CHMP Meeting highlights

February 2022

POSITIVE OPINIONS

TYPE OF ACTIVITY	PROPRIETARY NAME	INN	ATC	INDICATIONS	COMPANY	NOTE
New medicines	Kapruvia	difelikefalin	V03AX04	It is indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult patients on haemodialysis.	Vifor Fresenius Medical Care Renal Pharma France	
	Kimmtrak	tebentafusp	L01	It is indicated as monotherapy for the treatment of human leukocyte antigen (HLA) A*02:01 positive adult patients with unresectable or metastatic uveal melanoma.	Immunocore Ireland Limited	Orphan medicine
	Orgovyx	relugolix	L02BX04	It is indicated for the treatment of adult patients with advanced hormone-sensitive prostate cancer.	Myovant Sciences Ireland Limited	
	PreHevbri	hepatitis B vaccine (recombinant, adsorbed)	J07BC01	It is indicated for active immunisation against infection caused by all known subtypes of the hepatitis B virus in adults.	VBI Vaccines B.V.	
	Quviviq	daridorexant	--	It is indicated for the treatment of adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning.	Idorsia Pharmaceuticals Deutschland GmbH	
	Vydura	rimegepant	N02CD06	It is indicated for the - acute treatment of migraine with or without aura in adults; - preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month	Biohaven Pharmaceutical Ireland DAC	

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New biosimilar medicines	Inpremzia	insulin human (rDNA)	A10AB01	It is indicated for the treatment of diabetes mellitus.	Baxter Holding B.V.
	Truvelog Mix 30	insulin aspart	A10AD05	It is indicated for treatment of diabetes mellitus in adults, adolescents and children aged 10 years and above.	sanofi-aventis groupe
New generic medicines	Amversio	betaine anhydrous	A16AA06	It is indicated as adjunctive treatment of homocystinuria, involving deficiencies or defects in: - cystathionine beta-synthase (CBS), - 5,10-methylene-tetrahydrofolate reductase (MTHFR), - cobalamin cofactor metabolism (cbl).	SERB SA
	Dimethyl fumarate Mylan	dimethyl fumarate	L04AX07	Treatment of adult patients with relapsing remitting multiple sclerosis.	Mylan Ireland Limited
	Dimethyl fumarate Neuraxpharm				Laboratorios Lesvi S.L.
	Dimethyl fumarate Polpharma				Zaklady FarmaFarmaceutyczne Polpharma S. Aceutyczne Polpharma S.A.

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TYPE OF ACTIVITY	PROPRIETARY NAME	INN	ATC	INDICATIONS	COMPANY
New generic medicines	Sitagliptin Accord	sitagliptin	A10BH01	For adult patients with type 2 diabetes mellitus, Sitagliptin Accord is indicated to improve glycaemic control: - as monotherapy: - in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. - as dual oral therapy in combination with: - metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control. - a sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycaemic control and when metformin is inappropriate due to contraindications or intolerance. - a peroxisome proliferator-activated receptor gamma (PPARg) agonist (i.e. a thiazolidinedione) when use of a PPARg agonist is appropriate and when diet and exercise plus the PPARg agonist alone do not provide adequate glycaemic control. - as triple oral therapy in combination with: - a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control. - a PPARg agonist and metformin when use of a PPARg agonist is appropriate and when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.	Accord Healthcare S.L.U.

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TYPE OF ACTIVITY	PROPRIETARY NAME	INN	ATC	INDICATIONS	COMPANY	NOTE
Extensions of therapeutic indications	Beovu	brolucizumab	S01LA06	It is indicated in adults for the treatment of - neovascular (wet) age related macular degeneration (AMD), - **visual impairment due to diabetic macular oedema (DME).**	Novartis Europharm Limited	Additional monitoring
	Delstrigo	doravirine / lamivudine / tenofovir disoproxil	J05AG24	It is indicated for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir. **It is also indicated for the treatment of adolescents aged 12 years and older weighing at least 35 kg who are infected with HIV-1 without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir and who have experienced toxicities which preclude the use of other regimens that do not contain tenofovir disoproxil.**	Merck Sharp & Dohme B.V.	Additional monitoring
	Pifeltro	doravirine	J05AG06	It is indicated, in combination with other antiretroviral medicinal products, for the treatment of adults, **and adolescents aged 12 years and older weighing at least 35 kg** infected with HIV-1 without past or present evidence of resistance to the NNRTI class.	Merck Sharp & Dohme B.V.	Additional monitoring
	Spikevax (previously COVID-19 Vaccine Moderna)	COVID-19 mRNA Vaccine (nucleoside modified)	J07BX03	It is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals ~~12~~ **6** years of age and older. The use of this vaccine should be in accordance with official recommendations.	Moderna Biotech Spain, S.L.	• Additional monitoring • Conditionalmarketing authorisation

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TYPE OF ACTIVITY	PROPRIETARY NAME	INN	ATC	INDICATIONS	COMPANY
Extensions of therapeutic indications	Opdivo	nivolumab	L01XC17	Urothelial carcinoma Opdivo as monotherapy is indicated for the treatment of locally advanced unresectable or metastatic urothelial carcinoma in adults after failure of prior platinum-containing therapy. **Opdivo as monotherapy is indicated for the adjuvant treatment of adults with muscle invasive urothelial carcinoma (MIUC) with tumour cell PD-L1 expression ≥ 1%, who are at high risk of recurrence after undergoing radical resection of MIUC.** **Oesophageal squamous cell carcinoma (OSCC)** **Opdivo in combination with fluoropyrimidine- and platinum-based combination chemotherapy is indicated for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1%.** **Opdivo in combination with ipilimumab is indicated for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1%.** Opdivo as monotherapy is indicated for the treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based combination chemotherapy.	Bristol-Myers Squibb Pharma EEIG

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TYPE OF ACTIVITY	PROPRIETARY NAME	INN	ATC	INDICATIONS	COMPANY	NOTE
Extensions of therapeutic indications	Verzenios	abemaciclib	L01EF03	<u>Early Breast Cancer</u> **Verzenios in combination with endocrine therapy is indicated for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence (see section 5.1).** **In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.** <u>Advanced or Metastatic Breast Cancer</u> Verzenios is indicated for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a ~~luteinising hormone-releasing horme (LHRH)~~ agonis	Eli Lilly Nederland B.V.	Additional monitoring
	Yervoy	ipilimumab	L01FX04	<u>Mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) colorectal cancer (CRC)</u> Yervoy in combination with nivolumab is indicated for the treatment of adult patients with mismatch repair deficient or microsatellite instability-high metastatic colorectal cancer after prior fluoropyrimidine-based combination chemotherapy. **Oesophageal squamous cell carcinoma (OSCC)** **Yervoy in combination with nivolumab is indicated for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1%.**	Bristol-Myers Squibb Pharma EEIG	

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RE-EXAMINATION OF INITIAL APPLICATION FOLLOWING NEGATIVE

PROPRIETARY NAME	INN	OPINION	COMPANY
Aduhelm	aducanumab	The applicant for Aduhelm has requested a re-examination of EMA's December 2021 opinion. Upon receipt of the grounds of the request, the Agency will re-examine its opinion and issue a final recommendation.	Biogen Netherlands B.V.

RE-EXAMINATION OF EXTENSION OF INDICATION

PROPRIETARY NAME	INN	UPDATE	COMPANY
Tecfidera	dimethyl fumarate	The marketing authorisation holder for Tecfidera has requested a re-examination of EMA's January 2022 opinion. Upon receipt of the grounds of the request, the Agency will re-examine its opinion and issue a final recommendation. The marketing authorisation holder for Tecfidera has requested a re-examination of EMA's January 2022 opinion. Upon receipt of the grounds of the request, the Agency will re-examine its opinion and issue a final recommendation.	Biogen Netherlands B.V.

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READOPTED OPINION

PROPRIETARY NAME	INN	OPINION	COMPANY
Padcev	enfortumab vedotin	On 24 February 2022, the Committee for Medicinal Products for Human Use adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Padcev, intended for the treatment of adult patients with urothelial cancer.	Astellas Pharma Europe B.V.

OUTCOME OF RE-EXAMINATION

PROPRIETARY NAME	INN	OPINION	COMPANY
Ipique	bevacizumab	After re-examining its initial opinion, the European Medicines Agency has confirmed its recommendation to refuse marketing authorisation for the medicine Ipique. The medicine was intended for the treatment of neovascular (wet) age-related macular degeneration (AMD).	Rotterdam Biologics B.V.

https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-21-24-february-2022