EMA Respond to EMWA President, Dr Sam Hamilton's questions on the impact of EU gen court ruling 1 Sep 15 on EMA Policy 0700.

For the questions (submitted on 29 September) see:
http://www.emwa.org/Documents/News/EU%20Ruling%20impact.pdf

Below is the EMA's response received at 10.23 on 06 October 2015:

'Re: EMA request reference ASK-14819

Dear Ms Hamilton,

Many thanks for your query of 29th September 2015 regarding the recent Interim Order of the President of the EU General Court in Case T-235/15 R.

As a preliminary remark, the European Medicines Agency ("EMA") would like to highlight that the above mentioned Interim Order relates to a decision of the EMA to grant access to documents in accordance with Regulation (EC) No 1049/2001. This Interim Order neither relates nor affects in any way Policy 0070 and its implementation.

As you may be aware, Policy 0070 was adopted on the basis of Article 80 of Regulation (EC) No 726/2004 as an additional mechanism to increase the transparency of the activities of the EMA. Policy 0070 is, therefore, distinct from the provisions of Regulation (EC) No 1049/2001 and from the activities concerning access to the documents which are subject to the Interim Order.

The concerned documents in Case T-235/15 R do not include clinical study reports, in general, or case narratives in particular. In addition, the Interim Order does not give any ruling on whether the information at stake in the matter before the Court is confidential or not. Neither has the President of the General Court ruled that information that is available in the public domain could be considered commercially confidential.

For the above reasons, the position of the Agency is that in no way does the Interim Order bring into question Policy 0070 and its implementation.

Therefore, the content of the EMA presentation which you mention in your e-mail ('*Key aspects related to the submission of clinical reports for the purpose of publication in accordance with EMA Policy 0070'*, of 7th September 2015), remains valid. Case narratives should not be redacted in full and they should be instead anonymised. Further guidance on the anonymisation of clinical reports for the purpose of publication in accordance with Policy 0700 will be published in due time on the EMA website.

The Agency will continue to keep the public and stakeholders informed as the implementation of this Policy progresses.

For any further information please consult the Agency's dedicated webpage: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000555.jsp&mid=WC0b01ac0580607bfa

Finally, EMA is carefully considering our options, including the possibility to lodge an appeal against the Interim Order within the statutory limits.

I hope you find this information useful.

Kind regards,

Juan Garcia Burgos

Head of Medical and Health Information
European Medicines Agency.