

Medicines for human use

First half 2014

CHMP positive opinions in first half 2014*

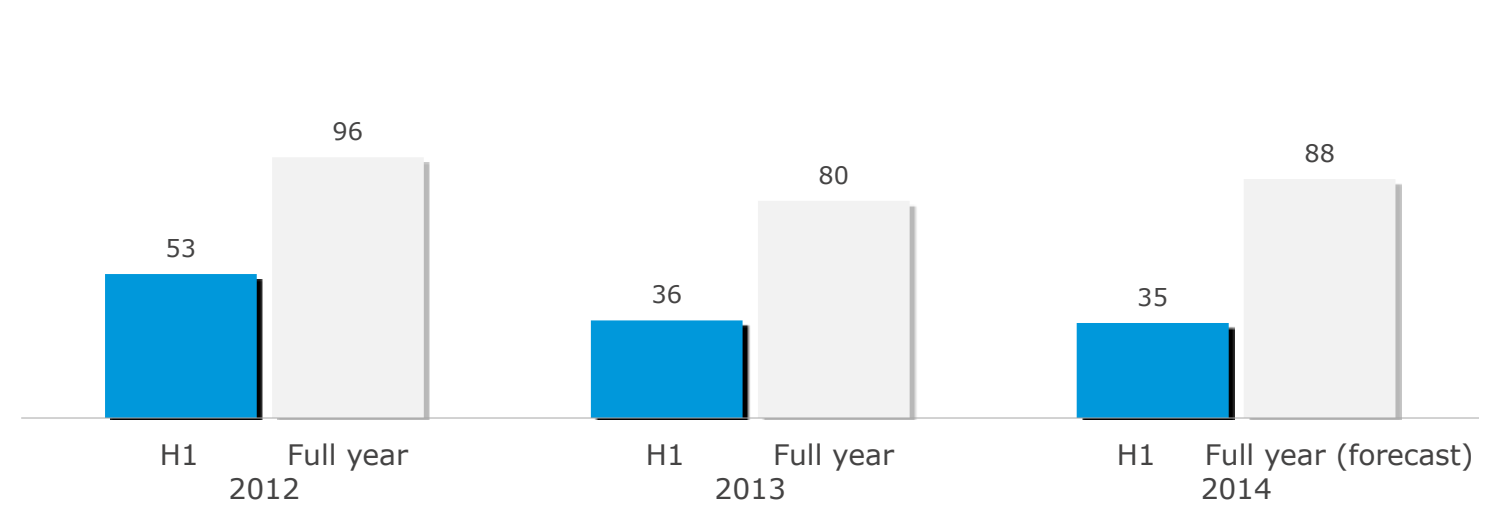
Total	New (non-orphan) medicines	Orphan medicines**
39	18	8
Biosimilars	Paediatric-use marketing authorisation	Generic, hybrid and informed-consent applications
2	1	10

Trends

CHMP opinions (2012-2014)

Year	New (non-orphan) medicine	Orphan medicine	Biosimilar	Paediatric -use marketing auth.	Generic, hybrid and informed-consent	Withdrawal prior to opinion	Negative opinion
H1 2012	15	4	0	0	14	4	2
H1 2013	21	5	2	0	16	7	4
H1 2014	18	8	2	1	10	4	3

Initial evaluations started (2012-2014)



* These figures include one positive opinion that was adopted following a re-examination procedure.
** Three marketing authorisation applications for medicines with an orphan designation were withdrawn by the sponsor after CHMP opinion.