



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HCPWP/PCWP meeting: feedback from CHMP

Presented by Concha Prieto (CHMP)

20 September 2017

An agency of the European Union





Summary

- CHMP opinions (June-September)
 - New medicines.
 - Scientific Advices/Protocol Assistance.
 - PRIME eligibility.
- HCP and patients input provided in the context of CHMP activities (June-September).



Positive opinions on new medicines June – Sept 2017

Cancer: 9

Name	Active S	Indication
Fotivda	tivozanib	Renal cell carcinoma
Kisqali	ribociclib	Breast cancer
Xermelo	telotristat ethyl	Carcinoid syndrome

 **EC**



 **EC**



 **EC**

EC Authorised

EC EC decision pending



monitored (supervision) HCP



Orphan



Restricted prescription



Positive opinions on new medicines June – Sept 2017

Cancer: 9

Name	Active S	Indication
Bavencio	avelumab	Metastatic Merkel cell carcinoma
Lutathera	lutetium (¹⁷⁷ Lu) oxodotreotide	Gastroenteropancreatic neuroendocrine tumours
Rydapt	midostaurin	Acute myeloid leukaemia, systemic mastocytosis.
Tecentriq	atezolizumab	Urothelial carcinoma and of non-small cell lung cancer
Zejula	niraparib	Ovarian cancer
Tookad	padeliporfin	Adenocarcinoma of prostate



Rx



EC



Rx

EC



Rx



EC

Rx



EC



Rx



EC

Rx



EC



Positive opinions on new medicines June – Sept 2017

Infectious diseases; 3

Name	Active S	Indication
Maviret	glecaprevir / pibrentasvir	Chronic hepatitis C virus infection
Vosevi	sofosbuvir / velpatasvir / voxilaprevir	Chronic hepatitis C virus infection
Symtuza	darunavir / cobicistat / emtricitabine / tenofovir alafenamide	HIV infection





Positive opinions on new medicines June – Sept 2017

Central Nervous System: 3

Name	Active S	Indication
Mavenclad	cladribine	Multiple sclerosis
Nyxoid	naloxone	Opioid overdose
Zubsolv	buprenorphine/ naloxone	Opioid dependence

Rx



EC

EC

Rx



EC



Positive opinions on new medicines June – Sept 2017

Ophthalmology

Name	Active S	Indication
Verkazia	Cyclosporin	Severe vernal keratoconjunctivitis in children and teenagers



EC

Blood products

Name	Active S	Indication
VeraSeal	human fibrinogen / human thrombin	Sealant during surgery



EC



Positive opinions on new medicines June – Sept 2017

Respiratory system

Name	Active S	Indication
Elebrato Ellipta Trelegly Ellipta	fluticasone/umeclidinium/ vilanterol	COPD

EC

Dermatology

Name	Active S	Indication
Dupixent	dupilumab	Severe atopic dermatitis

Rx



EC



Negative opinions on new medicines June – Sept 2017

Cancer

Name	Active S	Indication
Onzeald	etirinotecan pegol	Advanced breast cancer whit brain metastasis
Adlumiz	anamorelin hydrochloride	Anorexia, cachexia in patients with non-small cell lung cancer.
Human IGG1 monoclonal antobody for human IL-1 alpha		Debilitating symptoms of advanced colorectal cancer
Masipro	masitinib	Systemic mastocitosis



Negative opinions on new medicines June – Sept 2017

Central Nervous System

Name	Active S	Indication
Fanaptum	iloperidone	Treatment of schizophrenia



Scientific Advices (June - September 2017)

Final advices adopted

	June	July	Sept
Scientific Advices	30	19	39
Follow up SA	14	9	3
Protocol Assistance	8	8	6
Follow up PA	4	7	8
Qualification Advices	1	3	1
HTA	2	5	2
Total	59	51	59



PRIME eligibility – June – Sept 2017

Name	Substance type	Therapeutic area	Therapeutic indication	Date
2-hydroxy-6-((2-(1-isopropyl-1H-pyrazol-5-yl)pyridin-3-yl)methoxy)benzaldehyde (GBT440)	Chemical	Haematology	Treatment of Sickle Cell Disease	June-2017
Polatuzumab vedotin	Biological	Oncology	Treatment of relapsed and refractory patients with diffuse large B cell lymphoma	June-2017
Vocimagene amiretrorepvec	Advanced Therapy	Oncology	Treatment of high grade glioma	July-2017



Interaction between CHMP and HCP: Participation in SAG and Ad-Hoc Experts Groups

➤ Contributing for decision on recommendations

Name	Active S	Therapeutic area
Mavenclad	Cladribine	CNS
Ocrevus	Ocrelizumab	CNS
Gadolinium		Radiopharmaceutical
Onzeal	Etirinotecan pegol	Oncology
Factor VIII		Hematology
Adlumiz	Anamorelin hydrochloride	Oncology
Masipro	Masitinib	Oncology



Interaction between CHMP and patients: Participation of patients in CHMP meetings

➤ Contributing for decision on recommendations

Name	Active S	Therapeutic area
Raxone	Idebenone	Duchenne



Thank you!

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