

**Question for written answer P-005136/2014
to the Commission
Rule 117
Linda McAvan (S&D)**

Subject: Promoting research into the experimental off-label use of medicines

A number of academic researchers and senior doctors have raised with me the problem of a lack of funding for drug repurposing (i.e. experimental research into whether medicines developed for a certain use can be used to treat other things). They are having to find their own funding for clinical trials into the experimental off-label use of medicines, as the pharmaceutical industry has less economic incentive to invest in this area.

Does the Commission agree that this is an area where big breakthroughs could potentially be made relatively easily, because of the fact that the medicines have already been through clinical trials for their other indications, and so we already have a good picture of their general safety and impact? Is the Commission or the European Medicines Agency doing any work in this area to promote research into new off-label uses? Does the Commission think there is scope for an incentive scheme to encourage companies to invest in this area, along the lines of the schemes we have developed for antibiotics, orphan and paediatric medicines?

I understand that the revised Clinical Trials Regulation will make it much easier and cheaper to carry out clinical trials for established off-label use (i.e. where it is standard clinical practice to prescribe a certain medicine off-label), as these fall into a new category for low-intervention trials. But this does not cover experimental off-label use.