16 October 2015
EMA/681537/2015
Human Medicines Evaluation Division

Programme - Workshop on the role of pharmacokinetic and pharmacodynamic measurements in the use of direct oral anticoagulants

23 November 2015 at the European Medicines Agency, 30 Churchill Place, Canary Wharf, London, UK, meeting room 3A

General objectives

At this workshop we will bring together experts and stakeholders to discuss the utility of PK and PD measurements in the clinical use of the direct oral anticoagulants (DOACs). The objectives are to improve the understanding of:

1. Problems related to the use of DOACs in clinical practice, in the overall population of patients, in subgroups of patients at particular risk of bleeding or underexposure, and in patients presenting with a major bleeding or with a need for acute surgery or other invasive interventions
2. Need to further guide clinical decision-making on dose adjustment during routine use, when major bleedings occur, or when the need for acute surgery emerges
3. Recommendations regarding PK and PD measurements that can be implemented based on the current data
4. Gaps in the knowledge on PK and PD measurements of DOACs
5. Analytical methods, their validity, availability in the European Union and current use
6. Priorities in future research in the field of PK/PD measurements of DOACs

Scope

The scope of the workshop is to discuss the current knowledge and clinical experience in the use of the direct oral anticoagulants (DOACs) authorised in the European Union in particular aspects related to measurement of anticoagulant activity in view of available PK and PD data.

The medicinal products currently authorised in the EU are Pradaxa (dabigatran etexilate), Xarelto (rivaroxaban), Eliquis (apixaban) and Lixiana (edoxaban).

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Who will attend?

The presentations and discussions will include the following experts and impacted stakeholders:

- Regulators: EMA and its scientific committees CHMP and PRAC, FDA
- Academia
- Clinicians
- Healthcare professional representatives
- Patients representatives
- Pharmaceutical industry representatives

Programme committee

Jens Heisterberg (CHMP), Pieter de Graeff (CHMP), Kristina Dunder (CHMP), Concepcion Prieto Yerro (CHMP), Rafe Suvarna (CHMP/PRAC), Jean-Michel Dogné (PRAC), Heidi Janssen (EMA), Enrica Alteri (EMA), Catherine Drai (EMA) and Anna Baczynska (EMA)

	Programme	Presenter
8.30 - 8.45	**Welcome and opening**	
	European Medicines Agency	Dr Enrica Alteri
8.45 - 10.40	**Session 1: The oral anticoagulant landscape - setting the scene** This session aims to set the stage for the workshop and stimulate later discussion. It should delineate the problems in clinical practice associated with oral anticoagulant treatment.	Session Chairs: Prof Pieter de Graeff and Dr Kristina Dunder
8.45 - 8.55	Patient perspective	Christine Dehn (Patient representative)
8.55 - 9.40	Clinician perspective	Prof Peter Svensson Prof Menno Huisman
9.40 - 10.40	Questions and discussion	
10.40 - 11.00	***Coffee break***	
11.00- 12.00	**Session 2: What can we do now and what are the gaps in our knowledge?** This session aims to present the most up-to-date data and discuss gaps in current knowledge about the possibility of implementing targeted PK and PD measurements in subgroups of patients at increased risk.	Session Chairs: Dr Jens Heisterberg and Prof Joseph Emmerich
11.00 - 11.10	The direct thrombin inhibitor (dabigatran etexilate)	Dr Marie Louise Christiansen
11.10 - 11.30	The direct factor Xa inhibitors (rivaroxaban, apixaban, edoxaban)	Dr Antonio Gomez-Outes
11.30 - 12.00	Questions and discussion	
12.00 - 13.00	**Session 3: The analytical part** This session aims to present the analytical methods and challenges to determine concentrations or the anticoagulant activity of DOACs.	Session Chairs: Prof Jean-Michel Dogné and Dr Bengt Ljungberg
12.00 - 12.15	The direct thrombin inhibitor (dabigatran etexilate)	Prof François Mullier
12.15 - 12.30	The direct factor Xa inhibitors (rivaroxaban, apixaban, edoxaban)	Dr Steve Kitchen
12.30 - 13.00	Questions and discussion	
13.00 – 14.00	***Lunch break***	
14.00 - 16.00	**Session 4: Future perspectives. What could be done?** This session aims to discuss ways to fill the gaps in our knowledge about PK/PD measurements as well as how	Session Chair: Dr Tomas Salmonson

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	to better use the available data. Future scenarios on how knowledge can be obtained should be depicted.	
14.00 - 14.15	Academic perspective	Prof Hugo ten Cate
14.15 - 14.55	Industry perspective	Prof Jörg Kreuzer (Boehringer Ingelheim) Dr Scott Berkowitz (Bayer) Dr Robert Knabb (BMS/Pfizer) Dr Michele Mercuri (Daiichi Sankyo)
14.55 – 15.45	Panel discussion Questions and answers	Dr Mary Ross Southworth (FDA) Prof Sam Schulman Dr Susan Cole Dr Trevor Baglin
15.45 - 16.00	Wrap-up, conclusion	
16.00	**End of workshop**	