

A century ago thanks to the progress in preventing and treating diseases and to the revolution brought by Pasteur medical doctors were rather optimistic about the future health situation. Today despite substantial progress regarding health for all there are still severe inequalities with respect to disease and death, as was underlined by Gro Bruntland, former Director-General of WHO: «*More than a billion persons reach the XXIst century without benefitting from the health revolution : their lifespan remains short and hampered by disease.*»¹

The world health context has changed considerably during the last century. The World Health Organization (WHO), created on the 7th April 1948, has planned at the world level the fight against the most lethal diseases on the planet, among which poliomyelitis, tuberculosis, smallpox and many others. Its main aim has been to bring immediately all people of the earth to the highest possible level by guaranteeing the access to treatment and to essential drugs. From its creation in 1995 the World Trade Organization (WTO) has been involved in the health sector working out an Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS)². This agreement was approved at Doha at the end of 2001³ and the tenets of the neoliberal economy and the rights of intellectual property now cover fields which had so far not been considered purely commercial among which are pharmaceutical products.

As soon as this document was approved it caused strong reactions and it appears to constitute the main problem in the health sector at the eve of the third millennium⁴. It has triggered numerous discussions among all the concerned groups. Though there is at present a vast bibliography on the Agreement its real impact on the access to essential drugs and vaccines⁵ remains uncertain. But as was recently stated by the WHO : «The desperate situation of most persons among the poorest in the world due to the difficult access to essential drugs⁶ and to vaccines is absolutely obvious. It is clear that the high price of any new medication or vaccine will bear heavily over its availability in the Developing Countries (DC)⁷. High prices can be explained by many reasons, one of them being patents ; but – considering the fact that patents define monopoly rights on the market – it is obvious that they are the cause of a major concern»⁸

With this document the Centrale Sanitaire Suisse Romande (CSSR) wishes to inform readers eager for a deeper understanding and to offer a tool to persons professionally involved in this Agreement. That is why a series of quantitative data derived from various works of experts will be used; this will enable a reflection along four distinct axes.

The first part of this work presents the main aspects of the problem and the stakes of the Agreement. A brief summary of the most significant events will be given and a description of the parties involved. This Agreement consists of a large number of legal dispositions which will be explained.

Secondly it will be attempted to foresee the consequences of this Agreement on the access to essential drugs in the DC and on the relations between the main institutions concerned (WTO and pharmaceutical firms on one hand, WHO and national health services on the other hand).

¹ Ramonet (2003).

² OMC (1994).

Trade related aspects of intellectual property rights (TRIPS).

³ Doha (2001), Correa (2002) and Niveaux (2002).

⁴ OMS (2001a), Velasquez (2003).

⁵ A fairly complete view of the relation between *globalisation* and *health policy* (a more general framework than that of the TRIPS Agreement) is found in Lee *et al.* (2002); see in particular Ranson *et al.* (2002), Buse *et al.* (2002).

⁶ For the definition of *essential drug*, see the Glossary; for the selection criteria of essential drugs see WHO (2002); for fair access to essential drugs, see WTO (2004a).

⁷ *Developing countries* (DC's), *less advanced countries* (LAC's) and *industrialised countries* are referred to in agreement with the list established by the United Nations Development Programme (UNDP). This list was worked out on the basis of the Human Development Indicator (HDI) and consists of three elements : the life span measured according to life expectancy at birth; the education level measured for two thirds by the literacy rate of adults and for one third by the gross rate of combined schooling; the living standard measured by the gross domestic product per inhabitant (expressed in parity of buying power (PPP)).

⁸ OMS (2004), p.1

Thirdly as far as possible case studies will corroborate the points of view put forward in this text so as to maintain a strong link with the field situation. The situation in several countries will be analysed in detail.

Eventually as our conclusion the third part of this document will propose several approaches in view of stimulating the discussion on the consequences of this Agreement and how they could best be addressed.

Readers will find in the introduction an official text of WHO : *Protection of intellectual property : impact on public health*. This text was first published in 2005 in English. This document constitutes the starting point of the reflection effort in this work.

In the Appendix one can find a report written by Anne-Lise Lelong in 2004 during a stay at WHO when she was a student for a Master of Law in information techniques and communication of Poitiers. This text, *TRIPS Agreement and its consequences on access to essential medicines*, deals with the impact of the Agreement on access to essential medicines and public health.

Let us also mention that readers eager to examine this problem in greater depth would be well advised to refer to the CIPIH final report (Commission on intellectual property rights, innovation and public health). This document entitled *Public health, innovation and intellectual property rights* was published in April 2006 and is 239 pages long (French version). It can be downloaded from the CIPIH site where it is available in the 6 official languages of WHO: www.who.int/intellectualproperty/documents//thereport/en/.

Finally just after this report was published the *Bulletin of the World Health Organization (The international journal of public health)* issued a number devoted to the presentation of the report and to critical discussions (among which the position of the official representative of the pharmaceutical industry). This publication (in English only) can also be freely downloaded from the WHO site: www.who.int/bulletin.

A particularly important aspect of the present debate about the TRIPS Agreement, that of the flexibility of Agreement 1 for the DC's (see 1.2.2, 1.2.3) is treated in detail in a recent joint publication South Centre-WHO: F. Musungu and C. Oh: *The use of flexibilities in TRIPS by developing countries; Can they promote access to medicines?*, Geneva, South Centre-OMS, 2006.

These three publications constitute a mandatory source of information for any organization trying to be active in the field of access to medicines in the DC's, encompassing the possible flexibilities of the TRIPS Agreement and the Doha Declaration, and the relations between research, innovation and introduction of generic medicines.