRIPS' FLEXIBILITIES: PATENTABILITY OF SECOND MEDICAL USE AND POLYMORPHS

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Dr Beyer referred to Section 3(d) of the Indian Patent Law which raised the question "Where to draw the line". The recent changes or proposed changes in India, Brazil and Australia have been discussed in general terms. Dr Beyer said it would be good if FICPI could come up with proposals in respect of second medical use patents as well as the patenting of new forms of known substances (polymorphs) which, according to certain changes or proposed changes, would not be patentable unless the new form shows significant improvement over the known efficacy of the medicine. How to get certainty is an important issue. One of the issues is to draw the line in respect of a "significant improvement". FICPI will look at this in CET 5 but caution was expressed that it is not a simple task.

Dr Beyer also mentioned the difficulty in establishing in which countries a particular drug is patented and not patented. While it is relatively easy to establish this in the developed countries, it is often difficult to get accurate information in respect of developing and least developed countries. FICPI undertook to look at the matter through CET 3 to determine which patent family databases are the most reliable and also to list their limitations and identify which information is actually available in which country.

## TOBACCO PLAIN PACKAGING

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Dr Beyer indicated that annually more than 6 million deaths are reported as a result of tobacco. The WHO has a strong position on tobacco. Dr Beyer indicated that studies in Australia show that plain packaging will make smoking less attractive to non-smokers/young smokers who are not smoking to dis-encourage them from taking up smoking.

Another issue Dr Beyer mentioned is a concern of WHO is that tobacco companies are engaged in lawyers battles with some smaller countries in their fight against anti-smoking initiatives

## GENERAL

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Dr Beyer handed copies of the following documents to the delegation:

- Guidelines for examination of pharmaceutical patents: available online at <http://dspace.cigilibrary.org/jspui/bitstream/123456789/28890/1/Guidelines%20for%20the%20examination%20of%20pharmaceutical%20patents.pdf?1>
- Promoting access to medical technologies and innovation: intersection between public health, intellectual property and trade: available online at [http://www.wto.org/english/res\\_e/booksp\\_e/pamtiwhowipowtweb13\\_e.pdf](http://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtweb13_e.pdf)
- How to conduct patent searches for medicine – a step by step guide: available online at <http://apps.who.int/medicinedocs/documents/s17398e/s17398e.pdf>

*[End of document: prepared by Bastiaan Koster]*