



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HCPWP feedback from CHMP

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An agency of the European Union





Summary

- CHMP opinions (Apr 2018 – Sep 2018)
 - New medicines
 - Other issues related to authorised medicines
 - Scientific Advices/Protocol Assistance
 - PRIME eligibility (Apr 2018 – Jul 2018)

Alimentary tract & Metabolism (2)

Name	DS	Indication					
Mepsevii	vestronidase alfa	Mucopolysaccharidosis type VII	EC				
SO – Results from a Disease Monitory Program - long-term on effectiveness and safety and characterize MPS VII (clinical, progression, history)							
Myalepta	metreleptin	Leptin deficiency (lipodystrophy)	EC				
EP/EM – HCP and Patient/Carer EM							

Blood (3)

Name	DS	Indication	
Cablivi	caplacizumab	Acquired thrombotic thrombocytopenic	EC   ▼ R_X
<u>EP/EM</u> – Patient alert card			
Veyvondi	vonicog alfa	von Willebrand disease	EC  ▼ R_X
Jivi	damoctocog alfa pegol	haemophilia A (congenital factor VIII deficiency)	EC   R_X

Antiinfective drugs (5)

Name	DS	Indication	
Vabomere	meropenem / vaborbactam	Complicated urinary tract infection (cUTI), complicated intra-abdominal infection (cIAI), hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP)	EC  ▼ Rx
Xerava	eravacycline	complicated intra-abdominal infections in adults	EC

Antiinfective drugs

Name	DS	Indication	
Biktarvy	bictegravir / emtricitabine / tenofovir alafenamide	HIV-1 infection	EC  ▼ Rx
Delstrigo	doravirine / lamivudine / tenofovir disoproxil	HIV-1 infection	EC  ▼ Rx
Pifeltro	doravirine	HIV-1 infection	EC  ▼ Rx

Cancer (11)

Name	DS	Indication			
Apealea	paclitaxel	Ovarian cancer	EC		R _x
Alunbrig	brigatinib	anaplastic lymphoma kinase positive <u>advanced non-small cell lung cancer</u> previously treated with crizotinib	EC		R _x
Braftovi	encorafenib	In combination with binimetinib is indicated for the treatment of adult patients with <u>unresectable or metastatic melanoma</u> with a BRAF V600 mutation	EC		R _x
Imfinzi	durvalumab	Non-small cell lung cancer	EC		R _x
Kymriah	durvalutisagenlecl eucelmab	Acute lymphoblastic leukaemia (ALL) and Diffuse large B-cell lymphoma (DLBCL)	EC		 ▼ R _x
ATMP; <u>EP/EM</u> – HCP + Patients (Patient alert card); 1 st CAR-T cells approved EU 					



Cancer

Name	DS	Indication			
Mektovi	binimetinib	In combination with encorafenib is indicated for the treatment of adult patients with <u>unresectable or metastatic melanoma</u> with a BRAF V600 mutation	EC		R _X
Nerlynx	neratinib	breast cancer	EC	 ▼	R _X
<u>EP/EM</u> – HCP + Patients EM					
Verzenios	abemaciclib	locally advanced or metastatic breast cancer	EC		R _X
Vyxeos	daunorubicin / cytarabine	acute myeloid leukaemia	EC	 	

Cancer

Name	mogamulizumab	Indication	
Poteligeo	mogamulizumab	Mycosis fungoides or Sézary syndrome	EC   
Yescarta	axicabtagene ciloleucel	diffuse large cell lymphoma (DLBCL) and primary mediastinal B-cell lymphoma (PMBCL)	EC    
ATMP; <u>EP/EM</u> – HCP + Patients (Patient alert card); 1 st CAR-T cells approved 			

Immunomodulation

Name	DS	Indication		
Ilumetri	tildrakizumab	moderate to severe plaque psoriasis	EC	R _X

Respiratory system

Name	DS	Indication		
Symkevi	tezacaftor / ivacaftor	cystic fibrosis	EC   ▼ R _X	

Genetic Disorders

Name	DS	Indication		
Luxturna	voretigene neparvovec	retinal dystrophies caused by RPE65 mutations	EC   R _X	
ATMP; Gene Therapy				

Nervous system (6)

Name	DS	Indication		
Aimovig	erenumab	Prophylaxis of migraine	EC	 ▼
1 st monoclonal antibody therapy for prevention of migraine				
Emgality	galcanezumab	Prophylaxis of migraine	EC	
New medicine for the prevention of migraine				
Rxulti	brexpiprazole	Schizophrenia	EC	
Slenyto	melatonin	insomnia in children and adolescents with autism spectrum disorder or Smith-Magenis syndrome	EC	PUMA

Nervous system

Name	DS	Indication	
Onpattro	patisiran	hereditary transthyretin-mediated amyloidosis	EC   
Tegsedi	inotersen	Hereditary transthyretin amyloidosis	EC    

Metabolism

Name	DS	Indication	
Duzallo	lesinurad / allopurinol	Hyperuricaemia in gout patients	EC    



Changes in the Product Information

Name	DS	Indication	Change
Viekirax	Ombitasvir / paritaprevir / ritonavir	Hepatitis C	Contra-indication Patients with moderate to severe hepatic impairment (Child-Pugh B)
Xofigo	radium-223 dichloride	Cancer of the prostate	Restriction of indication To be used only after two previous treatments or when other treatments cannot be taken
Referral – Art. 20 – PRAC/CHMP/EC			



Referral Art. 31 - Valsartan

o Valsartan:

- EMA is currently reviewing medicines containing valsartan from Zhejiang Huahai Pharmaceuticals (Linhai, China) following detection of an impurity
 - o N-nitrosodimethylamine (NDMA) - probable human carcinogen (results from laboratory tests)
 - o Presence of NDMA was unexpected and possible related to changes in the active substance manufacturing.
- NCAs are recalling medicines containing valsartan supplied by Zhejiang Huahai.



Referral Art. 31 - Valsartan

o **Valsartan:**

- EMA is now evaluating potential impact on patients of the exposure to NDMA in valsartan medicines.
- Review will also consider whether other valsartan medicines may be affected.
- Information for patients (not stop treatment)/HCP

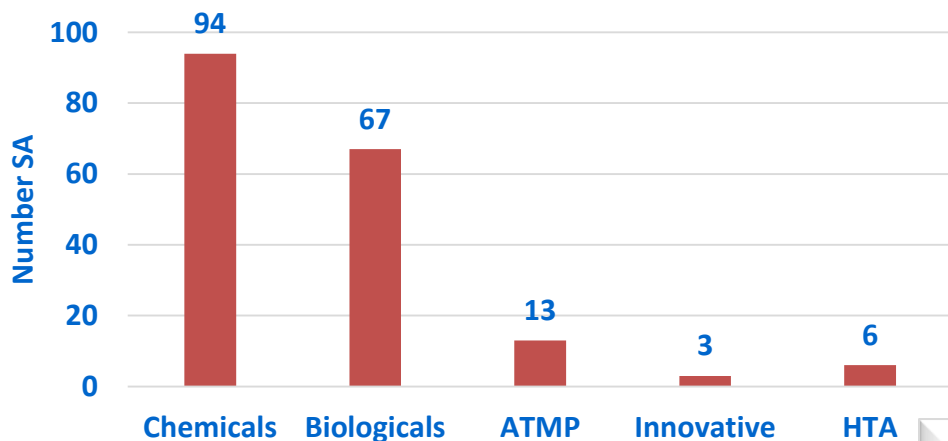
o **+ Losartan, candesartan, irbesartan, and olmesartan:**

- Low levels of N-nitrosodiethylamine (NDEA) present in one batch of Losartan from Hetero Labs, India
- Like valsartan – tetrazole ring – potential NDMA
- EMA is expanding review of valsartan for NDEA – no immediate risk (low levels NDEA)

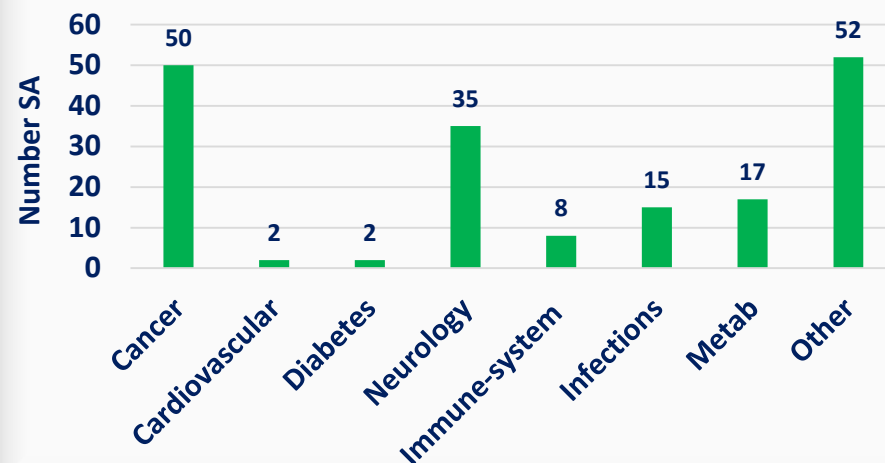


Scientific Advice / Protocol assis. (Apr 18 – Sep 18)

Drug substance type



Therapeutic area



PRIME eligibility – Abr – Sep 2018



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Name	Substance type	Therapeutic area	Therapeutic indication	Data of eligibility granted
Adeno-associated viral vector serotype 8 containing the human MTM1 gene (AT132)	Advanced Therapy	Other	Treatment of X-linked myotubular myopathy	05-2018
Allogeneic umbilical cord blood CD34+ cells cultured ex vivo with Notch ligand Delta1 (NLA101)	Advanced Therapy	Immunology-Rheumatology-Transplantation	Treatment in Haematopoietic Stem Cell Transplantation (HSCT)	05-2018
Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor (KTE-C19)	Advanced Therapy	Oncology	Treatment of adult patients with relapsed or refractory mantle cell lymphoma	05-2018
MV-CHIK vaccine	Biological	Vaccines	Prevention of Chikungunya fever	05-2018
Deoxycytidine / deoxythymidine	Chemical	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of Thymidine Kinase 2 Deficiency	06-2018

PRIME eligibility – Apr – Jul 2018



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Name	Substance type	Therapeutic área	Therapeutic indication	Data of eligibility granted
Mycobacterium tuberculosis (MTBVAC)	<i>Immunological</i>	<i>Vaccines</i>	Active immunization against tuberculosis disease in newborns, adolescents and adults	06-2018
Setmelanotide	Chemical	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of obesity and the control of hunger associated with deficiency disorders of the MC4R receptor pathway	06-2018
Chimeric 2'-O-(2-methoxyethyl) modified oligonucleotide targeted to huntingtin RNA (RO7234292)	Chemical	Neurology	Treatment of Huntington's Disease	07-2018
Autologous haematopoietic stem cells transduced with lentiviral vector Lenti-D encoding the human ATP-binding cassette, sub-family D (ALD), member 1 (ABCD1) from cDNA	Advanced therapy	Neurology	Treatment of cerebral adrenoleukodystrophy	07-2018