

Pharmaceuticals package

Parliament endorses 'compromise' on information to patients

By Sophie Petitjean | Wednesday 24 November 2010

Caught between initial proposals focusing strongly on the pharmaceuticals industry and the Council's strong misgivings, the European Parliament supported, on 24 November, the compromise approach adopted by rapporteur Christopher Fjellner (EPP, Sweden) on information to patients on prescription medicines. MEPs opted to oblige pharmaceutical firms to provide certain basic information on their prescription drugs while enabling patients to receive answers to more specific questions, on request. They also introduced several safety nets by providing that this information must be checked by the competent authorities, either at the time of market authorisation (summary of product characteristics, labelling and package leaflets and an accessible version of a drug assessment report), or through prior authorisation for other information.

Off the record, MEPs agreed that the rapporteur's position was "the lesser evil" since it "corrects" the flawed initial proposals. However, they are concerned about the reaction in the Council, which has so far been extremely reluctant "without ever having detailed the reasons for its refusal," regretted the Swedish rapporteur after the vote. "I hope that this legislation can enter into force in 2013, but that will depend on how long the negotiations take. We have the Commission's support at present but the Council of Ministers is relatively reluctant to address this issue," he added, referring to France, the Netherlands, Italy, Austria, Greece, Luxembourg, Portugal, Finland, Latvia and Poland, which are strongly opposed to legislation on this matter.

NEXT STEPS NOT CLEAR

Parliament's vote gives fresh impetus to the draft directive and regulation on public information on prescription drugs. However, what happens next is not clear: the Commission assures that it "will draw up a new proposal within six weeks" since the EP reports change the initial proposals significantly. Parliament's press service refuted such a procedure, however.

This lack of clarity is said to result from the address by Health Commissioner John Dalli at the start of the plenary session. He declared, on 22 November, that the position adopted by Parliament "enables the Commission to accept a number of key amendments when it presents its amended proposals". Things should become clearer at the beginning of January or perhaps earlier.

BEUC RELIEVED

The European Consumers' Organisation BEUC recognised Parliament's work and reacted with relief to the plenary's vote. The organisation welcomes the lengthening from 60 to 90 days of the time limit for the European Medicines Agency to approve the information submitted by pharmaceutical firms. "This is a good thing, since the information is considered to be accepted by the agency upon expiry of the deadline. However, given the huge amount of work this will mean for the agency, 60 days would have been too short," explained Ophélie Spanneut of BEUC. She nevertheless regrets certain derogations backed by MEPs: on the one hand, the directive excludes information on human health or

human illnesses, provided it contains no reference, even indirect, to a specific medicine. Another derogation concerns the information transmitted by health care professionals. “MEPs limited the derogation to information provided by pharmaceutical companies to health care professionals if intended for their own use. That’s an improvement over the initial amendment, which aimed to exclude information provided to the patient by the doctor in a personal capacity and during a consultation, but it is not perfect,” concluded Spanneut.

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