20th Anniversary

2015

2014

New Clinical Trial Regulation
Regulation (EU) No 536/2014

First stem-cell medicine recommended for approval
Holoclar

2012

First gene-therapy medicine
Glybera

2011

Falsified Medicines Directive
Directive 2011/62/EU

First European Surveillance of Veterinary Antimicrobial Consumption report published

2010

First paediatric-use marketing authorisation
Buccolam

New pharmacovigilance legislation
Directive 2010/84/EU
Regulation (EU) No1235/2010

2009

Minor-use-minor-species / limited-market policy

First marketing authorisation for an advanced-therapy medicinal product
ChondroCelect

2007

First centrally authorised over-the-counter medicine approved in the EU
Alli

First centrally authorised generic medicine
Zalasta

2006

Paediatric Medicines Regulation
Regulation (EU) No 1901/2006

Approval of first two biosimilar medicines
Omnitrope and Valtropin

First conditional approval
Sutent

2004

Review of the EU pharmaceutical legislation
Regulation (EC) 726/2004
Directive 2004/27/EC
Directive 2004/28/EC

Herbal Medicines Directive
Directive 2004/24/EC

2001

Clinical Trial Directive
Directive 2001/20/EC

First two orphan medicines authorised
Fabrazyme and Replagal

2000

Orphan Medicines Regulation
Regulation (EC) 141/2000

Patient representatives are full members of the Committee for Orphan Medicinal Products

1996

Launch of international harmonisation programme for pharmaceuticals

First centrally authorised medicine for veterinary use
Porcilis Porcoli

1995

First centrally authorised medicine for human use
Gonal-f

EMA is established