CASE AUTH/3079/9/18 ***NO BREACH OF THE CODE***

DIRECTOR v PFIZER

Clinical trial disclosure

A study published online in the British Medical Journal (12 September 2018) was entitled 'Compliance with requirement to report results on the EU Clinical Trials Register: cohort study and web resource' (Goldacre *et al* 2018).

The study objectives included assessing compliance rates with the European Commission's requirement that all trials on the EU Clinical Trials Register (EUCTR) posted results to the registry within 12 months of completion (final compliance date 21 December 2016). The study objectives also included identifying features associated with non-compliance, ranking sponsors by compliance and building a tool for live ongoing audit of compliance. The published paper listed the trial sponsors with the highest proportion of trials reported and the trial sponsors with the highest proportion of trials unreported. The results were that of 7,274 trials where results were due, 49.5% (95% confidence interval 48.4% to 50.7%) reported results.

Goldacre *et al* stated that the European Commission (EC) Guideline required the results of all trials to be reported in structured form on to the register itself. It was possible that some trials that did not report results to EUCTR reported results elsewhere eg in a conference presentation, an academic journal article, as part of a meta-analysis after data were requested by systematic reviewers, or in the grey literature. Such publications did not meet the reporting requirements of the EC Guideline and were therefore outside the scope of the study.

Goldacre *et al* listed sponsors with more than 50 trials on the EUCTR and did not mention products or specific clinical trials. Goldacre *et al* gave details of disclosure of clinical trial results for each sponsor.

The Director decided that the Goldacre *et al* article was such that she had received information from which it appeared that Pfizer might have breached the Code and decided in accordance with Paragraph 5.1 of the Constitution and Procedure to take the matter up as a complaint.

The detailed response from Pfizer is given below.

General detailed comments from the Panel are given below.

The Panel noted the data in Goldacre *et al* in that the results of seven of Pfizer's due trials had not been reported on EUCTR; the disclosure percentage was 95.8%.

The Panel noted Pfizer's submission that trials 2004-000035-28 and 2004-001586-18 involved diclofenac sodium cutaneous spray which was first licensed and commercially available before 1 November 2008 and the trials ended on 1 December 2004 and 19 May

2005 respectively and therefore pre-dated the requirements of any joint position and were not covered by the Code. However, the Panel noted the nature of the complaint as set out in its general comments below. According to Goldacre *et al* the results had not been published and Pfizer had not asserted that the trials had no UK nexus or provided any other explanation about why the trials were not published on the EUCTR according to the EU Guideline. The Panel therefore ruled a breach of the Code in relation to trials 2004-000035-28 and 2004-001586-18 which was appealed by Pfizer. The Panel noted from the evidence before it that there did not appear to have been any formal finding by any judicial authority or appropriate body charged with determining matters in relation to the Commission Guidelines that the company had not complied with the relevant laws and regulations. The Panel therefore ruled no breach of the Code in relation to these two trials. The Panel was unsure whether or not the results were now disclosed on EUCTR or elsewhere. On balance, the Panel did not consider that in the circumstances a breach of Clause 2 was warranted and ruled accordingly.

The Panel noted that four trials EudraCT numbers 2004-001637-41, 2004-003727-12, 2008-004088-21 and 2010-022955-43 were cancelled before any subjects were recruited so there were no results to publish. The Panel therefore ruled no breaches of the Code including no breaches of Clause 2.

The Panel noted that trial EudraCT number 2007-005695-14 which involved an investigational compound (PSI-697) ended on 8 July 2008. The Panel noted Pfizer's submission that the development programme for PSI-697 was terminated and so the product did not progress to marketing authorization and was never commercially available and therefore there was no requirement to disclose the trial results under the Joint Positions. However, the Panel noted the nature of the complaint.

The Panel noted that the results did not appear to be published on EUCTR within the required timeframe. The Panel therefore ruled a breach of the Code which was appealed by Pfizer. The Panel noted from the evidence before it that there did not appear to have been any formal finding by any judicial authority or appropriate body charged with determining matters in relation to the Commission Guidelines that the company had not complied with the relevant laws and regulations. The Panel therefore ruled no breach of the Code in relation to this trial. The Panel was unsure whether or not the results were now disclosed on EUCTR or elsewhere. On balance, the Panel did not consider that in the circumstances a breach of Clause 2 was warranted and ruled accordingly.

General detailed comments from the Appeal Board are given below.

The Appeal Board noted that Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006 required that clinical trial data be published on EUCTR. European Commission (EC) Guideline 2012/c302/03 gave guidance as to when the clinical trial results data should be published. According to the EC Guideline posting of results of clinical trials which ended one year or more prior to finalisation of the programming of the relevant database, should be done within 24 months of finalisation of that programming. According to the 'What's New' section of EudraCT public website (post-dated 13 January 2016) the deadline for submission of these results was 21 December 2016. This date was referred to in Goldacre *et al*. It appeared to the Appeal Board that whilst the regulation mandated disclosure of results on EUCTR, the EC Guideline and other material advised companies how to comply with the regulation

including in relation to the timing of such disclosures. The Appeal Board considered that it was within the spirit of the Code and good practice to comply with the guideline in question.

The Appeal Board noted Pfizer had published trial results for 161 of 168 trials. The Appeal Board noted the data in Goldacre *et al* in that the results of 7 of Pfizer's due trials had results due and yet they had not been reported on EUCTR; the disclosure percentage was 95.8%. Information provided by Pfizer did not include any reference to whether or not there was a UK nexus for the three trials which went ahead and which were at issue in the appeal. (The other four trials identified by Goldacre *et al* were either cancelled or terminated.)

The Appeal Board noted that the Panel had ruled breaches of the Code for Pfizer's failure to disclose results by 21 December 2016 or within the required timeframe in relation to three trials (trials 2004-000035-28, 2004-001586-18 and 2007-005695-14) and these were the subject of the appeal.

The Appeal Board noted Pfizer's appeal submission regarding trial 2007-005695-14 in that it had been incorrectly classified and was in fact a phase I pharmacodynamic trial in healthy subjects and as such according to EC Guideline the trial results did not require disclosure on EUCTR. The Appeal Board noted that it did not appear to be a clinical trial disclosure which was mandated by the relevant regulations. The Appeal Board consequently ruled no breach of the Code in relation to this trial. The appeal on this point was successful.

The Appeal Board noted that for trials 2004-000035-28 and 2004-001586-18 posting on EUCTR was delayed because the trials related to the asset TDS-943 and all rights and responsibilities related to this asset were returned to Mika Pharma GmbH, the marketing authorisation holder in 2008 by Wyeth Research Division of Wyeth Pharmaceuticals Inc, prior to Wyeth's acquisition by Pfizer. The Appeal Board noted Pfizer's submission that each trial was conducted and completed with Wyeth Consumer Health as the sponsor. The Appeal Board noted that the results data had been returned to, and was held by, Mika Pharma at the time the results were due to be posted.

The Appeal Board considered that there would be a difference between action to deliberately hide clinical trial data or systematic failure resulting in non or late disclosure and late disclosure of results as part of a retrospective exercise contrary to non-mandatory timelines due to mitigating factors. The Appeal Board, nonetheless, noted its view above about good practice and disclosure in accordance with the EC Guideline.

The Appeal Board noted that prior to this complaint, the Pfizer Global Clinical Trial Disclosure Group had already contacted Mika Pharma GmbH with the intention of working with it to post any available results for these two trials on EUCTR. Pfizer submitted that with Mika Pharma's permission, Pfizer had now posted these trials on EUCTR.

The Appeal Board was concerned about the failure to disclose the summary results of the two trials on EUCTR within the timelines advised by the EC Guideline and other relevant advice. In the exceptional circumstances of this case, the Appeal Board did not consider that the late posting of the results of two trials on the EUCTR as part of a

retrospective exercise warranted a breach of the Code. The Appeal Board ruled no breach of Code in relation to each trial. The appeal was successful.

Following its completion of the consideration of the appeals in this case and in Cases AUTH/3087/9/18 (GlaxoSmithKline), AUTH/3118/11/18 (Tesaro) and AUTH/3102/9/18 (Lilly) the Appeal Board noted that the respondent companies in Case AUTH/3084/9/18 (Boehringer Ingelheim), Case AUTH/3091/9/18 (UCB), Case AUTH/3097/9/18 (Teva), and Case AUTH/3099/9/18 (Allergan), accepted the Panel's rulings of breaches of the Code and had not appealed.

The Appeal Board agreed that Boehringer Ingelheim, UCB, Teva and Allergan should be contacted and informed of the outcome of the appeals in Cases AUTH/3079/9/18, AUTH/3087/9/18, AUTH/3118/11/18 and AUTH/3102/9/18. The PMCPA Constitution and Procedure did not cover this unusual situation where more than one company was involved in a similar set of circumstances and the Appeal Board had taken a different view to the Panel. Boehringer Ingelheim, UCB, Teva and Allergan should each be offered the opportunity to appeal out of time and the appeal process would operate in the usual way. The Appeal Board noted that each cases' circumstances might differ, and the result of any appeal could not be guaranteed. The reports for Case AUTH/3084/9/18 (Boehringer Ingelheim), Case AUTH/3091/9/18 (UCB), Case AUTH/3097/9/18 (Teva) and Case AUTH/3099/9/18 (Allergan), should be updated to reflect the situation and to cross refer to the cases which were successfully appealed. Allergan and UCB declined the opportunity to appeal. Boehringer Ingelheim and Teva successfully appealed the Panel's rulings of breaches of the Code.

A study published online in the British Medical Journal (12 September 2018) was entitled 'Compliance with requirement to report results on the EU Clinical Trials Register: cohort study and web resource' (Goldacre *et al* 2018).

The study objectives included assessing compliance rates with the European Commission's requirement that all trials on the EU Clinical Trials Register (EUCTR) posted results to the registry within 12 months of completion (final compliance date 21 December 2016). The study objectives also included identifying features associated with non-compliance, ranking sponsors by compliance and building a tool for live ongoing audit of compliance. The published paper listed the trial sponsors with the highest proportion of trials reported and the trial sponsors with the highest proportion of trials unreported. The results were that of 7,274 trials where results were due, 49.5% (95% confidence interval 48.4% to 50.7%) reported results. Results from trials with a commercial sponsor were substantially more likely to be posted than those from a non-commercial sponsor (68.1% v 11.0%, adjusted odds ratio 23.2, 95% confidence interval 19.2 to 28.2) as were trial results from a sponsor who conducted a large number of trials (77.9% v 18.4%, adjusted odds ratio 18.4, 15.3 to 22.1). More recent trials were more likely to report results (per year odds ratio 1.05, 95% confidence interval 1.03 to 1.07). Extensive evidence was found of errors, omissions, and contradictory entries in EUCTR data that prevented ascertainment of compliance for some trials.

The Director decided that the Goldacre *et al* article was such that she had received information from which it appeared that Pfizer might have breached the Code and decided in accordance with Paragraph 5.1 of the Constitution and Procedure to take the matter up as a complaint.

COMPLAINT

The study concluded that compliance with the European Commission requirement for all trials to post results on to the EUCTR within 12 months of completion had been poor, with half of all trials non-compliant. EU registry data commonly contained inconsistencies that might prevent even regulators assessing compliance. Accessible and timely information on the compliance status of each individual trial and sponsor might help to improve reporting rates.

Goldacre *et al* noted that any trial of any medicinal product conducted since 2004 in an EU country had already been required to register on the EUCTR, which was administered by the European Medicines Agency (EMA). Following the 2012 European Commission (EC) Guideline 2012/c302/03, sponsors must ensure that they disclosed their results of all trials registered on EUCTR since 2004 to the EMA within 12 months of trial completion; Phase I trials were exempt unless they were denoted as being part of a paediatric investigation plan. These trial reports were posted publicly on to the EUCTR within 15 working days of receipt by the EMA and were required to include salient features such as results for all pre-specified trial outcomes and statistical analyses, details of 'serious' and 'non-serious' adverse events, participants' baseline characteristics, and protocol deviations, as well as discussion of design limitations and caveats. Following various delays in the EMA's implementation of the software platform for results posting, the final date for sponsors' compliance was 21 December 2016.

Goldacre *et al* assessed compliance with the EU requirement to post results on to EUCTR for all trials on the registry, explored factors associated with non-compliance, identified the individual trial sponsors that were best at complying, and created a live online service, driven by regular updates of the EUCTR data, to give ongoing and regularly updated performance statistics for compliance.

The publication listed a number of variables.

Goldacre *et al* stated that the EUCTR data underlying this study were updated regularly. An interactive online website presenting the overall reporting rate for all due trials, the reporting rates for each sponsor, ranks for these reporting rates, and details of each sponsor's individual reported and unreported trials was developed. The data underlying this site was updated regularly following each new download of the EUCTR database: the results and ranks for each individual sponsor were therefore always current and changed as performance changed. All software underlying this service was shared as open source and available for open code review or for adaptation and re-use.

Goldacre *et al* stated that the European Commission (EC) Guideline required the results of all trials to be reported in structured form on to the register itself. Ascertainment of the outcome – a results report on EUCTR – was therefore accurate and complete. It was possible that some trials that did not report results to EUCTR reported results elsewhere eg in a conference presentation, an academic journal article, as part of a meta-analysis after data were requested by systematic reviewers, or in the grey literature. Such publications did not meet the reporting requirements of the EC Guideline and were therefore outside the scope of the study. A manual search of academic journals and grey literature for a random sample of 100 trials unreported on EUCTR was conducted as requested as part of the peer review of the publication. Five were reported in the grey literature and 46 in a journal publication.

Goldacre *et al* listed sponsors with more than 50 trials on the EUCTR and did not mention products or specific clinical trials. The study publication listed the sponsors with the highest proportion of trials reported and those with the lowest proportion of trials reported.

Goldacre *et al* gave details of disclosure of clinical trial results for each sponsor. The data for Pfizer were as follows:

Sponsors with highest proportion of trials reported

Sponsor	Total trials on EUCTR	Due trials	Due trials with results	% reported
Pfizer	744	168	161	95.8

When writing to Pfizer the Authority asked it to bear in mind the requirements of Clauses 2, 9.1, 1.11 and 13.1 of the Code. The Authority noted that previous editions of the Code might be relevant and provided details.

RESPONSE

Pfizer noted that the BMJ publication identified Pfizer as having published trial results for 161 of 168 trials and thus suggested that the results of 7 trials had not been reported.

The seven trials were as follows:

1 EudraCT number 2004-000035-28. This trial, on diclofenac sodium cutaneous spray, ended on 1 December 2004 and listed Wyeth Consumer Health as the sponsor. Wyeth was now a wholly owned subsidiary of Pfizer. The marketing authorization for the product (Spraymik) was held by Mika Pharma GmbH, in Germany. Wyeth Consumer Health entered into a licensing and know-how agreement with Mika Pharma GmbH on 4 December 2003 giving Wyeth the rights to develop and commercialise TDS-943 in certain territories of the world. The development programme covered by the agreement included this study (2004-000035-28) which was conducted and completed with Wyeth Consumer Health as the sponsor. Pfizer did not know the exact date that the product was first licensed but suggested that it was in March 2006. The first marketing authorization/renewal in the UK was 29 August 2008. Pfizer stated that no part of its organisation had ever held the marketing authorization or made the product commercially available anywhere in the world.

Pfizer submitted that, according to the PMCPA Disclosure decision tree, as the product was first licensed before 1 November 2008 and the study completed before 5 January 2005, it pre-dated the requirements of any Joint Position and was not covered by the Code.

2 Trial EudraCT number 2004-001586-18 was also on diclofenac sodium cutaneous spray. Pfizer submitted that, according to the PMCPA Disclosure decision tree, as the product was first licensed before 1 November 2008 and the trial was completed on 19 May 2005 which was between 5 January 2005 and 31 October 2008, it was not covered by the Code but was in scope of the Joint Position 2005.

3 Trial EudraCT number 2004-001637-41 involved Sinutab tablets, but the trial was cancelled before any subjects were recruited so there were no results to publish. Pfizer stated that it

and other sponsors were discussing with the EMA as to whether sponsors could directly notify the EMA of trial status updates.

4 Trial EudraCT number 2004-003727-12 was a trial on Refacto (moroctacog alfa) which was first licensed on 13 April 1999 but as above, the trial was cancelled prior to subject recruitment commencing meaning that the results were not due for this trial.

5 Trial EudraCT number 2007-005695-14 involved an investigational compound (PSI-697). The development programme for PSI-697 was terminated and so the product did not progress to marketing authorization and was never commercially available. Pfizer stated that in that regard, and with reference to the PMCPA Disclosure decision tree (May 2017), there was no requirement to disclose any trial results. The trial ended on 8 July 2008.

6 Trial EudraCT number 2008-004088-21 was also on an investigational compound (CP945598); again, the development programme was terminated and the product was never licensed or commercially available. The trial in question was cancelled before subject recruitment and so there were no results to publish. Pfizer submitted that there was no requirement to publish any trial results for this compound.

7 Trial EudraCT number 2010-022955-43 involved Lyrica (pregabalin) which was first licensed in July 2004. The trial, however, was cancelled prior to subject recruitment commencing so no results were due.

In conclusion, Pfizer did not consider that there were any breaches of the Code associated with the studies described above. The studies identified were either cancelled prior to subject recruitment, involved assets that were not licensed and made commercially available or were studies that were not covered by the Code.

PANEL RULING

The Panel noted that Goldacre *et al* was not the subject of external complaint but was taken up under Paragraph 5.1 of the Constitution and Procedure.

General comments

The Panel noted that Goldacre *et al* was the basis of the complaint in relation to the allegation that sponsors with less than 100% reported trials were not meeting the requirements of the EC Guideline.

The Panel noted that all the cases would be considered under the Constitution and Procedure in the 2016 Code as this was in operation when Goldacre *et al* was published and the complaint proceedings commenced.

The Panel noted that there had been three previous studies looking at the disclosure of clinical trial data all published in Current Medical Research and Opinion (CMRO). The first study was the subject of an external complaint which gave rise to 27 cases in 2013 and 2014. The second study (Rawal and Deane 2015) was not the subject of external complaint but was taken up under Paragraph 5.1 of the Constitution and Procedure in 2015 and led to 15 cases. The third study (Deane and Sivarajah 2016) was not the subject of external complaint but was also taken up under Paragraph 5.1 in 2016 and led to 17 cases. Most of these cases were not in breach of

the Code because they were not within the scope of the Code as there was no UK involvement and therefore only limited details were published on the PMCPA website.

The previous studies surveyed various publicly available information sources for clinical trial registration and disclosure of results searched between specific dates covering medicines (except vaccines) that were approved by the European Medicines Agency (EMA) in a particular year or years. The Panel noted that the previous cases had established a number of principles including deciding which Code applied.

Goldacre *et al* was different to the previous three studies which assessed compliance with the Joint Positions; it only assessed compliance with the EU requirement to post results on to the European Union Clinical Trial Register (EUCTR) for all trials listed on the registry. In that regard, trials involving investigational products that were not licensed for use anywhere in the world might be included. Companies had not made a detailed submission on this point.

The Panel noted that the European Clinical Trials Database (EudraCT) was a database hosted by the EMA in which clinical trial sponsors would upload summary results. These results would then be published on the EUCTR.

The Panel considered that in these circumstances the trial completion date would be the trigger for results disclosure on EUCTR. The Panel noted that the publicly available EudraCT and EUCTR Q&A document stated in response to the question 'if the trial is prematurely ended/early terminated due to lack of subjects or lack of data to analyse, do I have to provide results?', that in the case that no subjects were recruited, it was not appropriate to complete the full dataset. However, there was currently no functionality for sponsors to inform that recruitment never started or that the trial was prematurely ended in the results data model. In this specific case sponsors had to liaise directly with the National Competent Authority confirming that no results would be available for a specific trial due to 'lack of subjects' or that the trial was 'prematurely ended' so a statistical analysis could not be provided. The Panel noted that according to the Commission Guideline 'Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) and Regulation No 726/2001 and Article 41(2) of Regulation No 1901/2006', if the clinical trial ends prematurely, that date should be considered the end of trial date.

The Panel noted that according to Goldacre *et al* any trial of any medicinal product conducted since 2004 in an EU country had already been required to register on the EUCTR, which was administered by the European Medicines Agency (EMA). Following the 2012 European Commission (EC) Guideline 2012/c302/03, sponsors must ensure that they disclosed the results of all trials registered on EUCTR since 2004 to the EMA within 12 months of trial completion; Phase I trials were exempt unless they were denoted as being part of a paediatric investigation plan. These trial reports were posted publicly on to the EUCTR within 15 working days of receipt by the EMA and were required to include salient features. Goldacre *et al* noted that following delays in the EMA's implementation of the software platform for results posting, the final date for sponsors' compliance was 21 December 2016.

The Panel considered that the subject matter of the complaint was failure to publish results on EUCTR. It appeared to the Panel that under EUCTR for non-paediatric trials, at least one investigator site of the clinical trial should be located in Europe or in a contracting state of the European Economic Area (EEA). The Panel noted that it could only consider the matter with

regard to the Code. In the Panel's view, only those with a UK nexus would be considered to be within the scope of the Code.

The Panel noted that the Code did not explicitly refer to publication on the EUCTR. Clause 13.1 referred, *inter alia*, to disclosure of clinical trials in accordance with the Joint Positions on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the Publication of Clinical Trial Results in the Scientific Literature. According to the 2009 Joint Position, publication of clinical trial results in any free, publicly accessible internet-based clinical trials database should achieve the intended objectives.

The Panel noted the differences between the Joint Positions and the requirement to publish clinical trial results on the EUCTR; it was possible that results might not need to be published under the Joint Positions (for instance because the medicine was not licensed for use or commercially available) but might nonetheless be required to be published on the EUCTR. The Panel considered that companies would be well advised to ensure that all the clinical trial results were disclosed as required by the law, codes and Joint Positions. The Panel noted that Goldacre *et al* had not commented on whether the results disclosed met the requirements of the Joint Positions so this was not considered; in the Panel's view, the only matter for consideration was whether or not trial results had been disclosed within the required timeframe as required by the Commission Guideline 2012/C302/03 which came into operation in 2012, and by 21 December 2016 which was referred to by Goldacre *et al* as the final data for sponsor's compliance. The Panel considered, therefore, that in this particular case it would make its rulings under the Code in operation on 21 December 2016, the 2016 Code. The Panel considered that its approach was a fair one.

The Panel noted that the companies had been asked to respond, *inter alia*, to Clause 13.1. Given that Goldacre *et al* did not refer to the Joint Positions and noting the differences between the requirements to disclose under the Joint Positions and under the Commission Guidelines the Panel considered, taking a pragmatic approach, that the matters raised by Goldacre *et al* would be considered under Clause 9.1, rather than Clause 13.1. The companies had been asked to respond to, *inter alia*, Clauses 9.1 and 1.11 at the outset and had been provided with a copy of Goldacre *et al*. The Panel noted that the publicly available EudraCT and EUCTR Q&A document referred to sponsors who were not fulfilling the legal requirements in providing results in EudraCT.

The Panel considered that the first issue to be determined was whether the matter was covered by the ABPI Code. If the clinical trial was conducted on behalf of a UK pharmaceutical company (whether directly or via a third party) then it would be covered by the ABPI Code. If a trial was run by a non-UK company but had UK involvement such as centres, investigators, patients etc it was likely that the Code would apply. The Panel appreciated the global nature of much pharmaceutical company sponsored clinical research and a company located in the UK might not be involved in research that came within the ABPI Code. It was a well-established principle that UK pharmaceutical companies were responsible for the activities of overseas affiliates if those activities came within the scope of the Code such as those related to UK health professionals or carried out in the UK.

The Panel noted that the Authority was not an investigative body as such and its consideration of these cases relied upon the information provided by the parties. The quantitative data published by Goldacre *et al* formed the basis of the complaint. The Panel noted that in that

regard the case preparation manager had not used the live data web resource to identify the trials at issue.

Panel ruling in Case AUTH/3079/9/18

The Panel noted its general comments above about the subject matter of the complaint as set out in Goldacre *et al.* The Panel had decided that the alleged failure to publish results in accordance with the Commission Guidelines was more appropriately covered by Clause 9.1 and potentially Clause 1.11. The Panel made no ruling in relation to Clause 13.1.

The Panel noted the data in Goldacre *et al* in that the results of seven of Pfizer's due trials had not been reported on EUCTR; the disclosure percentage was 95.8%.

The Panel noted Pfizer's submission that trials 2004-000035-28 and 2004-001586-18 involved diclofenac sodium cutaneous spray which was first licensed and commercially available before 1 November 2008 and the trials ended on 1 December 2004 and 19 May 2005 respectively and therefore pre-dated the requirements of any joint position and were not covered by the Code. However, the Panel noted the nature of the complaint as set out in it general comments above. According to Goldacre *et al* the results had not been published and Pfizer had not asserted that the trials had no UK nexus or provided any other explanation about why the trials were not published on the EUCTR according to the EU Guideline. The Panel therefore ruled a breach of Clause 9.1 in relation to trials 2004-000035-28 and 2004-001586-18. The Panel noted from the evidence before it that there did not appear to have been any formal finding by any judicial authority or appropriate body charged with determining matters in relation to the Commission Guidelines that the company had not complied with the relevant laws and regulations. The Panel therefore ruled no breach of Clause 1.11 in relation to these two trials. The Panel was unsure whether or not the results were now disclosed on EUCTR or elsewhere. On balance, the Panel did not consider that in the circumstances a breach of Clause 2 was warranted and ruled accordingly.

The Panel noted that trial EudraCT number 2004-001637-41 involved Sinutab tablets. The Panel noted Pfizer's submission that the current SPC for Sinutab 500/30mg tablets indicated that the date of first authorisation/renewal of the authorisation was 23 February 2011. The end of trial date was listed as 25 March 2008.

The Panel noted Pfizer's submission that the trial was cancelled before any subjects were recruited so there were no results to publish. The Panel noted that there were no results to publish. The Panel therefore ruled no breach of Clauses 1.11. 9.1 and 2.

The Panel noted that trial EudraCT number 2004-003727-12 involved Refacto (moroctacog alfa). The Panel noted that from the information provided by Pfizer it appeared that Refacto was first licensed on 13 April 1999 in the EU. The end of trial date was listed as 23 November 2005. The Panel noted that the trial was cancelled before any subjects were recruited. The Panel therefore ruled no breach of Clauses 1.11. 9.1 and 2.

The Panel noted that trial EudraCT number 2007-005695-14 which involved an investigational compound (PSI-697) ended on 8 July 2008. The Panel noted Pfizer's submission that the development programme for PSI-697 was terminated and so the product did not progress to marketing authorization and was never commercially available and therefore there was no

requirement to disclose the trial results under the Joint Positions as set out in the PMCPA decision tree. However, the Panel noted the nature of the complaint as set out in its general comments above.

The Panel noted that the results did not appear to be published on EUCTR within the required timeframe. The Panel therefore ruled a breach of Clause 9.1. The Panel noted from the evidence before it that there did not appear to have been any formal finding by any judicial authority or appropriate body charged with determining matters in relation to the Commission Guidelines that the company had not complied with the relevant laws and regulations. The Panel therefore ruled no breach of Clause 1.11 in relation to this trial. The Panel was unsure whether or not the results were now disclosed on EUCTR or elsewhere. On balance, the Panel did not consider that in the circumstances a breach of Clause 2 was warranted and ruled accordingly.

The Panel noted that trial 2008-004088-21 also involved an investigational compound (CP945598); again, the development programme was terminated and the product was never licensed or commercially available. The Panel noted that the trial was cancelled on 9 September 2008 prior to subject recruitment and so there were no results to report. The Panel therefore ruled no breach of Clauses 1.11, 9.1 and 2.

The Panel noted that trial 2010-022955-43 involved Lyrica (pregabalin) which was first licensed in July 2004. The trial, however, was cancelled prior to subject recruitment. The end of trial date was listed as 4 April 2012. There were no results to disclose. The Panel therefore ruled no breach of Clauses 1.11, 9.1 and 2.

APPEAL BY PFIZER

Pfizer submitted that the rulings of breaches of Clause 9.1 in relation to trials 2004-000035-28, 2004-001586-18 and 2007-005695-14 were inappropriate for the following reasons:

1 **Applicability of the Code:** It was not within the PMCPA's jurisdiction to rule Pfizer in breach of the Code on matters that were not described in the Code. The rulings of breaches of Clause 9.1 in this case were inappropriate and extended beyond the remit of the PMCPA in administering the Code.

2 **Specific details of the studies and assets in question:**
   i) Pfizer was not responsible for posting results for trials 2004-000035-28 and 2004-001586-18 as all rights and responsibilities related to TDS-943 were returned to Mika Pharma GmbH in 2008.
   ii) Trial 2007-005695-14 was a phase I pharmacokinetic trial in healthy subjects and as such according to EC Guideline 2012/c302/03, the trial results did not require disclosure on the EUCTR.

Applicability of the Code

Pfizer submitted that since the 2008 edition of the Code, companies had been required to disclose clinical trial results according to the commitments set out in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (The Joint Position). With each revision of the Joint Position, the subsequent edition of the Code had been updated to reference the latest Joint Position, and the PMCPA had only held companies to

account against the requirements of the Joint Position referenced in the relevant edition of the Code. This was reflected in the PMCPA Clinical Trial Disclosure Decision Tree which showed a delay between the Joint Position date and applicable edition of the Code. Pfizer was not aware of any instances of companies being found in breach of Clause 9.1 for not meeting the requirements of the current Joint Position, prior to that version of the Joint Position being referenced in the Code.

Clause 13.1 of both the 2016 and 2019 Codes required that companies disclose details of clinical trials in accordance with the Joint Position.

Pfizer noted the EC Guideline 2012/c302/03 – Guidance on posting and publication of results-related information on clinical trials was published on 6 October 2012. As described in Goldacre *et al* implementation of the guidance was delayed until the European Medicines Agency had completed programming of the relevant databases, which resulted in a final date for compliance with the guidance being 21 December 2016.

At no point since the publication of this guideline in 2012 or the final implementation date for disclosure of trial results in 2016, had any reference to the requirements of EC Guideline 2012/c302/03 been added to the provisions within the Code relating to disclosure of clinical trial results.

Pfizer's interpretation of the Code:

Whist Pfizer recognised that companies must act in accordance with all applicable regulations and laws irrespective of what was specified in the UK Code, it submitted that surely it was for the European Commission to scrutinise companies' implementation of EC regulations and not a third party. If the PMCPA considered that it had a responsibility to hold companies to account against the specific requirements of EC Guideline 2012/c302/03 then this should be set out within the Code, particularly given that the requirements of the Joint Position referred to in the Code were substantially different to those of the EC Guideline.

Key differences between EC Guideline 2012/c302/03 and the Joint Position 2009:

Pfizer submitted that the EC Guideline did not require disclosure of phase I trials that were not part of a paediatric investigation plan (PIP) (Section 5), whereas the Joint Position required disclosure of all interventional trials in human subjects from Phase 1 and beyond. The EC Guideline required disclosure of results irrespective of whether an asset had been commercialised (Section 2), whereas the Joint Position only required disclosure of results of trials associated with assets that had been approved for marketing and were commercially available in at least one country. Pfizer stated that it was not within the PMCPA's jurisdiction to rule companies in breach of the Code on matters that were not described in the Code.

Pfizer submitted that as the Panel noted Goldacre *et al* did not refer to the Joint Position as described in the Code and, therefore, despite asking companies to respond to Clause 13.1 of the Code, the Panel decided that it was not appropriate to rule on this clause. The Panel also acknowledged that no formal findings had been made by anybody charged with determining matters in relation to the EC Guideline and ruled no breaches of Clause 1.11. The Panel, however, continued to consider the matter under Clause 9.1 despite no breaches being ruled of any specific clause of the Code. Pfizer understood Clause 9.1 to require companies to maintain high standards in relation to the provisions set out in the Code. The supplementary information

to Clause 9.1 specifically referred to the promotion of medicines and gave no indication that this clause might be applied much more broadly to matters not set out within the Code. The application of Clause 9.1 in this broad manner set a concerning precedent preventing companies from being able to identify the full remit of the Code.

Pfizer submitted that the rulings of breaches of Clause 9.1 in this case were inappropriate and extended beyond the remit of the PMCPA in administering the Code.

Specific details of the studies and assets in question

Pfizer submitted that in its response to the complaint it provided evidence for why each of the 7 trials identified by Goldacre *et al* were in fact out of scope of the Code. Due to the complex nature of this matter, for each trial highlighted the simplest and most comprehensive reason for the trial being considered out of scope of the Code. Given that the PMCPA had applied Clause 9.1 in a much broader capacity than Pfizer had anticipated, it highlighted other details for the 3 trials ruled in breach of Clause 9.1, that further explained why the results were not posted by Pfizer on the EUCTR and why the rulings of breaches of Clause 9.1 were inappropriate.

Trial 2004-000035-28 and 2004-001586-18

Pfizer submitted that in its response to the complaint, it had identified these two as being out of scope of the Code according to the PMCPA Disclosure Decision Tree (May 2017) by virtue of the fact that they were completed prior to 31 October 2008, predating any Code requirements for the disclosure of clinical trial results. Further to this, Pfizer highlighted the following relevant information:

Pfizer submitted that Wyeth Consumer Health had entered into a 'licensing and know-how agreement' with Mika Pharma GmbH on 4 December 2003 giving Wyeth the rights to develop and commercialise TDS-943 in certain territories of the world. The agreement included the two trials which were conducted and completed with Wyeth Consumer Health as the sponsor. Wyeth Consumer Health terminated the agreement with Mika Pharma GmbH on 18 July 2008, returning all rights including those related to all data, reports, records and materials related to the clinical programme to Mika Pharma GmbH. The termination of this agreement predated Pfizer's acquisition of Wyeth by 14 months. Neither Wyeth Consumer Health nor subsequently any part of the Pfizer organisation had ever been the Marketing Authorisation Holder (MAH) for TDS-943, nor had either made the product commercially available anywhere in the world.

Pfizer submitted that in Case AUTH/3119/11/18, Pfizer was held responsible for disclosure of clinical trial data related to an asset acquired from another named company following the completion of study 2005-000768-19. This case was ruled out of scope of the Code based on lack of UK involvement in the study. However, Pfizer understood by the fact that the PMCPA referred the complaint to Pfizer, which had acquired the asset and all its rights and responsibilities, that the PMCPA saw responsibility for disclosure of clinical trial results as sitting with the MAH and asset owner, Pfizer, rather than the original trial sponsor. Based on this precedent Pfizer believed that responsibility for disclosure of trials 2004-000035-28 and 2004-001586-18 lay with Mika Pharma GmbH and not Pfizer Ltd as the asset TDS-943 was returned to Mika Pharma GmbH along with all rights, including those related to all data, reports, records and materials related to the clinical programme. The ruling of breaches of Clause 9.1 against Pfizer in relation to these two trials, for which it was not the MAH, was inappropriate.

Pfizer submitted that it was fully committed to disclosure of clinical trial data and had since contacted Mika Pharma GmbH to facilitate the disclosure of these trial results. Pfizer did not have ultimate responsibility for the disclosure of the results of these two trials, with the permission of Mika Pharma GmbH it had posted a public disclosure synopsis for the results of each of these two trials.

Trial	2004-000035-28
EudraCT/EU Trial tracker Trial ID	2004-000035-28
ClinicalTrials.gov ref	Not listed
Sponsor Protocol Number PFE	TD-04-06
Investigational Medicinal Product	TDS-943 SPRAYMIK 4% diclofenac sodium cutaneous spray
Study Sponsor	Wyeth Consumer Healthcare (Wyeth was now a wholly owned subsidiary of Pfizer)
Study Title	TDS-943 Maximum use tolerance study
EUCTR End of Trial status	Completed
EUCTR Date of global end of the trial	1 December 2004
Marketing Authorisation Holder (MAH)	MIKA Pharma GmbH Auestraße 39, 67346 Speyer, Germany PL 18017/0008
Date product was first licensed	Pfizer submitted that it did not have direct access to this information as the MAH was Mika Pharma GmbH. The current MIKA Pharma UK Spraymik SPC indicated that date of first marketing authorisation/renewal of authorisation in the UK was 29 August 2008. Day 90 of the Public Assessment Report was 6 February 2006 suggesting that marketing authorisation was granted in the Concerned Member States (CMS) in March 2006.
Relevant study Information relating to disclosure of trial results	Pfizer submitted that according to the PMCPA Disclosure Decision Tree (May 2017) as the product was first licensed before the 1 November 2008 and the trial was completed before 5 January 2005, it predated the requirement of any Joint Position and was not covered by the Code. Wyeth Consumer Health terminated the 'licensing and know-how agreement' with Mika Pharma GmbH on 18 July 2008 returning all rights including those related to all data, reports, records and materials related to the clinical programme to Mika Pharma GmbH. Responsibility for disclosure of the trial results after the termination of this agreement rested with Mika Pharma GmbH the MAH.
Pfizer explanatory note	Pfizer submitted that Wyeth Consumer Health entered into a 'licensing and know-how agreement' with Mika Pharma

	GmbH on 4 December 2003 giving Wyeth the rights to develop and commercialise TDS-943 in certain territories of the world. The development programme covered by the agreement included this trial (2004-000035-28) which was conducted and completed with Wyeth Consumer Health as the sponsor. Wyeth Consumer Health terminated the agreement with Mika Pharma GmbH on 18 July 2008 returning all rights including those related to all data, reports, records and materials related to the clinical programme to Mika Pharma GmbH. Neither Wyeth Consumer Health nor subsequently any part of Pfizer had ever been the marketing authorisation holder for TDS-943 nor had either made the product commercially available anywhere in the world.
Pfizer actions undertaken	Pfizer submitted that following the launch of the EU Trials Tracker in September 2018, the Pfizer Global Clinical Trial Disclosure Group identified this study as not having results available on the EUCTR despite the study having been listed as completed. Prior to investigations related to this complaint, Pfizer had already contacted Mika Pharma GmbH with the intention of working with it to post any available results for this trial on the EUCTR. With Mika Pharma's permission Pfizer had now posted TD-04-06_Public Disclosure Synopsis.

Trial	2004-001586-18
EudraCT/EU Trial tracker Trial ID	2004-001586-18
ClinicalTrials.gov ref	Not listed
Sponsor Protocol Number PFE	TD-04-14
Investigational Medicinal Product	TDS-943 SPRAYMIK 4% diclofenac sodium cutaneous spray
Trial Sponsor	Wyeth Consumer Healthcare (Wyeth was now a wholly owned subsidiary of Pfizer)
Trial Title	A safety trial of TDS-943
EUCTR End of Trial status	Completed
EUCTR Date of global end of the trial	19 May 2005
Marketing Authorisation Holder (MAH)	MIKA Pharma GmbH Auestraße 39, 67346 Speyer, Germany PL 18017/0008
Date product was first licensed	Pfizer submitted that it did not have direct access to this information as the MAH was Mika Pharma GmbH.

	Pfizer submitted that the current UK SPC indicated that the date of first marketing authorisation/renewal of authorisation in the UK was 29 August 2008. The Public Assessment report data suggesting that marketing authorisation was granted in the Concerned Member States in March 2006.
Relevant trial Information relating to disclosure of trial results	Pfizer submitted that according to the PMCPA Disclosure Decision Tree (May 2017) as the product was first licensed before the 1 November 2008 and the trial was completed between 5 January 2005 and 31 October 2008, it was not covered by the Code but was in scope of the Joint Position 2005. Wyeth Consumer Health terminated the 'licensing and know-how agreement' with Mika Pharma GmbH on 18 July 2008 returning all rights including those related to all data, reports, records and materials related to the clinical programme to Mika Pharma GmbH. Responsibility for disclosure of the trial results after the termination of this agreement rested with Mika Pharma GmbH the MAH.
Pfizer Explanatory note	Pfizer submitted that Wyeth Consumer Health entered into a 'licensing and know-how agreement' with Mika Pharma GmbH on 4 December 2003 giving Wyeth the rights to develop and commercialise TDS-943 in certain territories of the world. The development programme covered by the agreement included this study (2004-001586-18) which was conducted and completed with Wyeth Consumer Health as the sponsor. Wyeth Consumer Health terminated the agreement with Mika Pharma GmbH on 18 July 2008 returning all rights including those related to all data, reports, records and materials related to the clinical programme to Mika Pharma GmbH. Neither Wyeth Consumer Health nor subsequently any part of Pfizer had ever been the marketing authorisation holder for TDS-943 nor had either made the product commercially available anywhere in the world.
Pfizer actions undertaken	Pfizer submitted that following the launch of the EU Trials Tracker in September 2018, the Pfizer Global Clinical Trial Disclosure Group identified this trial as not having results available on the EUCTR despite the trial having been listed as completed. Prior to investigations related to this complaint, Pfizer had already contacted Mika Pharma GmbH with the intention of working with it to post any available results for this trial on the EUCTR. With

	Mika Pharma's permission Pfizer had now posted TD-04-14 Public Disclosure Synopsis.

Trial 2007-005695-14

Pfizer submitted that in its response to the complaint, it had identified trial 2007-005695-14 as being out of scope of the Code according to the PMCPA Disclosure Decision Tree (May 2017) by virtue of the fact that asset PSI-697 was not licensed and made commercially available in any country in the world. Further to this Pfizer highlighted additional information related to the classification of this trial. This trial was incorrectly classified as a therapeutic exploratory phase II trial on the EUCTR. Pfizer's records indicated that it was a phase I trial designed with a primary objective of assessing the pharmacodynamics of PSI-697. PSI-697 Abridged CSR was posted on the EUCTR on 29 November 2018 confirming that this was a phase I healthy volunteer pharmacodynamic trial. The trial was not part of a paediatric investigation plan and was therefore exempt from the requirements for public disclosure under EC Guideline 2012/c302/03. Pfizer submitted that the ruling of a breach of Clause 9.1 in relation to this phase I trial was incorrect.

Trial	2007-005695-14
EudraCT/EU Trial tracker Trial ID	2007-005695-14
ClinicalTrials.gov ref	Not listed
Pfizer Protocol Number PFE	3165A1-1108-EU
Investigational Medicinal Product (IMP)	PSI-697 2-(4-chlorobenzyl)-3-hydroxy-7, 8, 9, 10-tetrahydrobenzo [h] quinoline-4-carboxylic acid monohydrate
Trial Sponsor	Wyeth Research Division of Wyeth Pharmaceuticals Inc
Trial Title	A Double-Blind, Placebo-Controlled, Randomized, Single-Dose, 2-Period Crossover Trial of the Pharmacodynamics of Orally Administered PSI-697 in Healthy Subjects Who Smoke
EUCTR End of Trial status	Completed
EUCTR Date of global end of the trial	8 July 2008
Marketing Authorisation Holder (MAH)	N/A. This development programme was terminated and the asset was not progressed to marketing authorisation and was not made commercially available.
Date product was first licensed	N/A.
Relevant trial Information relating to disclosure of trial results	Pfizer submitted that according to the PMCPA Disclosure Decision Tree (May 2017), as PSI-697 was not licensed and made commercially available there was no requirement to disclose any trial results. It was a phase I trial designed to assess the pharmacodynamics of a single oral dose of PSI-697 in

	healthy subjects who smoke. Trial 2007-005695-14 was not part of a Paediatric Investigation Plan and as such the results did not require disclosure under EC Guideline 2012/c302/03.
Pfizer Explanatory note	Pfizer submitted that this trial was classified as a therapeutic exploratory phase II trial on the EUCTR. Pfizer submitted that its records indicated that the trial was actually a phase I trial designed to assess the pharmacodynamics, safety and pharmacokinetics of PSI-697. The trial was therefore exempt from the requirements to disclose results under the EC Guideline 2012/c302/03.
Pfizer actions undertaken	Pfizer submitted that following the launch of the EU Trials Tracker in September 2018, the Pfizer Global Clinical Trial Disclosure Group had identified this trial as not having results posted despite the trial having a completed status on the EUCTR. Although not a requirement for this phase I trial, PSI-697 Abridged CSR had now been posted on the EUCTR. Pfizer submitted that it was exploring how to correct the classification of this trial in the protocol listed on the EUCTR.

APPEAL BOARD RULING

The Appeal Board noted that a series of cases had been taken up by the PMCPA as a result of the data published in Goldacre *et al*. Four cases were the subject of an appeal by the respondent companies. Each would be determined on their own merits but there were a number of common themes.

The Appeal Board noted that Goldacre *et al* formed the basis of the complaint. Goldacre *et al* did not refer to disclosure of clinical trial results and the Joint Position which was covered by Clause 13.1 of the Code. The article assessed companies' compliance with EC Guideline 2012/c302/03. The Appeal Board noted that disclosure of clinical trial results on EUCTR was not mentioned in Clause 13 and its supplementary information, or indeed elsewhere in the Code. The Appeal Board noted that the Code was not exhaustive and in such circumstances the Appeal Board did not consider it unreasonable to consider the subject matter of the complaint in relation to Clause 9.1. In this regard the Appeal Board noted the long-established broad application of Clause 9.1 to promotional and non-promotional materials and activities including matters within the scope of the Code but not expressly referred to. The Appeal Board did not consider that a ruling of a separate clause was required as a condition precedent to ruling under Clause 9.1; in the Appeal Board's view, Clause 9.1 could be ruled upon in isolation.

The Appeal Board noted that Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006 required that clinical trial data be published on EUCTR. European Commission (EC) Guideline 2012/c302/03 gave guidance as to when the clinical trial results data should be published. According to the EC Guideline posting of results of clinical trials which ended one year or more prior to finalisation of the programming of the relevant

database, should be done within 24 months of finalisation of that programming. According to the 'What's New' section of the EudraCT public website (post-dated 13 January 2016), the deadline for submission of these results was 21 December 2016. This date was referred to in Goldacre *et al*. In this regard, it appeared to the Appeal Board that whilst the regulation mandated disclosure of results on EUCTR, the EC Guideline and other material advised companies how to comply with the regulation including in relation to the timing of such disclosures. The Appeal Board considered that it was within the spirit of the Code and good practice to comply with the guideline in question.

The Appeal Board noted that, where companies had merged or the rights to a particular product had been bought or sold, there appeared to be difference of opinion as to which company would be responsible for posting the retrospective results. There were also said to be difficulties in correcting information once posted.

The Appeal Board also noted that, according to Goldacre *et al*, Phase I trials that were not part of a paediatric plan did not need to be disclosed.

The Appeal Board noted that Goldacre *et al* assessed all relevant trials on the EUCTR database including those with no UK nexus which were not covered by the Code. There might therefore be a difference between a company's overall disclosure rate and the disclosure rate of those clinical trials with a UK nexus. The results of trials on the registry which did not have a UK nexus and were not disclosed still needed to be disclosed on the registry and the failure to do so would potentially be covered by another code of practice in the relevant jurisdiction.

The Appeal Board noted Pfizer had published trial results for 161 of 168 trials. The Appeal Board noted the data in Goldacre *et al* in that the results of 7 of Pfizer's due trials had results due and yet they had not been reported on EUCTR; the disclosure percentage was 95.8%. Information provided by Pfizer did not include any reference to whether or not there was a UK nexus for the three trials which went ahead and which were at issue in the appeal. (The other four trials identified by Goldacre *et al* were either cancelled or terminated.)

The Appeal Board noted that the Panel had ruled breaches of Clauses 9.1 for Pfizer's failure to disclose results by 21 December 2016 or within the required timeframe in relation to three trials (trials 2004-000035-28, 2004-001586-18 and 2007-005695-14) and these were the subject of the appeal.

The Appeal Board noted that whilst Pfizer's written appeal focused on the applicability of the Code, its presentation at the appeal focused on the specific details of the trials.

The Appeal Board noted Pfizer's appeal submission regarding trial 2007-005695-14 in that it had been incorrectly classified and was in fact a phase I pharmacodynamic trial in healthy subjects and as such according to EC Guideline the trial results did not require disclosure on EUCTR. The Appeal Board noted that the guideline did not mandate disclosure as implied by Pfizer and noted its comments above in this regard. The Appeal Board noted that, nonetheless, it did not appear to be a clinical trial disclosure which was mandated by the relevant regulations. The Appeal Board consequently ruled no breach of Clause 9.1 in relation to this trial. The appeal on this point was successful.

The Appeal Board noted that for trials 2004-000035-28 and 2004-001586-18 posting on EUCTR was delayed because the trials were related to the asset TDS-943 and all rights and

responsibilities related to this asset were returned to Mika Pharma GmbH, the marketing authorisation holder (MAH) in 2008 by Wyeth Research Division of Wyeth Pharmaceuticals Inc, prior to Wyeth's acquisition by Pfizer. The Appeal Board noted Pfizer's submission that each trial was conducted and completed with Wyeth Consumer Health as the sponsor. The Appeal Board noted that the results data had been returned to, and was held by, Mika Pharma at the time the results were due to be posted.

The Appeal Board considered that there would be a difference between action to deliberately hide clinical trial data or systematic failure resulting in non or late disclosure and late disclosure of results as part of a retrospective exercise contrary to non-mandatory timelines due to mitigating factors. The Appeal Board, nonetheless, noted its view above about good practice and disclosure in accordance with the EC Guideline.

The Appeal Board noted that prior to this complaint, the Pfizer Global Clinical Trial Disclosure Group had already contacted Mika Pharma GmbH with the intention of working with it to post any available results for these two trials (2004-000035-28 and 2004-001586-18) on EUCTR. Pfizer submitted that with Mika Pharma's permission, Pfizer had now posted these trials on EUCTR.

The Appeal Board was concerned about the failure to disclose the summary results of two trials (trials 2004-000035-28 and 2004-001586-18) on EUCTR within the timelines advised by the EC Guideline and other relevant advice. In the exceptional circumstances of this case, the Appeal Board did not consider that the late posting of the results of two trials on the EUCTR as part of a retrospective exercise warranted a breach of Clause 9.1. The Appeal Board ruled no breach of Clause 9.1 in relation to each trial. The appeal was successful.

Following its completion of the consideration of the appeals in this case and in Cases AUTH/3087/9/18 (GlaxoSmithKline), AUTH/3118/11/18 (Tesaro) and AUTH/3102/9/18 (Lilly) the Appeal Board noted that the respondent companies in Case AUTH/3084/9/18 (Boehringer Ingelheim), Case AUTH/3091/9/18 (UCB), Case AUTH/3097/9/18 (Teva), and Case AUTH/3099/9/18 (Allergan), accepted the Panel's rulings of breaches of the Code and had not appealed.

The Appeal Board agreed that Boehringer Ingelheim, UCB, Teva and Allergan should be contacted and informed of the outcome of the appeals in Cases AUTH/3079/9/18, AUTH/3087/9/18, AUTH/3118/11/18 and AUTH/3102/9/18. The PMCPA Constitution and Procedure did not cover this unusual situation where more than one company was involved in a similar set of circumstances and the Appeal Board had taken a different view to the Panel. Boehringer Ingelheim, UCB, Teva and Allergan should each be offered the opportunity to appeal out of time and the appeal process would operate in the usual way. The Appeal Board noted that each cases' circumstances might differ, and the result of any appeal could not be guaranteed. The reports for Case AUTH/3084/9/18 (Boehringer Ingelheim), Case AUTH/3091/9/18 (UCB), Case AUTH/3097/9/18 (Teva) and Case AUTH/3099/9/18 (Allergan), should be updated to reflect the situation and to cross refer to the cases which were successfully appealed. Allergan and UCB declined the opportunity to appeal. Boehringer Ingelheim and Teva successfully appealed the Panel's rulings of breaches of Clause 9.1.

Complaint received 12 September 2018

Case completed **18 September 2019**