Pharmaceutical products: compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

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The committee adopted the report by Johan VAN HECKE (ALDE, BE) amending the proposal under the 1st reading of the codecision procedure:

- the scope of the regulation should not be limited to WTO members but should also include developing countries and least-developed countries;

- the committee deleted various administrative requirements laid down in the proposal which it said were unnecessary as they were not stipulated in the WTO decision and would simply deter potential applicants from using the system;

- countries should be able to file an application together, and the system should also enable NGOs, UN bodies or other international health organisations to act for one or more importing countries in the search for a producer and to import the pharmaceutical products;

- MEPs inserted new provisions allowing for the possibility of re-exportation to members of a regional trade agreement, which is permitted under paragraph 6 of the WTO Decision;

- whereas the proposal merely referred to "a reasonable period of time" for the prior negotiation with a patent-holder before an applicant may request a compulsory licence, MEPs said that this period should be 30 days. They added that this waiting period would not apply in the event of "situations of national emergency....or cases of public non-commercial use under Article 31(b) of the TRIPS Agreement";

- on the question of "adequate remuneration" which the licence holder must pay to the patent holder, the committee said that, when determining the amount, the competent authority must take into account the "humanitarian and non-commercial reasons underlying the issue of the licence". Moreover, the amount should be determined "in accordance with guidelines to be established by the Commission";

- to ensure that the supply of medicines is not blocked for a long time as a result of court injunctions, any appeals by patent holders against a decision to grant a compulsory licence should not suspend the execution of that licence;

- lastly, the committee called for the Commission to report to Parliament and the Council every three years on the application of the regulation, presenting proposals for amendments where necessary. Moreover, the Commission should also present any necessary proposals for revising the regulation when the TRIPS Agreement has been amended.