

EMA Backs Record Number of Drugs in 2014



The European Medical Agency (EMA) has shown its support for a record number of orphan medicines in 2014.

Out of a total of 82 medicines for human use, 17 are indicated for the treatment of a rare disease.

EMA has given positive opinions on 40 new non-orphan drugs, three biosimilars, one drug for paediatric use and 21 generic, hybrid and informed consent applications.

Among the orphan drugs include ataluren, the first medicine for the treatment of Duchenne muscular dystrophy. It is available under the brand name of Translarna from PTC Therapeutics. Other drugs to get a nod from the EMA include afamelanotide (brand name Scenesse from Clinavel) indicated for the treatment of erythropoietic protoporphyria and Holoclar from Chiesi Farmaceutici S.p.A., the first medicine for the treatment of limbal stem cell deficiency.

In addition, EMA recommended eight cancer drugs in 2014 including four drugs that target rare and hard to treat cancers. These include olaparib (Lynparza from AstraZeneca), ibrutinib (Imbruvica from Janssen), obinutuzumab (Gazyvaro from Roche) and ramucirumab (Cyramza from Eli Lilly).

"Overall, the number of medicines containing new active substances continues to increase," the EMA notes. "One in two medicines, either orphan or non-orphan, recommended for approval in 2014, contains a substance that has never been used in medicines before. These medicines have the potential to treat diseases for which no treatments were previously available or bring added benefit to patients over existing therapies," the agency says.

The EMA has also granted seven positive opinions to speed up the assessment of medicines that could be of a major benefit for public health. These include four drugs for chronic hepatitis C daclatasvir (*Daklinza*, Bristol-Myers Squibb), ledipasvir/sofosbuvir (*Harvoni*, Gilead), dasabuvir (*Exviera*, AbbVie), and ombitasvir + paritaprevir + ritonavir (*Viekirax*, AbbVie). The other three drugs are nintedanib (*Ofev*, Boehringer Ingelheim) for idiopathic pulmonary fibrosis, siltuximab (*Sylvant*, Janssen) for Castleman's disease, and ketoconazole (Ketoconazole HRA, Laboratoire HRA Pharma) for Cushing's syndrome.

Source: Medscape

Image Credit: European Medicines Agency

Published on : Mon, 12 Jan 2015