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as Mrn Childs

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15 JUN 2006

Re: Avian Influenza

I refer to your letter of 9 March 2006 and to antecedents (your letter of 19 October 2005, and reply of 5 December 2005). I am replying to your letter also on behalf of Vice-President Verheugen.

I am glad to provide the clarification you are asking for:

1. As I pointed out in my precedent letter, the WTO General Council Decision of 30 August 2003 (which will, following a Decision of the WTO General Council of 6 December 2005, be replaced by a permanent modification of the TRIPs Agreement) was adopted in order to supply the needs of countries without production facilities. The EU and its Member States have announced that they would not use this system as importers.

By contrast, every WTO member (including the EU Member States) can, on the basis of Article 31 of the TRIPs Agreement, grant a compulsory license to domestic producers in order to supply predominantly the domestic needs. This is what we expect to happen if ever a holder of a pharmaceutical patent should use her/his patent to prevent access of consumers to an essential drug.

You should, however, note that the granting of compulsory licenses on patents falls under the responsibility of the competent authorities of the Member States, not of the European Commission.

2. With regard to the exhaustion of patent rights, I would clarify that patent rights are exhausted EU-wide (and cannot be used to prevent parallel trade within the EU) if the patented product has been marketed in one EU Member State with the consent of the right-holder. This does not apply to products manufactured under a compulsory license, as these are not marketed with the consent of the right-holder.

Your interpretation of our letter is therefore not correct.

The Commission continuously monitors the Member States' activities on building up national stockpiles of antivirals against influenza. 20 Member States now avail of national stockpiles, some are even able to cover more than 20 % of their national populations. So far, in total 8 % of the whole EU population is covered by influenza antivirals, the target for the end of this year is to cover altogether 16 % of the total population. Compared to 2000 when stockpiling was practically non existent, this development constitutes a considerable progress.

Peter Mandelson