

26 November 2010 EMA/MB/719548/2010

Report on the impact of the volcanic ash cloud disruption on EMA activities

Management Board meeting 16 December 2010

Background note

This report describes the events and subsequent actions taken following the impact of the volcanic ash cloud which affected the activities of the EMA in April and May 2010.

Matters for consideration

This report covers the period from 16 of April until end of May and focuses on the steps taken to deal with the disruption including alternative meeting formats, business continuity, budget and security issues.



Report on the impact of the volcanic ash cloud disruption on EMA activities

Executive summary:

In April 2010, some delegates were stranded in London because of a volcano blast in Iceland. Due to airport disruptions, other means of transportation were investigated and additional hotel nights were provided. As the evolution of the situation was unpredictable, meetings were cancelled and/or postponed until the end of May. Other meetings like the CHMP successfully experienced Europe-wide teleconference and web conferencing in order to comply with deadlines related to medical products legislation.

This report describes the steps taken in order to deal with such a situation and subsequent lessons learned including alternative meeting formats, business continuity, budget and security issues.

Background information

Measures for stranded delegates

Following the closure of the UK and of most of Europe's airspace, from 16 to 22 of April 2010, 150 delegates attending meetings at the European Medicines Agency (EMA) premises were stranded in London for several days and others were waiting for information regarding their participation in meetings.

Alternative means of transport for 100 delegates willing to go back to their home countries had to be found and decisions had to be made for the next scheduled meetings.

On Friday 16 April, travel solutions to the continent were investigated including Eurostar trains, European trains, buses and ferries. However, delegates had to stay in London over the weekend as all means of transport were fully booked until the following week, and the situation was also expected to continue for a further two or three days. Difficulties were encountered in terms of accommodation availability, as more than 500 000 people were stranded in the UK and hotels were faced with a high demand during the first three days. In addition, some hotels increased their rates significantly and consequently delegates had to change hotels in order to keep within budget.

In order to facilitate the delegates' stays in London, it was decided to support the cost of extra hotel nights for all delegates stranded in London and to provide a daily allowance of 52 Euros per extra day.

On average, delegates stayed between 5 or 6 days in London before they were able to travel back to their home countries.

Measures taken for scheduled meetings

As the situation lasted for longer than expected with a lot of uncertainties regarding the evolution of the situation - air traffic disruptions were foreseen for days/weeks depending on the intensity of the volcanic disruption and the level of airborne ash contaminants - meetings in London were postponed or cancelled until 30 April.

However, some meetings took place by teleconference / web conference through Adobe Connect and Vitero technologies. Feedback from users on all of these meetings was very positive and most of them were held with good participation without /or with only minor technical difficulties.

CHMP meeting (19/04/2010 - 22/04/2010)

In order to ensure compliance with legislation legal deadlines and other relevant obligations affecting medicinal products assessment procedures, it was decided to hold the CHMP meeting using teleconference and Adobe Connect. Taking into account the exceptional circumstances and the business continuity scenario, members who joined the meeting by teleconference were deemed to be present with regard to the quorum.

Delegates welcomed the possibility to maintain the meeting, albeit in a "virtual" form. It also provided a useful, if unexpected opportunity to pilot the web conferencing facility.

There was an almost 100% participation of CHMP members either in person (i.e. delegates from UK, France and Belgium as well as those stranded in London from the previous week) or remotely, as 22 participants were connected remotely via Adobe Connect.

The CHMP Chairman preferred to attend in person to chair this mixed format meeting. The meeting also included two oral explanations with companies, who also joined the meeting remotely.

• Other meetings held virtually via Vitero or Adobe connect (web conferencing system)

During the same period, the Pharmacovigilance Working Party meeting (19/04/2010 to 20/04/2010) and CMDh Plenary meeting (21/04/2010) were partly organised remotely via Adobe Connect and Vitero technologies for the application sharing and via telephone conference for the audio communication. 14 participants were connected remotely for the first meeting.

Due to the return of the volcanic ash cloud, in May, 4 further meetings were held via the same technologies. There were also a number of remote participants during CVMP Safety (06/05/2010), CHMP Plenary meeting (17/05/2010 - 20/05/2010), CMDh Plenary meeting (17/05/2010 - 19/05/2010) and PDCO Plenary meeting (17/05/2010 - 21/05/2010).

As a consequence, it is important to highlight that the ash cloud initiated meeting organisers to provide all members of CVMP and CMDh with Vitero accounts to be ready for virtual meetings at short notice in case more emergency meetings should be necessary.

Matters for consideration

Budget impact

From the table reported in Annex, it can be seen that the additional night bookings and travel arrangements increased the cost of meetings. However, it was widely compensated through cancellation of meetings between 15 and 30 April and a total of 167 989 Euros were saved

Lessons learned

- In case of future similar situations affecting travel, the Meeting and Conference Management sector will launch and coordinate a Business Continuity Plan involving all EMA sectors.
- The possibility to hold meetings in a virtual manner, with almost no notice, via teleconference, and by setting up web conferencing facility, was successfully demonstrated.
- Technical security to ensure that confidentiality of meeting discussions is maintained before allowing companies to join specific parts of meetings will be further investigated.

- The challenges for the chair of mixed format meetings will have to be considered, with respect to ensuring participation of members participating in person and remotely as well as challenges with respect to the voting procedure
- The difficulty in some cases to chair the meeting remotely
- The importance of an on site travel agent and its availability during outside working hours was confirmed
- The availability of support resources, as well as of necessary working tools, i.e. software was highlighted.

Annex - Meetings Cost during the events related to the ash cloud disruption

				Initial		- Lac
Title	Date	Delegates		budget	Real cost	Difference
CAT Mosting	15 16 04 10	32	Travel back delayed	26 000 00	46 166 00	20 166 00
CAT Meeting	15-16.04.10	32	Travel back delayed	26,000.00	46,166.00	20,166.00
Paediatric Committee Meeting	14-16.04.10	42	Travel back delayed	47,000.00	73,465.00	26,465.00
CVMP Plenary	13-15.04.10	34	Travel back delayed	38,000.00	61,089.00	23,089.00
Presentation bioequivalence			·	· ·	·	·
guideline	19.04.10	0	Cancelled without fees		-	-
			Teleconference +			
CHMP Plenary	19-22.04.10	11	participants	57,200.00	20,974.00	- 36,226.00
Reporting on Pandemic			1 UK delegate (Only			
Influenza Activities to CHMP	19-22.04.10	1	19/04)	4,500.00	105.00	- 4,395.00
Bio-coordination Group	19.04.10	1	Delegate was in London	6,000.00	322.00	- 5,678.00
			Teleconference +	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
CHMP Pharmacovigilance WP	19-21.04.10	4	participants	31,000.00	12,204.00	- 18,796.00
SAG CNS Chair report to CHMP						
Meeting	20.04.10	1	UK delegate Cost = € 105	105.00	298.00	193.00
Workshop on Scientific Aspects						
of Serology Essays for influenza vaccines	20-21.04.10	0	Cancelled with fees	40,000.00	640.00	- 39,360.00
vaccines	20 21.04.10	O .	Caricelled With rees	40,000.00	040.00	33,300.00
Interlinking Group Meeting	20.04.10	0	Cancelled with fees	3,750.00	817.00	- 2,933.00
EC/EMA/CAT/NB-MED/NBOG						
Coordination Group	21.04.10	0	Cancelled with fees	4,500.00	578.00	- 3,922.00
Pre Special Activity ad						
hoc/Expert Meeting	21.04.10	0	Cancelled without fees	-	-	-
Eudravigilance Expert WG	21-22.04.10	0	Cancelled with fees		2,364.00	- 5,636.00

				Initial	Initial		
Title	Date	Delegates		budget	Real cost	Difference	
				8,000.00			
Eudranet TIG	21.04.10	0	Meeting postponed to 24/06 (fees)	-	5,118.00	5,118.00	
Nanomedicines Workshop	26-27.04.10	0	Cancelled with fees	21,250.00	2,684.00	- 18,566.00	
Scientific Advice WP	26-28.04.10	8	Teleconference + participants	53,900.00	6,444.00	- 47,456.00	
PK Assessors training on the new Bioequivalence guideline	27.04.10	0	Cancelled with fees	21,750.00	2,585.00	- 19,165.00	
VEDDRA Subgroup	28.04.10	0	Cancelled without fees	5,250.00	-	- 5,250.00	
"Lessons learnt" - Meeting with experts and industry	29.04.10	0	Cancelled without fees	25,000.00	-	- 25,000.00	
			Refunds from airlines			- 10,637.40	
				TOTAL	- 167,989.40		