EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HCPWP feedback from CHMP

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15 March 2017

Summary

- CHMP opinions
  - New medicines (overview 2016 – Jan/Feb 2017)
  - Scientific Advices/Protocol Assistance (October 2016 – February 2017)
  - PRIME eligibility (October 2016 – February 2017)
- HCP input provided in the context of CHMP activities

Human medicines highlights 2016

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Human medicines highlights 2016

Cancer

Alecensa
Bortezomib Hospira
Bortezomib SUN
Cabometyx
Darzalex
Empliciti
Ibrance
Kisplyx
Lartruvo
Ledaga
Lonsurf
Ninlaro
Onivyde
Pemetrexed Fresenius Kabi
SomaKit-TOC
Truxima (biosimilar)
Venclyxto

Infections

Atazanavir Mylan
Darunavir Mylan
Descovy
Emtricitabine / Tenofovir disoproxil Mylan
Emtricitabine / Tenofovir disoproxil Krka
Emtricitabine - Tenofovir disoproxil Zentiva
Epclusa
Odefsey
Tenofovir disoproxil Mylan
Tenofovir disoproxil Zentiva
Vemlidy
Zavicefta
Zepatier
Zinplava

- Orphan medicine
- Conditional marketing authorisation
- Accelerated assessment
- Approval under exceptional circumstances

The medicines that contain a new active substance are highlighted in blue

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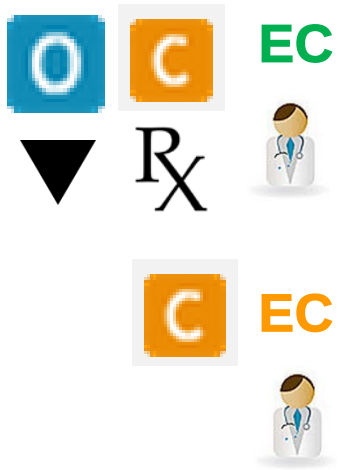
Positive opinion on new active substances – Oct – Dec 16

Cancer

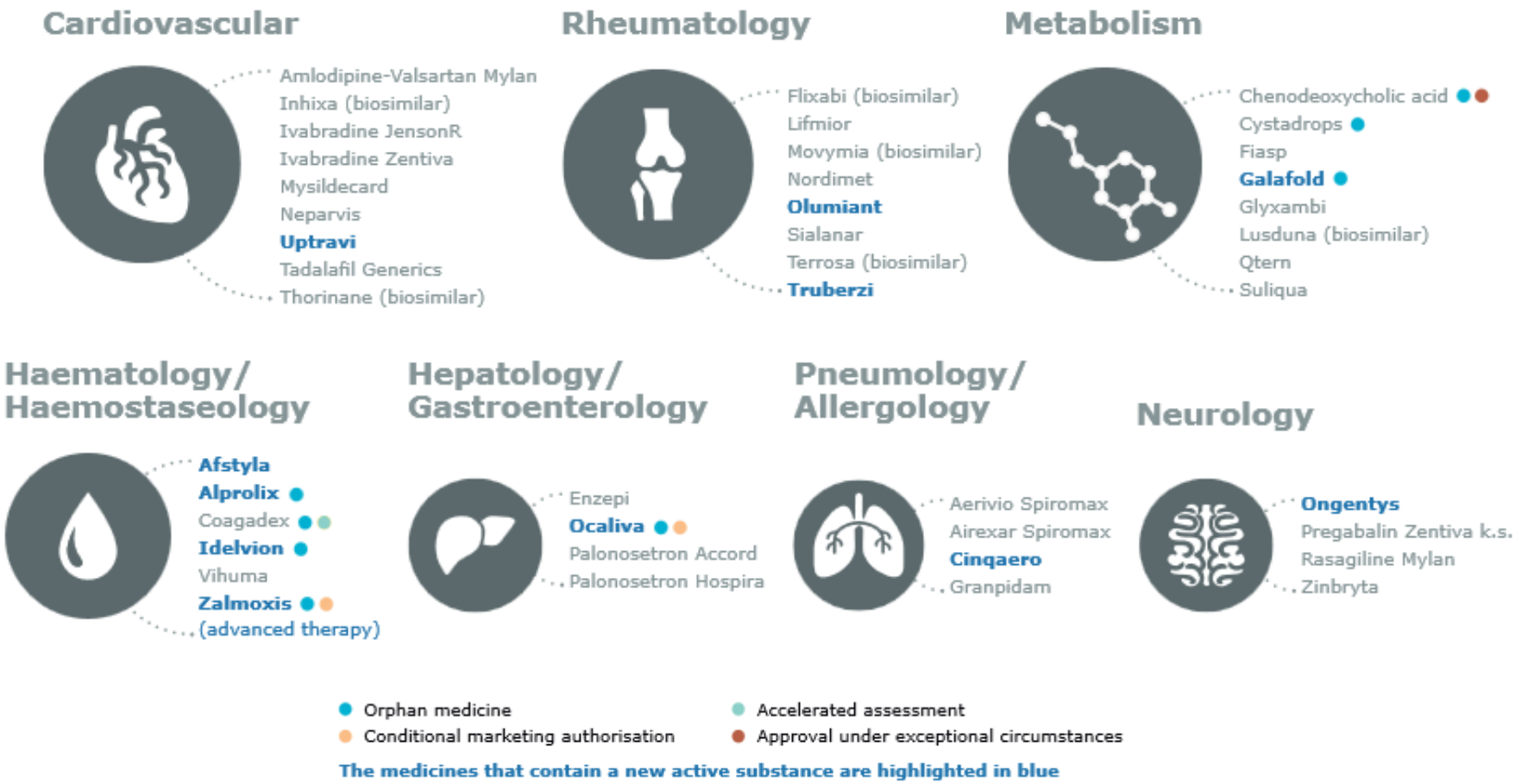
Name	Active S	Indication
Venclyxto	Venclyxto	Treatment of adult patients with chronic lymphocytic leukaemia
Alecensa	alectinib	Treatment of anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib



EC Authorised EC EC decision pending monitored (supervision) HCP

C conditional marketing authorisation O orphan Rx Restricted prescription additional monitoring

Human medicines highlights 2016



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Positive opinion on new active substances – Oct – Dec 16

Rheumatology

Name	Active S	Indication
Olumiant	baricitinib	Treatment of rheumatoid arthritis

EC

Innovation

EC Authorised

EC EC decision pending

monitored (supervision) HCP

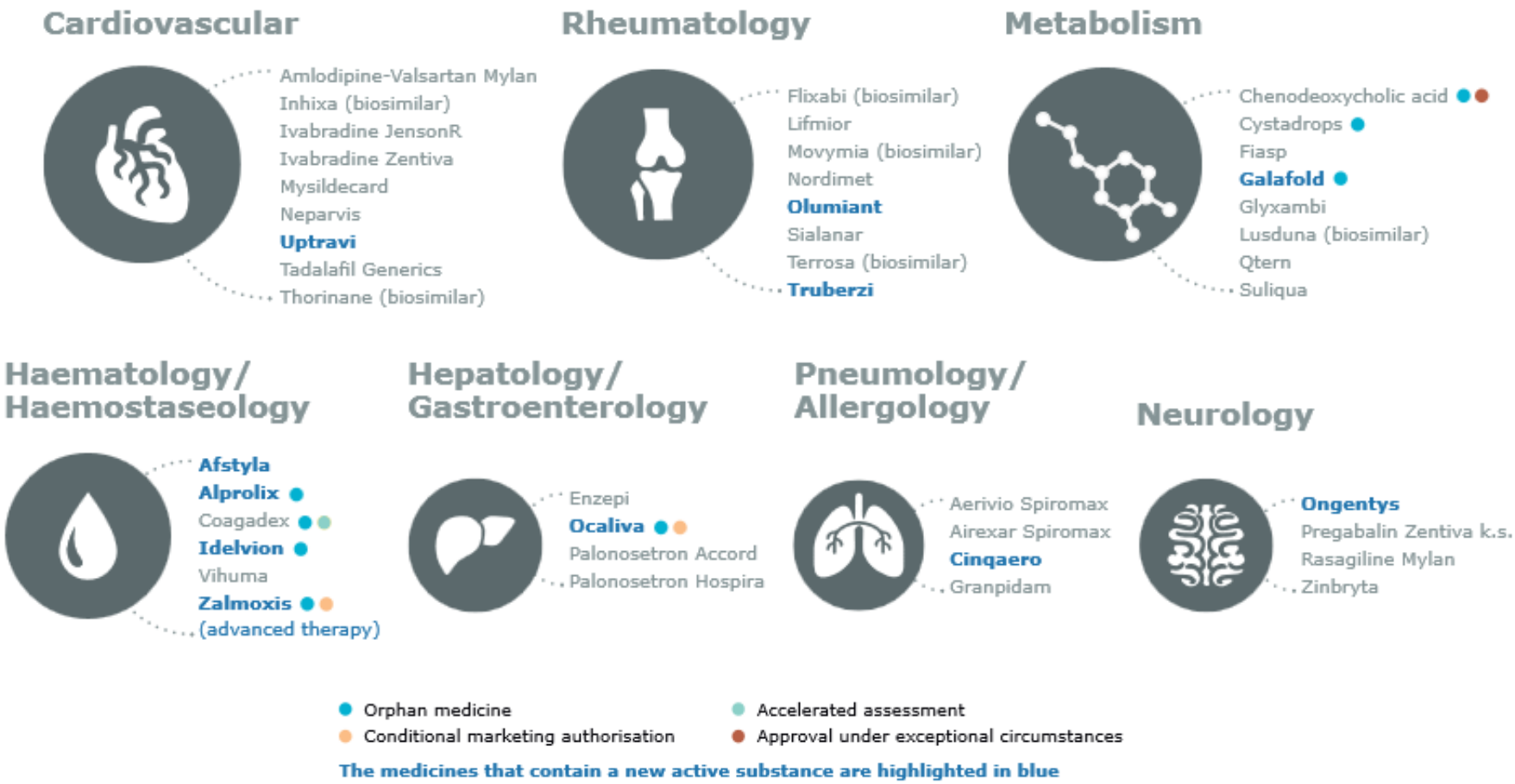
C conditional marketing authorisation

O orphan

℞ Restricted prescription

▼ additional monitoring

Human medicines highlights 2016



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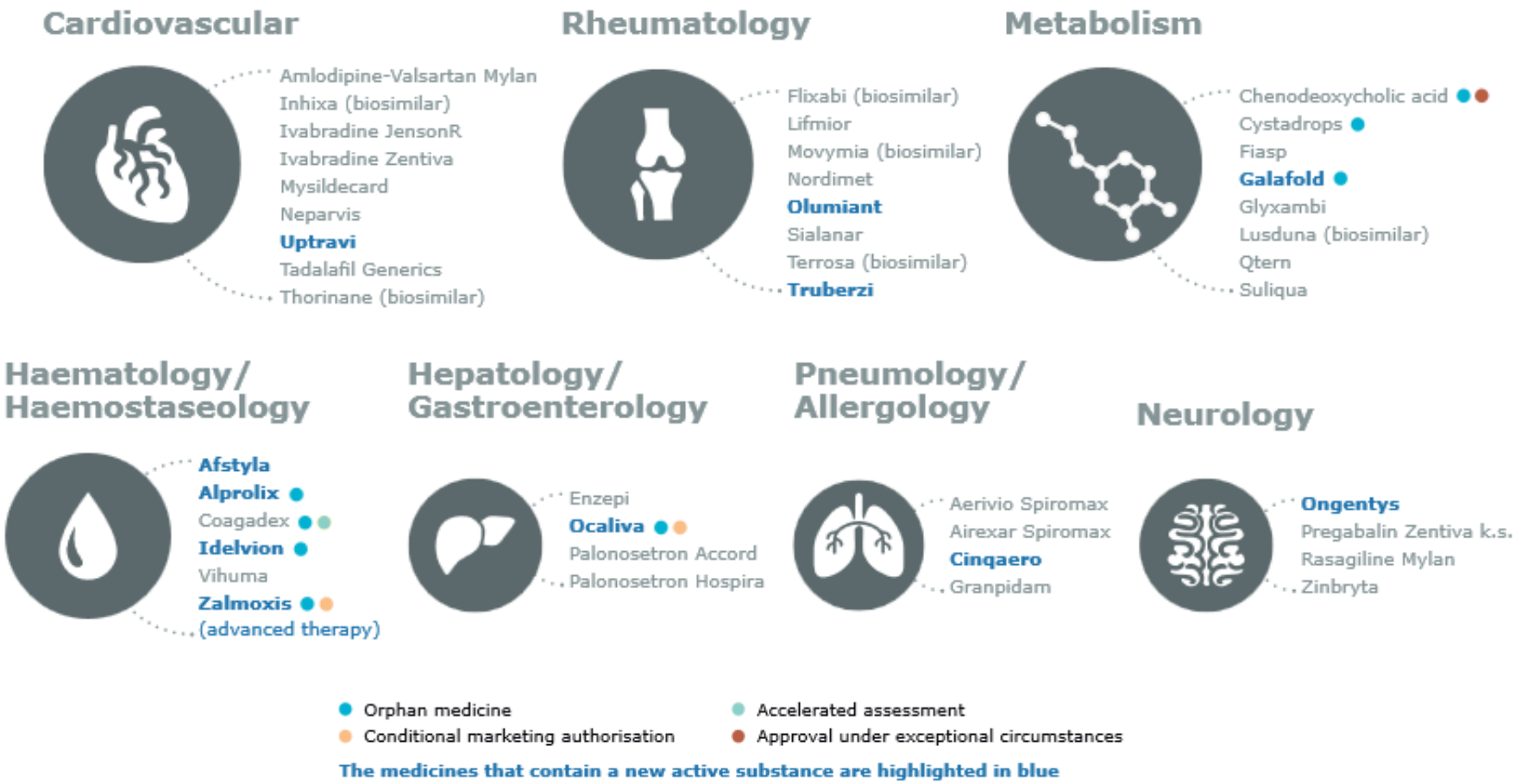
Positive opinion on new active substances – Oct – Dec 16

Haematology

Name	Active S	Indication	
Afstyla	acid lonoctocog alfa	Treatment and prophylaxis of bleeding in patients with haemophilia A	EC

Human medicines highlights 2016



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Positive opinion on new active substances – Oct – Dec 16

Hepatology / Gastroenterology

Name	Active S	Indication	O C ▼
Ocaliva	obeticholic acid	Treatment of primary biliary cholangitis (also known as primary biliary cirrhosis)	EC

EC Authorised EC EC decision pending monitored (supervision) HCP

C conditional marketing authorisation O orphan Rx Restricted prescription ▼ additional monitoring

Human medicines highlights 2016

Endocrinology

Parsabiv

Rekovelle

Immunology

Strimvelis ●

(advanced therapy)

Psychiatry

Zonisamide Mylan

Dermatology

Taltz

Radiolabelling agent

EndolucinBeta

Vaccine

Pandemic influenza vaccine (H5N1) MedImmune ●

● Orphan medicine

● Conditional marketing authorisation

● Accelerated assessment

● Approval under exceptional circumstances

The medicines that contain a new active substance are highlighted in blue

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Positive opinion on new medicines – January - February 17

- **4 positive recommendations on new medicines**

Rheumatology

Name	Active S	Indication
Xeljanz	tofacitinib	Treatment of rheumatoid arthritis

EC

Metabolism

Name	Active S	Indication
Lokelma	sodium zirconium cyclosilicate	Treatment of hyperkalaemia

EC

Generics, art. 58, biossimilars, hibrids, not included

Positive opinion on new medicines – January - February 17

- **4 positive recommendations on new medicines**

Endocrinology

Name	Active S	Indication
Natpar	parathyroid hormone	Treatment of hypoparathyroidism

EC

Hepatology / Gastroenterology / Cancer

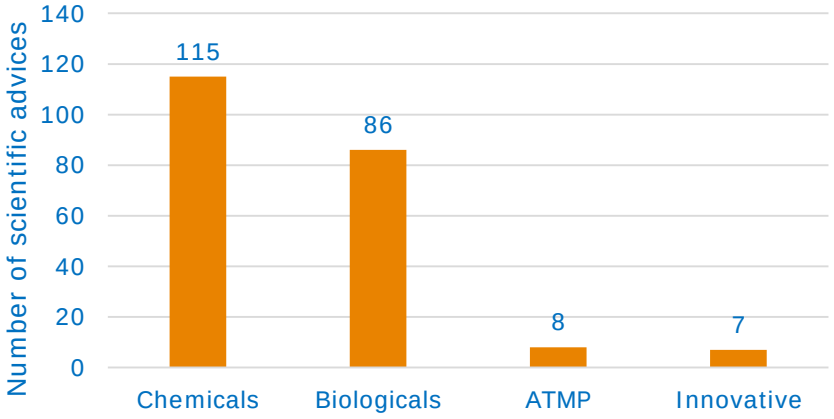
Name	Active S	Indication
Varuby	rolapitant	Prevention of nausea and vomiting in cancer patients

EC

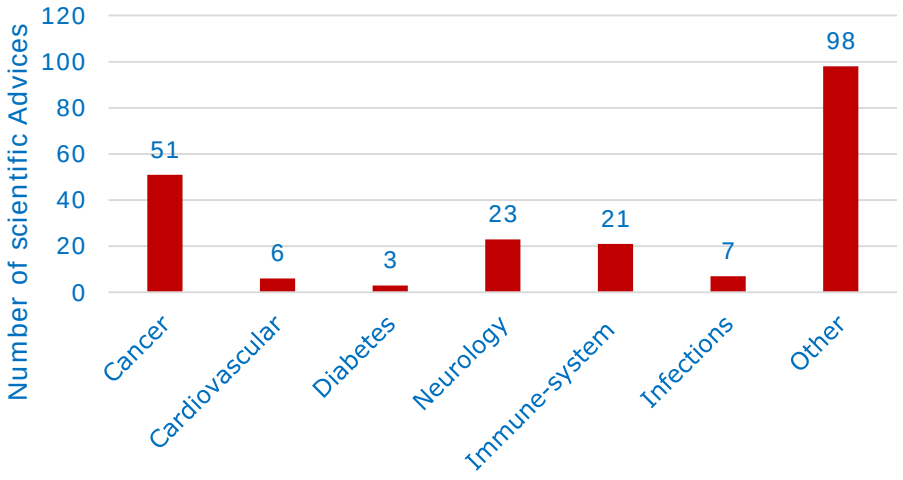
Generics, art. 58, biossimilars, hibrids, not included

Scientific Advice (October 16 – February 17)

Drug substance type



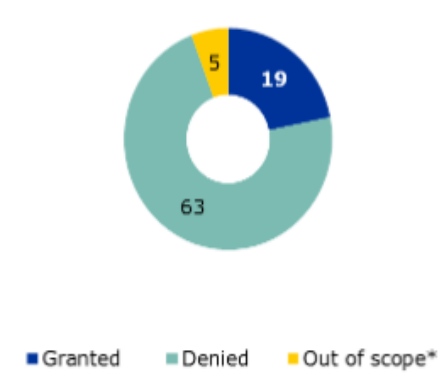
Therapeutic area

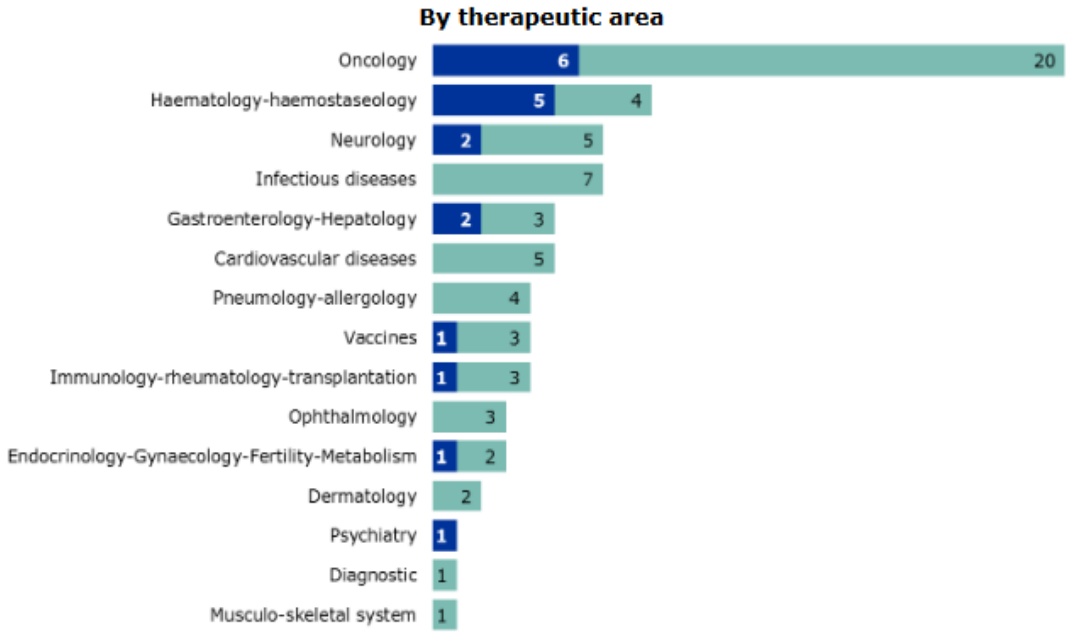


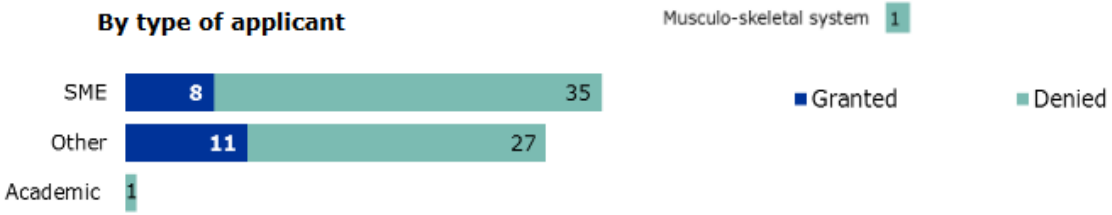
PRIME

- Enhance support for the development of medicines that target an unmet medical need.
- Interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation so these medicines can reach patients earlier.
- Built on the existing regulatory framework and tools already available such as scientific advice and accelerated assessment.
- Improving clinical trial designs - data generated suitable for evaluating a MAA
- Patients only participate in trials designed to provide the data necessary for an application - best use of limited resources.

PRIME eligibility up to 23 February 2017







* This indicates eligibility requests received but not started by EMA as they were deemed outside the scope of the scheme or with a format and content inadequate to support their review. These are not included in the breakdown by type of applicant or by therapeutic area.

PRIME eligibility – Oct 16 – Feb 2017

Name	Substance type	Therapeutic área	Therapeutic indication	Data of eligibility granted
A4250	Chemical	Gastroenterology-Hepatology	Treatment of Progressive Familial Intrahepatic Cholestasis	10-2016
Allogeneic Epstein-Barr virus-specific cytotoxic T lymphocytes (ATA129)	Advanced therapy	Haematology	Treatment of patients with Epstein-Barr Virus-associated Post Transplant Lymphoproliferative Disorder in the allogeneic hematopoietic cell transplant setting who have failed on rituximab.	10-2016
MBX-8025	Chemical	Gastroenterology-Hepatology	Treatment of Primary Biliary Cholangitis	10-2016
Allopregnanolone (SAGE-547)	Chemical	Psychiatry	Treatment of Postpartum depression	11-2016
Autologous CD4+ and CD8+ T cells Expressing a CD19-Specific Chimeric Antigen Receptor (JCAR017)	Advanced therapy	Oncology	Treatment of relapsed/refractory diffuse large B-cell lymphoma (DLBCL)	12-2016

PRIME eligibility – Oct 16 – Feb 2017

Name	Substance type	Therapeutic área	Therapeutic indication	Data of eligibility granted
Adeno-associated viral vector serotype 5 containing a B-domain deleted variant of human coagulation factor VIII gene (BMN 270)	Advanced therapy	Haematology	Treatment of haemophilia A	01-2017
Adeno-associated viral vector serotype 9 containing the human SMN gene (AVXS-101)	Advanced therapy	Neurology	Treatment of paediatric patients diagnosed with spinal muscular atrophy Type 1	01-2017
Adeno-associated viral vector containing factor IX gene variant (PF-06838435/SPK-9001)	Advanced therapy	Haematology	Treatment of haemophilia B	02-2017
Givosiran	Chemical	Endocrinology-Gynaecology-Fertility-Metabolism	Prevention of acute attacks of hepatic porphyria	02-2017

Interaction between CHMP and HCP

Participation in Scientific Advisory Groups and ad-hoc Experts Groups

- **Contributing for decision on recomendations (Xeljanz, Lokelma)**