European Ombudsman

EMA policy on publication of and access to clinical-trial data

Letter - 13/05/2014

Mr Guido Rasi Director European Medicines Agency 7 Westferry Circus Canary Wharf GB - London E14 4HB

Strasbourg, 13 May 2014

EMA policy on publication of and access to clinical-trial data

Dear Mr Rasi,

On 7 May 2014, EMA sent a number of documents concerning the above-mentioned policy to my Office, including a power-point presentation, a document entitled 'Redaction principles' and the 'Terms of use'.

In your letter of 31 July 2012 to my predecessor, you had pointed out that EMA was moving ahead with its plans 'proactively to publish clinical trial data and enable access to full data sets to interested parties'. I had understood that EMA's intention was to give proactive access to the relevant documents in order to make it unnecessary for interested parties to exercise the fundamental right of access to documents by making requests under Regulation 1049/2001.

However, from the documents that I received, it appears that EMA now envisages a policy that very much differs from what I had understood to be EMA's initial approach.

In fact, on the basis of these documents, it appears that EMA envisages to make available clinical-trial data, with the exception of what it considers to constitute 'Commercial confidential Information', to natural or legal persons or organisations that have registered with EMA and that agree to the conditions for such access that are set down in the 'Terms of use'.

Unless I am very much mistaken, the relevant documents do not contain any reference to Regulation 1049/2001. However, it cannot be excluded that EMA considers that its proposed new policy provides the same level of transparency that would also be guaranteed by the said regulation.

I think it is obvious that such an assumption would not be well-founded. To highlight just one fundamental difference, a person exercising the fundamental right of public access under Regulation 1049/2001 does not have to state any reasons for his or her application. Nor does Regulation 1049/2001 foresee any conditions that an applicant would have to accept as regards the use he or she intends to make of the documents to which access is requested. It may be useful to recall that, according to Article 73 of Regulation 726/2004, Regulation 1049/2001 shall apply to documents held by EMA.

I should therefore be grateful if you could inform me, by 31 May 2014, about how EMA proposes to deal with requests for public access, submitted under Regulation 1049/2001, to clinical-trial data in the future. I would also very much appreciate it if you could explain to me the reasons, and the legal basis, for what appears to be an important change in direction as regards EMA's approach to transparency in this area.

Yours sincerely,

Emily O'Reilly