DOES THE EU GENERAL COURT RULING (01 SEPTEMBER 2015) BRING EMA POLICY 0700 INTO QUESTION? SHARING INFORMATION WITH THE MW COMMUNITY

Fellow medical writers, today (29 September 2015), I was in direct contact with EMA's Dr Burgos (Head of EMA Communication for Medical and Health Information) with the following:

******Extract:
'....Regarding EMA policy on publication of clinical data for medicinal products for human use. Policy 0700. 01 January 2015. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf

The following appears to question the entire EMA Policy 0070 (a court decision which basically stops "clinical report" sharing by the EMA).

On 01 September 2015 the EU General Court issued an interim order in favour of Pari Pharma GmbH ("Pari") to suspend the European Medicines Agency's ("EMA") decision to grant a third-party, Novartis Europharm Ltd ("Novartis"), access to certain documents prepared during the Marketing Authorisation ("MA") application process (the "MA Documents"). The MA Documents at issue included EMA Assessment Reports on similarity and superiority between Pari's product (Vantobra) and Novartis' product (TOBI Podhaler), which has an EU MA as an orphan medicine. Novartis made the request to the EMA for access to the MA Documents under the Transparency Regulation 1049/2001. The main case is currently pending before the General Court (Case T-235/15):
http://curia.europa.eu/juris/document/document_print.jsf?doclang=EN&text=&pageIndex=0&part=1&mode=DOC&docid=166882&occ=first&dir=&cid=588022
As you know, EMWA-AMWA are working hard on the CORE Reference - a CSR job aid in development to help medical writers navigate ICH guidelines as they create CSR content relevant for today's clinical studies whilst offering practical suggestions for developing CSRs **that will require minimum redaction prior to public disclosure**. My team are also writing in parallel, a manuscript to accompany CORE Reference; commissioning a website to host CORE Reference and; we are due to present an update on our work in early November at the EMWA conference to be held in The Hague.

With all that in mind, I have some general questions of immediate interest to medical writers:

1. Do EMA agree with the above interpretation that the EU General Court's interim order brings EMA Policy 0700 into question?
2. Is Policy 0700 on hold for now?
3. Does EMA intend to appeal - and if so, is a date set for any appeal?
4. In the 07 September 2015 EMA presentation

(http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2015/09/WC500194091.pdf) it states that full redaction of narratives in the CSR for public disclosure is not allowed. EMA states that 'Case narratives should not be redacted in full regardless of their location within the clinical reports (body of the report or listings). They should be instead anonymised.'
This presentation postdates the 01 September court ruling above. Can you comment on how medical writers should now interpret this?

I have thought carefully about these questions ... I would like to share your responses publicly with the medical writing community - we are after all writers of CSRs and closely involved with dossier submission...'

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Dr Burgos has kindly forwarded my questions to experts within EMA and a response is pending. I will share any insights with the medical writing community. Feel able to share this information with your own networks.

[My thanks to EMWA member Christopher Marshallsay (Grunenthal) for passing through the information about the EU General Court ruling above].

Dr Sam Hamilton
Chair of the EMWA-AMWA CORE Reference Project and EMWA President.