A European Parliament committee has passed amendments to improve the detection of potentially unsafe drugs and speed up action to take them off the market.

The European Parliament's environment and health (ENVI) committee has adopted two reports by UK Social Democrat MEP Linda McAvan calling for urgent changes in pharmacovigilance legislation, including empowering EU member states to order a medicine be urgently removed from market if its manufacturer or sponsor decides not to renew its licence due to safety reasons.
The Parliament's ENVI committee adopted Ms Mcavan's reports this month and also inserted amendments to the existing pharmacovigilance legislation. If the Council and Parliament reach agreement on these changes at the first reading, they can be incorporated into law before the planned implementation date for adoption of the new Pharmacovigilance directive and legislation (adopted by the EU in December 2010) of July 2012.
The committee's amendments include:

- if a company decides not to renew a marketing licence due to safety reasons, the member state concerned may order the medicine to be removed urgently from shelves;
- when companies voluntarily withdraw a drug, they must specifically declare if it is due to a safety concern; and
- the need for a longer list of medicines which should be subject to additional monitoring, including all drugs which are subject to certain post-authorisation studies.

More information **here** [1].
Video **here** [2].

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Links
[1] http://www.pharmatimes.com/Article/12-05-17/EU_Parliament_seeks_urgent_review_of_drug_monitoring.aspx [2] http://europarltv.europa.eu/en/player.aspx?pid=ad0ed458-5b4e-40a7-800b-a04b01199516