

28 July 2011 EMA/612572/2011 Press Office

Press release

Identifying research priorities for the study of drugrelated progressive multifocal leukoencephalopathy (PML)

EMA workshop co-chaired with the FDA brings stakeholders to a common purpose of reducing the burden of PML

The European Medicines Agency (EMA), in close cooperation with the United States Food and Drug Administration (FDA) held a two-day workshop at the EMA offices in London on drug-related progressive multifocal leukoencepalopathy (PML) on 25-26 July 2011. The purpose of the meeting was to bring together experts and stakeholders of PML to identify research questions that will address knowledge gaps in order to reduce the burden of the disease.

PML is a rare, debilitating and sometimes fatal disease that is characterised by progressive damage to the white matter of the brain. It is caused by the JC virus. PML can occur in different conditions that affect immune response and it has been identified as an adverse drug reaction to some medicines that affect immunological functions.

Some of the medicines associated with PML bring major benefits to large numbers of patients. As a result effective ways to manage the risk of PML through identification of patients at risk as well as early diagnosis and treatment of PML are of major public-health importance. Medicines regulators in Europe and the US are therefore taking a leading role in shaping the research agenda to broaden the knowledge base for medicines regulation, thereby contributing to better public health protection.

Some 170 experts and stakeholders from regulatory authorities, research funding bodies, academic and clinical researchers, patients and healthcare representatives and industry discussed a common way forward for research in drug-related PML, including possibilities for funding and partnerships, and mechanisms for information sharing.

While the workshop was focused on PML, it was acknowledged that this type of collaborative research model could become a blueprint for research into other drug-induced diseases.

The immediate follow-up to the workshop will include finalising a research agenda on PML and its dissemination to funding bodies and the research community, as well as fostering further partnerships and research collaboration.



Notes

- 1. This press release, together with all related documents, is available on the Agency's website.
- 2. The presentations from the workshop will be made available shortly on the Agency's website.
- 3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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