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Press Office

Press release

European Medicines Agency holds first scientific workshop on nanomedicines

European and international experts prepare for the evaluation of future nanomedicines

On 2-3 September 2010, the European Medicines Agency (EMA) hosted the first international scientific workshop on nanomedicines. Some 200 European and international participants from 27 countries including Australia, Canada, India, Japan and the United States discussed benefits and challenges arising from the application of nanotechnologies to medicines. Participants included representatives from patients' organisations, health care professionals' organisations, academia, regulatory authorities and pharmaceutical industry.

The participants of the workshop shared experience, reviewed existing and emerging nanomedicines and discussed a number of specific aspects, including characterisation, biodistribution and interactions of nanomedicines with biological systems, to identify gaps in scientific knowledge and to prepare for the evaluation of future nanomedicines.

"Preparedness is essential for enabling timely introduction of safe and efficacious nanomedicines of a high quality, as nanotechnologies bring not only opportunities to improve current treatments but also the potential to change the way we approach healthcare and diseases", said Patrick Le Courtois, Head of Unit Human Medicines and Development at the EMA.

Nanotechnologies have a wide and still only partially exploited potential in the development of medicines. They provide scope for engineered nano-systems that could lead to a spectrum of useful functions such as refined drug delivery, advanced combined diagnostics/therapeutic functions, matrices and support structures for regenerative medicines.

Some eighteen marketing authorisation applications for nanomedicines have been reviewed by the EMA so far. These include liposomal formulations, nanoparticles and polymers/conjugates, mainly related to anti-infectives, anti-neoplastic and immuno-modulating agents. The applications were assessed under the existing regulatory framework using established principles of benefit/risk analysis with the scientific flexibility of accepting new development models and testing methods in the evaluation of such products.

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Emerging therapies give rise to questions on the appropriateness of current regulatory frameworks, the relevance and adequacy of existing requirements and guidelines, and on the availability of adequate expertise to regulators. The assessment of existing nanomedicines has provided valuable experience in examining certain aspects of emerging nanomedicines.

Scientific challenges arise from the limitations of current testing methods and the reliability of novel ones, because of the 'nanosize' and the unique behaviour of such nano-systems in biological structures.

Further scientific research will be needed to provide a sound scientific basis for an adequate evaluation of the quality, safety and efficacy of emerging nanomedicines, supported by a continued dialogue between scientists and regulators.

The participants of the workshop agreed that the application of nanotechnologies to emerging therapies requires the pooling of knowledge and expertise at a global level and across society. The EMA will extend existing platforms for further dialogue on emerging science, needs of patients, and expectations from all stakeholders, to keep abreast with the scientific progress and to provide a regulatory environment adequate for innovation based on science centred around patients' needs.

Notes

1. The following are examples of nanomedicines that have been centrally authorised: the anti-neoplastic agent Caelyx includes stealth liposomes of doxorubicine hydrochloride; the antineoplastic agent Mepact contains mifamurtide in multilamellar liposomes; the antineoplastic agent Abraxane contains paclitaxel nanoparticles bound to human serum albumin; the immunosuppressant Rapamune contains sirolimus particles in nanocrystal colloidal dispersion.
2. Presentations, podcasts of talks of the keynote speakers, together with a summary report on the workshop will be published on the Agency's website shortly.
3. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website.

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