



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 October 2011
EMA/CHMP/832561/2011
Press Office

Opinions on annual reassessments, 5-year renewals

Adopted at the CHMP meeting of 17-20 October 2011

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
N/A		

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
N/A		

Table 3. Opinions for 5-year renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Tandemact (pioglitazone / glimepiride), Takeda Global Research and Development Centre (Europe) Ltd.	Positive Opinion	Recommending additional renewal
Lucentis (ranibizumab), Novartis Europharm Ltd.	Positive Opinion	Recommending additional renewal
Invanz (ertapenem), Merck Sharp & Dohme Ltd.,	Positive Opinion	Unlimited validity
Irbesartan Hydrochlorothiazide Winthrop (irbesartan / hydrochlorothiazide), Sanofi-aventis	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Irbesartan Winthrop (irbesartan), Sanofi-aventis	Positive Opinion	Unlimited validity
Viread (tenofovir disoproxil fumarate), Gilead Sciences International Ltd.	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

Substance (Chemical/Biological)	Outcome	Comments
N/A		