

25 November 2011 EMA/876327/2011

# EMA preparations for the impact of the 2012 Olympic Games

Management Board meeting 15 December 2011

## **Background note**

London will host the 2012 Olympic Games from 29 July until 12 August and the Paralympic Games from 29 August until 9 September with events taking place at venues across the capital and the UK. The event will have a major impact on all activities in London both during and prior to the Games. The huge number of spectators, tourists and people using the transport system and hotels means that London will be significantly busier than usual. The main areas of activity which will be affected by the Games have been identified as staff travel to and from the EMA, staff and human resources management, business travel (missions), deliveries and collections from suppliers and meeting organisation.

At their meeting of 16 May 2011, the Heads of Unit agreed to set up a Business Continuity Planning Core Group in order to prepare for the impact of the Olympics on the activities of the Agency. The mandate of the Group is to investigate the impact of the Games on all areas of activity at the EMA and to find suitable solutions in order to minimise the negative consequence it may have on EMA business. Following their meeting on 23 June, the Business Continuity Planning Core Group drew up a list of proposals covering meetings organisation in June and July 2012, business areas reorganisation and staff management.

### **Matters for consideration**

#### **Meeting Organisation**

A list of mandatory meetings scheduled for June and July 2012 was identified. Where meetings could not be cancelled, postponed or held virtually, alternative solutions were sought. In order to host the EMA meetings at a location outside the Agency, issues of confidentiality, security and cost had to be addressed. In seeking alternative arrangements for meetings taking place in July, several options were investigated including meeting venues in hotels and conference centres.

However given the need for security and confidentiality during the meetings in question together with the additional cost for hiring such venues, the National Competent Authorities, EU Decentralised Agencies and European Commission provided the better solution.



For June 2012, hotel accommodation has been secured to allow only mandatory Committee meetings and Working Parties to be held as planned with the exception of the Scientific Advice Working Party which will be held at the Medicines Authority in Malta. All non-mandatory meetings in June will be held virtually or cancelled.

For mandatory meetings in July, several options were investigated and the National Competent Authorities, the EU Decentralised Agencies and the European Commission were all contacted to express their interest in hosting meetings during the period concerned. The EMA was most grateful for the number of proposals which were received and, after careful consideration, the senior management of the EMA gave their approval to the locations for meetings outside the UK at their meeting of 10 October 2011. In reaching their decision, the main criteria including the availability of the meeting and IT facilities, the seat of the Chair and Vice Chair of the committees and the number of proposals received were taken into account. All other mandatory meetings in July will be held either virtually, postponed or cancelled. Annex I lists the meetings for June and July and the proposal for each meeting.

In August, the Paediatric Committee Plenary Meeting and Scientific Advice Working Party will be held as planned during the last two weeks. For September, it is planned to hold all meetings as usual.

An announcement has been published on the EMA's external website with regards to meeting organisation prior to the Olympics and the Committee members concerned have been notified where the meeting has been relocated to a venue outside the UK.

#### Staff management

At their meeting of 17 October 2011, the Heads of Unit approved the proposal to allow for a Business Continuity Plan situation for the period 15 June to 15 September 2012, in order to allow more flexible working arrangements for staff. During this time, and with the written agreement of their Head of Sector, staff will be given the opportunity to work from home using Location Independent Working (LIW). A letter outlining Health and Safety requirements if working from home will be issued to each staff member concerned.

The possibility to derogate from core hours will also be introduced allowing staff more flexibility in order to travel to the Agency at less busier times of the day during the Games.

Solutions with regard to recruitment have also been confirmed by the Human Resources Sector who is preparing to conduct interviews through Skype or alternative video-conference tools as required.

With regards to staff missions and training, forward planning and authorisation of critical missions/training only during the period in question is essential. Mission requests would have to be planned in advance in order to secure travel arrangements and no training involving travel would be accepted from 1 July until 15 August 2012. Language training and exams will be scheduled accordingly and will run up to the end of June.

The policy also urges staff to take leave during the period concerned whilst taking account of the needs of their colleagues and the Agency. In addition, staff wishing to apply for parental leave during the period concerned were asked to submit their applications by October 2011.

In order to ensure smooth business continuity, the list of IT applications required is also being updated to allow staff to work remotely.

With regards to business areas reorganisation, Unit requirements are being analysed taking into account the activities which need to be maintained, the competences to perform these activities and the necessary staff members required.

In order to ensure a core decisive management group, a decision with regards to the presence of senior management during the period concerned will be taken.

A Business Continuity Plan will be established and tested prior to the period concerned.

An Olympics microsite was launched for staff in October 2011 providing information on the measures which have been put in place together with an analysis of the impact of the Games on the EMA activities and suggested guidance which will be updated on a regular basis.

Annex I

Meetings for June 2012

MEETING TITLES	JUNE	REIMBURSED PARTICIPANTS	APPROVED PROPOSAL
Pediatric Committee Plenary	06-08/06/2012	46	To be held as planned
Management Board Plenary	07/06/2012	37	To be held as planned
CHMP Biologics Working Party	11-13/06/2012	21	To be held as planned
CHMP ORGAM Meeting	11/06/2012	10	To be held virtually
COMP Plenary	12-14/06/2012	32	To be held as planned
CVMP Plenary	12-14/06/2012	45	To be held as planned
Scientific Advice Working Party – Veterinary	12/06/2012	1	To be held as planned
Advanced Therapies	13/06/2012	35	To be held as planned
CMD(v)	14-15/06/2012	N/A	To be held as planned
CHMP Pharmacovigilance WP	18-20/06/2012	41	To be held as planned
CHMP Plenary	18-21/06/2012	50	To be held as planned
CMD(h) Plenary Meeting	18-20/06/2012	N/A	To be held as planned
Scientific Advice Working Party	25-27/06/2012	38	To be held at the Medicines Authority, Malta

# Meetings for July 2012

MEETING TITLES	JULY	REIMBURSED PARTICIPANTS	APPROVED PROPOSAL
Paediatric Committee Plenary	04-06/07/2012	46	To be held at Paul-Ehrlich Institut, Germany
HMPC Plenary and Working Party	09-12/07/2012	35	To be cancelled
COMP Plenary	10-12/07/2012	32	To be held at Medical Products Agency, Sweden
CVMP Plenary	10-12/07/2012	45	To be held at Medicines Evaluation Board, The Netherlands
Scientific Advice Working Party – Veterinary	10/07/2012	1	To be held at Medicines Evaluation Board, The Netherlands
Committee for Advanced Therapies (CAT)	11-13/07/2012	35	To be held virtually/cancelled
CHMP Plenary	16-19/07/2012	50	To be held at Federal Institute for Drugs and Medical Devices (BfArM), Germany
Pharmacovigilance Working Party	16-18/07/2012	41	To be held at Federal Institute for Drugs and Medical Devices (BfArM), Germany
CMD(h) Plenary Meeting	16-17/07/2012	N/A	To be held at Medicines Evaluation Board, The Netherlands
PRAC Plenary	19-20/07/2012	38	To be held at European Commission, Brussels