



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# PCWP & HCPWP feedback from CHMP

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An agency of the European Union





# Summary

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- CHMP opinions on medicines
  - New medicines Sept - Dec 2013
- HCP & patient input provided in the context of CHMP activities



# Positive recommendations on new medicines

- **25 positive recommendations on new medicines**

- 3 conditional marketing authorisation



- 1 exceptional circumstances marketing authorisation



- 7 orphan



- **19 subject to additional monitoring**



- 5 with Educational material/programme; Prescriber Kit; Patient reminder card



- 1 with communication plan addressing “medication error” prevention



- **15 initiated / monitored (supervision) HCP**

- 13 subject to Restricted prescription





# Positive recommendations on new medicines

## Diabetes

Name	Active S	Indication
Eperzan	albiglutide	Treatment of type 2 diabetes mellitus
Xigduo	dapagliflozin, metformin	Treatment of type 2 diabetes mellitus
Invokana	Canagliflozin	Treatment of type 2 diabetes mellitus



## HIV

Name	Active S	Indication
Tivicay	dolutegravir	Treatment of Human Immunodeficiency Virus (HIV)
Vitekta	Elvitegravir	Treatment of human immunodeficiency virus-1 (HIV-1) infection in antiretroviral treatment-experienced adults



R<sub>x</sub>



New HIV medicine shown to be effective in patients with resistant HIV virus

## Neurology

Name	Active S	Indication
Latuda	lurasidone	Treatment of schizophrenia
Brintellix	vortioxetine	Treatment of major depressive episodes
Abilify Maintena	Aripiprazo	Treatment of schizophrenia (prolonged-release suspension for injection)



Only be administered by a HCP (instructions in SmPC)



# Positive recommendations on new medicines

## Tuberculosis

Name	Active S	Indication
Sirturo	Bedaquiline	Treatment of pulmonary tuberculosis
Para-aminosalicylic acid Lucane	para-aminosalicylic acid	Treatment of tuberculosis
Deltyba	Delamanid	Treatment of multidrug-resistant pulmonary tuberculosis.



## Radiopharmaceutical

Name	Active S	Indication
Neuraceq	florbetaben (18F)	Detection of $\beta$ -amyloid in the brain
Xofigo	Radium-223	treatment of castration-resistant prostate cancer



**Educational programme:**  
physicians expected to use have  
access to a training programme



**Educational material:** all HCP  
involved in the prescribing,  
dispensing, handling or  
administration

## Pulmonary arterial hypertension (PAH)

Name	Active S	Indication
Adempas	riociguat	Treatment of chronic thromboembolic pulmonary hypertension and pulmonary arterial hypertension
Opsumit	macitentan	Treatment of pulmonary arterial hypertension (PAH)



**Educational material:** Prescriber  
Kit, Patient reminder cards



# Positive recommendations on new medicines

Name	Active S	Indication
Cometriq	cabozantinib	Treatment of medullary thyroid carcinoma
Izba	travoprost	Treatment of ocular hypertension and open-angle glaucoma
Mirvaso	brimonidine	Treatment of facial erythema of rosacea in adult patients
Cholic Acid FGK	cholic acid	Treatment of inborn errors of primary bile acid synthesis
Sovaldi	sofosbuvir	Treatment of chronic hepatitis C
Fluenz Tetra	influenza vaccine (tetraivalent live attenuated)	Prophylaxis of influenza in individuals 24 months to less than 18 years
Kadcyla	Trastuzumab emtansine	Treatment of metastatic breast cancer
Lidocaine/Prilocaine Plethora	Lidocaine/Prilocaine	Treatment of primary premature ejaculation in adult men
NovoEight	Turoctocog alfa	Treatment of haemophilia A (congenital factor VIII deficiency)
Rekvar Ellipta	fluticasone, vilanterol	Treatment of asthma and COPD







## Kadcyla (Trastuzumab emtansine) vs. Herceptin (Trastuzumab)

### Additional risk minimisation measures



In order to **prevent medication errors** it is important to check the vial labels to ensure that the medicinal product being prepared and administered is Kadcyla (trastuzumab emtansine) and not Herceptin (trastuzumab)



### **HCP educational pack:**

- Kadcyla and Herceptin are two very different products with different active substances never to be used interchangeably. Kadcyla is NOT a generic version of Herceptin and has different properties, indications and dose
- Do not substitute or combine Kadcyla with or for Herceptin
- Check the vial labels to ensure not change Kadcyla (trastuzumab emtansine) by Herceptin (trastuzumab).



## HCP & patient input in the context of CHMP activities

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### Presentation and discussion of at CHMP plenary in March – currently planned pilot phase:

- With Patients suffering from disease under discussion
  - Two patients per procedure plus “guide” from PCWP
  - Alternatively with caretakers where appropriate
- With selected procedures
  - Focus for pilot on procedures with oral explanation
  - Predictably controversial
  - With possibly or probable negative CHMP opinion
  - With impact of value judgment on benefit risk decision
- Input by PCWP members welcome!