

ANONYMOUS, NON-CONTACTABLE EX-EMPLOYEE v CHUGAI

Consultancy arrangements

An anonymous, non-contactable complainant who described themselves as an ex-employee and as the complainant in Case AUTH/2749/2/15, contacted the Authority stating that he/she was disappointed in the outcome of that case. The complainant noted the Panel's reference to the previous complaint not being backed with any evidence. In light of this, the complainant submitted a complaint that was closely similar to that in Case AUTH/2749/2/15 and referred to specific pieces of new evidence that were available to support this complaint but did not provide any of them. The complainant hoped Chugai would conduct a more rigorous investigation this time.

A summary of the detailed response from Chugai is given below.

The Panel noted that anonymous and non-contactable complaints were accepted and like all complaints, judged on the evidence provided by the parties. Complainants had the burden of proving their complaint on the balance of probabilities.

The Panel noted that Case AUTH/2749/2/15 included *inter alia*, allegations about consultancy arrangements with a named individual. In that case, the Panel had ruled a breach of the Code on one matter but no breach of the Code on other matters raised. The Panel had made it clear that the complainant had not provided any evidence to support his/her allegations.

The Panel noted Chugai's comments about the decision under Paragraph 5.2 of the Constitution and Procedure to allow the present complaint to proceed. Paragraph 5.2 detailed the situations where a matter closely similar to one which had been the subject of a previous adjudication could be allowed to proceed: these were, at the discretion of the Director, where new evidence was adduced or if the passage of time or change in circumstances raised doubts as to whether the same decision would be made about the current complaint. The Director should normally allow a complaint to proceed if it covered matters similar to those in a decision of the Panel where no breach of the Code was ruled and which was not the subject of appeal. The case preparation manager had noted that the no breach rulings in the previous case were not the subject of an appeal and thus referred the entire case to the Panel for consideration.

The Panel noted that it was not possible to contact the complainant for more information. The complaint appeared to consist largely of references to evidence which the complainant had not provided. Given the Constitution and Procedure and that the previous case had made both the burden of proof, and the

need for the complainant to provide evidence clear, the Panel queried why no evidence had been provided in the present case. The burden was firmly on the complainant in that regard.

Noting its comments above and the complete absence of evidence the Panel considered that as in the previous case the complainant had failed to demonstrate a breach of the Code on several matters. No breach of the Code was ruled.

The Panel noted, however, that the previous case included a ruling of a breach of the Code in relation to one matter regarding the arrangements with the consultant and considered that the rulings in the previous case about the consultancy applied here including the breach of the Code. This ruling was appealed by Chugai.

The Panel noted that in the previous case, although it had some concerns about the consultancy arrangements it considered that Chugai had not brought discredit upon, or reduced confidence in the pharmaceutical industry. The Panel noted its rulings above in the present case and again ruled no breach of Clause 2.

The Panel did not consider that the complainant had shown that Chugai's response to Case AUTH/2749/2/15 was inadequate; no breach of the Code was ruled. In the Panel's view the manner in which Chugai had responded to Case AUTH/2749/2/15 was not such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. No breach of Clause 2 was ruled.

With regard to Chugai's appeal, the Appeal Board noted Paragraph 5.2 of the Constitution and Procedure included:

'If a complaint concerns a matter closely similar to one which has been the subject of a previous adjudication, it may be allowed to proceed at the discretion of the Director if new evidence is adduced by the complainant or if the passage of time or a change in circumstances raises doubts as to whether the same decision would be made in respect of the current complaint. The Director should normally allow a complaint to proceed if it covers matters similar to those in a decision of the Panel where no breach of the Code was ruled and which was not the subject of appeal to the Appeal Board.'

The Appeal Board noted that the case preparation manager appeared to have relied only on the second sentence so that as no breach of the Code

had been ruled in Case AUTH/2749/2/15, the matters now at issue in Case AUTH/2790/8/15 were referred to the Panel.

In the Appeal Board's view the first sentence of the relevant section of Paragraph 5.2 above was a condition precedent. The Director had to decide that the conditions set out in that sentence had been met before exercising any discretion as to whether a complaint about a matter closely similar to one which had been the subject of a previous adjudication should be allowed to proceed.

The Appeal Board noted that the matters now at issue were closely similar to those raised in Case AUTH/2749/2/15. The questions to be considered were 'Had new evidence been adduced?' or 'Had the passage of time or a change in circumstances raised doubts as to whether the same decision would be made?'. The Appeal Board considered that no new evidence had been provided by the anonymous complainant who, as previously, had chosen to be non-contactable. The Appeal Board considered that this was extremely regrettable given that in Case AUTH/2749/2/15 the Panel had criticised the lack of evidence provided by the complainant and had noted that he/she had the burden of proving his/her complaint on the balance of probabilities. The Appeal Board also noted that the complainant referred to providing evidence upon publication of the Panel's ruling. The complainant should have provided any such evidence with the complaint. The Appeal Board noted that Chugai had not identified any new material in its response to Case AUTH/2790/8/15. The Appeal Board noted that the current complaint was received only three months after the completion of the previous case and there was apparently no change in circumstances. In the Appeal Board's view, therefore in relation to the first part of the sentence in Paragraph 5.2, the case preparation manager should have decided that neither condition precedent had been met and so the exercise of the Director's discretion in relation to the second sentence did not arise. The complaint should not have proceeded. Consequently, there could be no breach of the Code.

An anonymous, non-contactable complainant who described themselves as an ex-employee and as the complainant in Case AUTH/2749/2/15, contacted the Authority stating that he/she was disappointed in the outcome of that case. Case AUTH/2749/2/15 concerned, *inter alia*, the use of a consultant. The complainant in that case had not been able to appeal the Panel's rulings of no breach of the Code as he/she was non-contactable.

COMPLAINT

In summary, the complainant referred to Case AUTH/2749/2/15 and noted the Panel's reference to his/her previous complaint not being backed with any evidence. In light of this the complainant alleged that new evidence was available to support this fresh set of allegations about the use of a consultant and listed some of the evidence available but provided none. The complainant referred to legal advice received which directed him/her to make this fresh set of allegations

and to provide all evidence upon publication of the Panel's ruling in the hope that Chugai would conduct a more rigorous investigation.

When writing to Chugai the Authority asked it to respond to the requirements of Clauses 2, 9.1, 18.1, 21, 22 and 23.1 in relation to the consultancy arrangements and Clauses 2 and 9.1 in relation to the implied allegation that Chugai's investigation into the previous complaint was not sufficiently rigorous.

RESPONSE

In summary, Chugai submitted that this complaint raised no new issues to those raised in Case AUTH/2749/2/15, but simply disputed the Panel's findings in that case and referred to additional evidence (which had not been disclosed) in relation to the same matters. While Chugai accepted that the Director had a discretion (under Paragraph 5.2 of the Constitution and Procedure), to allow a complaint to proceed, even where it concerned a matter closely similar to one that had been the subject of a previous adjudication if (i) new evidence had been adduced or (ii) the passage of time or a change in circumstances raised doubts as to whether the same decision would be made in respect of the current complaint, this case was the same, rather than 'closely similar' to Case AUTH/2749/2/15, no new evidence had in fact been adduced beyond the references to the existence of evidence set out in the second complaint and there was no passage of time or change in circumstances to cast doubt on the original decision. Paragraph 5.2 further stated that the Director should normally allow a complaint to proceed if it covered matters similar to those in a decision of the Panel where no breach of the Code was ruled and which was not the subject of an appeal. In this instance however, a breach of the Code was ruled in Case AUTH/2749/2/15.

Chugai therefore submitted that the current complaint was an abuse of process as it sought to reopen matters previously ruled upon by the Panel in Case AUTH/2749/2/15, which had already been investigated and decided. Chugai thus requested the Director to reconsider the decision to proceed with the current complaint.

Chugai stated that all of the matters raised in this complaint were previously ruled upon by the Panel in Case AUTH/2749/2/15, were *res judicata* and should not be the subject of further proceedings.

However, and despite this view, Chugai had nevertheless conducted a focused and rigorous re-investigation regarding arrangements with the consultant. Details were provided to show that no evidence was found to suggest the previous response to refute the claim was incorrect or to alter the response to Case AUTH/2749/2/15.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. As stated in the introduction to the Constitution and Procedure such complaints were accepted and like all complaints, judged on the evidence provided by the parties. Complainants had

the burden of proving their complaint on the balance of probabilities.

In summary, the Panel noted that the previous case, Case AUTH/2749/2/15, concerned allegations, *inter alia*, about consultancy arrangements with a named individual. In that case, the Panel had ruled a breach of Clause 9.1 in relation to one matter but no breach of the Code in relation to the remaining allegations. The Panel had made it clear that the complainant had not provided any evidence to support his/her claim. As the complainant in that case was non-contactable he/she was not able to appeal the rulings of no breach of the Code. The Panel noted that the previous case, Case AUTH/2749/2/15, had now been published. The complainant in the present case, Case AUTH/2790/8/15, had stated that he/she was also the complainant in the previous case but the Panel noted that there was no way of verifying whether that was so.

The Panel noted Chugai's comments about the decision under Paragraph 5.2 of the Constitution and Procedure to allow the present complaint to proceed. The Panel noted Paragraph 5.2 detailed the situations where a matter closely similar to one which had been the subject of a previous adjudication could be allowed to proceed: these were, at the discretion of the Director, where new evidence was adduced or if the passage of time or change in circumstances raised doubts as to whether the same decision would be made about the current complaint. The Director should normally allow a complaint to proceed if it covered matters similar to those in a decision of the Panel where no breach of the Code was ruled and which was not the subject of appeal. The case preparation manager had noted that the no breach rulings in the previous case were not the subject of an appeal and thus referred the entire case to the Panel for consideration.

The Panel noted that it was not possible to contact the complainant for more information. The complaint appeared to consist largely of references to evidence which the complainant had not provided. Given the Constitution and Procedure and that the previous case had made both the burden of proof and the need for the complainant to provide evidence clear, the Panel queried why no evidence had been provided in the present case. It was not, as implied by the complainant, for Chugai to provide the requisite evidence although it should submit a complete response. The burden was firmly on the complainant in that regard. The failure to adduce evidence was, in the Panel's view, odd given the complainant's reference to legal advice.

Noting its comments above and the complete absence of evidence the Panel considered that as in the previous case the complainant had failed to show that there had a breach of the Code in most of the matters he/she raised with regard to the engagement of a consultant. No breaches of the Code were ruled as in Case AUTH/2749/2/15.

The Panel noted, however, that the previous case included a ruling of a breach of Clause 9.1 in relation to one matter. The Panel noted that the rulings in the previous case about the consultancy applied here

including the breach of Clause 9.1. This ruling was appealed by Chugai.

The Panel noted that in the previous case, Case AUTH/2749/2/15, although it had some concerns about the consultancy arrangements it considered that Chugai had not brought discredit upon, or reduced confidence in the pharmaceutical industry. The Panel noted its rulings above in the present case and again ruled no breach of Clause 2.

In relation to the implied allegation that Chugai's investigation into the previous complaint was not sufficiently rigorous, the Panel noted that the company's response had been wide ranging and detailed. The Panel did not consider that the complainant had shown that the company's response to Case AUTH/2749/2/15 was inadequate. In that regard the Panel ruled no breach of Clause 9.1. In the Panel's view the manner in which Chugai had responded to Case AUTH/2749/2/15 was not such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. No breach of Clause 2 was ruled.

APPEAL BY CHUGAI

Whilst Chugai did not appeal the Panel's rulings in Case AUTH/2749/2/15 and did not challenge the findings of the Panel that no new breaches of the Code were established as a result of the second complaint in the current case, Chugai submitted that the procedure followed by the PMCPA in relation to these two complaints was unfair and did not reflect the Constitution and Procedure. In particular, Chugai was concerned that the Panel's approach in Case AUTH/2790/8/15 could result in unlimited further complaints by the same complainant raising the same allegations, unsupported by evidence, each admitted by the PMCPA for consideration by the Panel and each resulting in a repeat of the ruling of a breach of Clause 9.1, found in Case AUTH/2749/2/15.

This appeal therefore related to the PMCPA's decision to refer the second complaint to the Panel and the fact that the breach of the Code in Case AUTH/2749/2/15 was repeated in Case AUTH/2790/8/15 with the requirement of a further undertaking and that the published decision of the Panel would, seemingly, suggest a second finding of breach of Clause 9.1 even though, no new breach of the Code arising from the second complaint, had been ruled.

Chugai submitted detailed reasons as to why it considered that this case should not have proceeded.

In summary, Chugai alleged that the second complaint, submitted with no new evidence adduced, a mere three months after the conclusions of the Panel following the first complaint, was an abuse of process and that the issues considered by the Panel in Case AUTH/2749/2/15 were *res judicata* and might not be reopened.

Chugai therefore asked the Appeal Board to conclude:

- that the second complaint should not have been admitted by the Director for consideration by the Panel;

- that, in the absence of any new evidence, any finding of a breach of Clause 9.1 in the context of Case AUTH/2790/8/15 should be quashed;
- that the Panel's request for a second undertaking and assurance by Chugai arising from the finding of the Panel in Case AUTH/2749/2/15 was inappropriate and unnecessary and there should be no further administrative charge;
- if the Appeal Board concluded in favour of the proposal that Case AUTH/2790/8/15 should not have been referred to the Panel then no summary would be published;
- if the Appeal Board did not find in favour of the above proposal then the summary of Case AUTH/2749/2/15 published by the PMCPA should make clear that no new breach of Clause 9.1 was ruled and that the finding in Case AUTH/2749/2/15 might be referenced, the finding had not been repeated.

APPEAL BOARD RULING

The Appeal Board noted Paragraph 5.2 of the Constitution and Procedure included:

'If a complaint concerns a matter closely similar to one which has been the subject of a previous adjudication, it may be allowed to proceed at the discretion of the Director if new evidence is adduced by the complainant or if the passage of time or a change in circumstances raises doubts as to whether the same decision would be made in respect of the current complaint. The Director should normally allow a complaint to proceed if it covers matters similar to those in a decision of the Panel where no breach of the Code was ruled and which was not the subject of appeal to the Appeal Board.'

The Appeal Board noted that the case preparation manager appeared to have relied only on the second sentence in relation to whether the complaint should proceed. The case preparation manager's response to Chugai's submission that the complaint should not proceed to the Panel stated that as no breach of the Code had been ruled in Case AUTH/2749/2/15, the matters now at issue in Case AUTH/2790/8/15 had been referred to the Panel.

In the Appeal Board's view the first sentence of the relevant section of Paragraph 5.2 above was a condition precedent. The Director had to decide that the conditions set out in that sentence had been met before exercising any discretion as to whether a complaint about a matter closely similar to one which had been the subject of a previous adjudication should be allowed to proceed.

The Appeal Board noted that the matters now at issue were closely similar to those raised by someone who appeared to be the same complainant as in Case AUTH/2749/2/15. The questions to be considered were 'Had new evidence been adduced?' or 'Had the passage of time or a change in circumstances raised doubts as to whether the same decision would be made?'. The Appeal Board considered that no new evidence had been provided by the anonymous complainant who, as previously, had chosen to be non-contactable. The Appeal Board considered that this was extremely regrettable given that in Case AUTH/2749/2/15 the Panel had been critical of the lack of evidence provided by the complainant and had noted that the complainant had the burden of proving his/her complaint on the balance of probabilities. The Appeal Board also noted that the complainant referred to legal advice which included providing evidence upon publication of the Panel's ruling. The complainant should have provided any such evidence with the complaint. The Appeal Board noted that Chugai had not identified any new material in its response to Case AUTH/2790/8/15. The Appeal Board noted that the current complaint was received only three months after the completion of the previous case and there was apparently no change in circumstances. In the Appeal Board's view, therefore in relation to the first part of the sentence in Paragraph 5.2, the case preparation manager should have decided that neither condition precedent had been met and so the exercise of the Director's discretion in relation to the second sentence did not arise. The complaint should not have proceeded. Consequently, there could be no breach of Clause 9.1.

Complaint received	14 August 2015
Case completed	21 January 2016