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Press Office

Press release

European Medicines Agency finalises review of medicines concerned by Roche pharmacovigilance inspection

No new safety concerns identified; no new recommendations on use of these medicines

The European Medicines Agency (EMA) has finalised a thorough review of all medicines manufactured by Roche that was initiated following a routine pharmacovigilance inspection in early 2012. The 2012 inspection had identified some safety data relating to these medicines that had not previously been provided by Roche. The EMA review examined whether these further data impacted on the balance of benefits and risks of these medicines. Included in this review were nineteen centrally-authorised medicines as well as various medicines that have been nationally authorised.

The assessment by the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) of the impact of the additional data provided by Roche on the medicines concerned has not identified any important new safety concerns. The balance of benefits and risks of these medicines has not been affected and there is no new advice regarding their use. Patients should continue to take these medicines as previously advised. The Agency's Committee for Medicinal Products for Human Use (CHMP) has agreed with these conclusions by the PRAC.

However, as Roche continues to provide additional data as part of their obligatory follow-up, they are required to ensure that these data are included and considered in their routine pharmacovigilance activities, including the periodic cumulative reviews of the benefits and risks of these medicines.

The conclusions reached by the PRAC and the CHMP are without prejudice to the infringement procedure against Roche Registration Ltd, started in October 2012 based on allegations that the company has failed to comply with pharmacovigilance obligations in relation to 19 centrally-authorised medicines.

Notes

1. This press release, together with all related documents, is available on the Agency's website.

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2. Centrally-authorised medicines concerned: Avastin, Bondenza, Bondronat, Bonviva, Cellcept, Fuzeon, Heceptin, Invirase, Mabthera, Mircera, Neorecormon, Pegasys, Roactemra, Tamiflu, Tarceva, Viracept, Xeloda, Xenical and Zelboraf

3. Nationally-authorised medicines concerned contain the following active substances: allopurinol, benzerapide/levodopa, bromazepam, calcitriol, carvedilol, ceftriaxone, cilazapril/cilazapril hydrochlorothiazide, clodronate, clonazepam, diazepam, dornase alfa, flumazenil, flunitrazepam, ganciclovir, glibenclamide, granisetron, interferon alfa-2a, isotretinoin, ketorolac tromethamine, lactulose, mefloquine, midazolam, naproxen, phytomenadione, pyrimethamine/sulfadoxine, ribavirin, tretinoin, trimethoprim/sulfamethoxazole, and valganciclovir

4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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