ANONYMOUS, NON-CONTACTABLE PHARMACIST v BOEHRINGER INGELHEIM

Ofev supply programme

An anonymous, non-contactable complainant who described him/herself as a hospital pharmacist raised two concerns about a programme to provide Ofev (nintedanib) free of charge by Boehringer Ingelheim. Ofev was indicated for the treatment of adults with idiopathic pulmonary fibrosis (IPF). The medicine was first authorised in January 2015 but was not yet reimbursable under the NHS.

The complainant's first concern was that surely this was similar to the old days of providing free medicine and then the NHS being charged once the free programme was finished. Secondly the complainant queried, given that the programme was for those who had 'failed' on Esbriet (pirfenidone), what the criteria were for switching from one medicine to another. The complainant stated that he/she had not received a clear answer to either concern.

A medical member of the company saw the complainant and he/she did not believe this was a clinical trial. When the complainant asked about a protocol, none was forthcoming. The complainant did not believe that this was the role of the medical team and was upset that he/she had agreed to take this appointment.

The complainant believed strongly that this type of programme and behaviour was why the pharmaceutical industry was viewed poorly by the wider community.

The detailed response from Boehringer Ingelheim is given below.

The Panel noted that every complainant bore the burden of proving his/her complaint on the balance of probabilities. As the complainant in this case had not provided contact details the Panel could not ask him/her for more information. Boehringer Ingelheim had not been able to identify from the information given, the interaction between the complainant and one of its employees that was alleged to have taken place.

The Panel noted that the commercial teams' briefing document provided stated that the Ofev Supply Programme would only be offered to specialist centres which had, *inter alia*, experience of prescribing Ofev via the Individual Patient Supply Programme. The programme addressed unmet clinical need by making Ofev available to those IPF patients for whom no other licensed and reimbursable treatment was available. The programme was led by medical and was not to be raised proactively with customers by the commercial teams. The briefing explained that Ofev could be offered for use in patients unable to take Esbriet and who had a forced vital capacity (FVC) >50%. Arrangements would change when national guidance about the use of Ofev was agreed.

A 'Dear Doctor' letter, appended to the briefing document and intended to be sent to eligible sites, explained the above and clearly stated that Ofev would only be supplied to patients that could not be treated with a licensed and reimbursable alternative and only to those who met certain inclusion criteria of the pivotal registration studies. The Panel noted Boehringer Ingelheim's submission that no promotional material was associated with the supply programme.

The Panel noted that the complainant had stated that the Ofev supply programme was aimed at those who had failed on Esbriet. This was not so; Ofev would only be supplied to those patients who could not take Esbriet. There was no reference in either the briefing document or the 'Dear Doctor' letter to patients who had failed on Esbriet. In that regard the programme could not be a switch programme as alleged and the Panel ruled no breach of the Code.

The Panel considered that there was no evidence before it to show that the programme was such as to offer, supply or promise any gift, pecuniary advantage or benefit to health professionals or any other relevant decision makers, as an inducement to prescribe, supply, administer, recommend, buy or sell Ofev. No breach of the Code was ruled.

The Panel noted that the supply programme was led by the medical team; commercial teams could not raise the matter proactively with customers. There was no associated promotional material. In the Panel's view the programme was non-promotional and thus it could not be disguised promotion. No breach of the Code was ruled. Further, the supply programme could thus not be a promotional activity disguised as a clinical assessment or the like. No breach of the Code was ruled.

The Panel noted its rulings above and considered that there was no evidence to show that Boehringer Ingelheim had not maintained high standards. No breach of the Code was ruled

Given its rulings above, the Panel ruled no breach of Clause 2.

An anonymous, non-contactable complainant who described him/herself as a pharmacist in a major London teaching hospital complained about the provision of Ofev (nintedanib) by Boehringer Ingelheim. Ofev was indicated for the teatment of adults with idiopathic pulmonary fibrosis (IPF). The

medicine was first authorised in January 2015 but was not yet reimbursable under the NHS.

COMPLAINT

The complainant stated that he/she was advised of a programme related to Ofev aimed at those who had failed on another treatment. The complainant was then advised, with enthusiasm, that Boehringer Ingelheim would supply the medicine free of charge. The complainant had two questions, which could not be answered to his/her satisfaction. The complainant stated that surely this was similar to the old days of free medicine given, like samples, and then the NHS being charged once the free programme was finished; he/she received no answer to this apart from a discussion around patient treatment, which he/she believed was his/her domain and not that of a pharmaceutical company. The second related to the fact that the programme was for those who had 'failed' on Esbriet (pirfenidone) marketed by Intermune. When the complainant asked what the criteria were for switching from one medicine to another he/she was met with a complete lack of clarity. Surely this was an issue, and one, which reminded the complainant of 'switching' programmes when he/she was a junior in asthma.

A medical member of the company saw the complainant and he/she did not believe this was a clinical trial. When the complainant asked about a protocol, none was forthcoming. The complainant did not believe on reading the 2015 Code that this was the role of the medical team and was upset that he/she had agreed to take this appointment.

The complainant stated that he/she had read the Code and believed strongly that this type of programme and behaviour was why the pharmaceutical industry was viewed poorly by the wider community.

Boehringer Ingelheim was asked to respond in relation to Clauses 2, 9.1, 12.1, 12.2, 18.1 and 19 of the 2015 Code.

RESPONSE

Boehringer Ingelheim stated that it was unfortunate that the complainant had chosen to remain anonymous as this limited the company's ability to identify the episode which the complainant referred to and subsequently gather further information about the encounter. Accepting this limitation, Boehringer Ingelheim believed the complainant had referred to a confidential discount available to specific IPF treating hospitals.

Boehringer Ingelheim explained that Ofev was granted a marketing authorization by the European Commission in January 2015. It was one of only two licensed therapies for the treatment of IPF, a rare, progressive and debilitating disease which affected less than 1 in 2,000 of the population. IPF was associated with substantial morbidity and a median life-expectancy of approximately two years following diagnosis. Due to timelines laid out by the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC), there was a substantial period of time between the licensing of Ofev and any possible reimbursement for NHS treated patients eg NICE estimated publication of the nintedanib health technology appraisal (HTA) in January 2016, with commissioning of care from NHS England likely to be 90 days after that. Because of either a medical contraindication to Esbriet, or because of national restrictions in the reimbursement of Ofev, there was a cohort of IPF patients who fell within the licensed indications for Ofev who currently could not access any other licensed and reimbursed therapy for their disease.

Boehringer Ingelheim explained that in response to demand from physicians, it provided a confidential discount exclusively to interstitial lung disease (ILD) specialist centres which were already commissioned to treat patients with IPF. The discount was only available to treat patients who were unable to access Esbriet, either because they fell outside of its national reimbursement criteria or because they had a medical contraindication to it. In the event of a national agreement for the reimbursement of Ofev treatment, sites where IPF care was commissioned would no longer be eligible for this discount when they purchased Ofev for patients who now became eligible for reimbursement. All participating sites were aware of this and Boehringer Ingelheim would not retrospectively charge for the supply of Ofev to patients who received treatment by way of this discount prior to the reimbursement decision and had subsequently become eligible for reimbursement. Any site with patients that were not covered by these reimbursement guidelines would continue to receive the agreed discount specifically to treat these patients up until the responsible physician made a clinical decision to stop treatment. This approach was discussed and agreed with NHS England before the discount was provided, with the express agenda of formulating an approach that would not produce additional expense for the NHS, but would benefit these patients where no other licensed and reimbursed alternative was available.

Boehringer Ingelheim stated that given the above complexities, the 'Patient in Need Programme', had been established to ensure consistent and appropriate application of the discount.

The provision of this discount was in response to clinicians' requests and reflected Boehringer Ingelheim's ethical responsibility as the marketing authorization holder for a treatment of such a serious orphan disease. In order to ensure clear differentiation of this ethical provision of a medicine from any inappropriate perception of commercial activity, all proactive communication with ILD centres was through Boehringer Ingelheim's medical team. There was no associated promotional material and the Ofev promotional teams had been briefed not to raise the issue proactively and to reactively direct enquiries to the medical team.

Following an internal review, given that the complainant was anonymous, Boehringer Ingelheim could not identify a member of a medical team who had had a discussion with a London pharmacist in

this context and it thus could not comment further on the complainant's statements regarding his/her perception of the interaction. However, to ensure that the best possible standard with regard to the communication of this programme by Boehringer Ingelheim's promotional and non-promotional field forces was maintained it had, subsequent to receiving this complaint, undertaken further discussion and training with all the relevant individuals.

With regard to Clauses 2 and 9.1, Boehringer Ingelheim stated that the confidential discount provided to sites commissioned to treat IPF was entirely non-promotional with no activities or material associated with promotion of Ofev. All promotional Ofev team members had been briefed to this effect (briefing document provided). The discount scheme was provided by Boehringer Ingelheim to help clinicians manage IPF patients who had no alternative licensed and reimbursed treatment option, to bridge the time between the grant of the marketing authorization and any future reimbursement decisions. Further, Boehringer Ingelheim believed that it had taken appropriate steps to help provide, for ethical reasons, a treatment alternative to those with a debilitating disease that had no other licensed and reimbursed alternative. Boehringer Ingelheim strongly rejected any claim that it had discredited or reduced confidence in the industry, or maintained anything but the highest standards, indeed, it believed the reverse was true. Boehringer Ingelheim considered that failure to offer Ofev to patients in this limited situation, where no licensed and reimbursed alternative was available for such a rare and debilitating disease, prior to the grant of reimbursement approval, would discredit the industry.

With regard to Clause 12.1, Boehringer Ingelheim stated that as noted above, the provision of the discount was non-promotional and as such there was no disguised promotional activity or material.

With regard to Clause 12.2, Boehringer Ingelheim stated that as noted above, the provision of the discount was a non-promotional activity. It was not a market research activity, a clinical assessment, post marketing surveillance or experience programme, or a post-authorization study as referred to in Clause 12.2.

With regard to Clause 18.1, Boehringer Ingelheim stated that it had provided a discount to commercial stock prior to reimbursement as part of its ethical obligation to provide access to patients as the marketing authorization holder in an orphan indication. The discount was only available for patients for whom there was no licensed and reimbursed alternative treatment available, in this specific orphan disease setting, in a non-promotional manner. The alternative to using the provided discount in this situation was to offer no treatment. Boehringer Ingelheim strongly maintained this was not an inducement to prescribe, supply, administer, recommend, buy or sell Ofev.

With regard to Clause 19, Boehringer Ingelheim stated that the discount to commercial stock was not part of any medical or educational goods or service programme. More importantly, provision of the discount was not a switch or therapy review programme. The discount was only available to recognised ILD centres which were commissioned to treat IPF patients, exclusively for patients unable to receive the only other alternative licensed and reimbursed therapy, thus meeting a clear unmet clinical need.

In summary, Boehringer Ingelheim reiterated the following points:

- Due to the anonymity of the complainant, Boehringer Ingelheim was unable to discover the nature of the interaction described, however it believed the complainant had referred to a confidential discount scheme for Ofev.

- The discount for Ofev was only available to sites commissioned to treat IPF patients and was only available for the treatment of those who had no alternative licensed and reimbursed treatment option. It was not a switch programme. Boehringer Ingelheim stressed that if it did not provide this discount to this group of patients, given the current lack of reimbursement for Ofev and the limited treatment options available, these patients would have no alternative licensed and reimbursed treatment option for their serious disease.

- The discount would continue to be applied up until the point that Ofev treatment was commissioned in the treating hospital. Boehringer Ingelheim would not offer the discount to any patients who were, from that point onwards, eligible for reimbursed treatment. There would be no retrospective costs applied for the patients treated under this discount who subsequently become eligible for reimbursed therapy. Any patient offered the discount prior to the publication of reimbursement guidance that was subsequently not eligible for reimbursed nintedanib treatment would continue to receive Ofev at the previously agreed discount until a clinical decision was made to cease treatment.

- Provision of the discount was managed by the medical team in a non-promotional manner. Promotional teams were briefed not to raise the discount proactively and if asked, they were to direct enquiries to the medical team.

- Boehringer Ingelheim believed it had acted with the highest integrity to provide a discount for Ofev at the current time, where it was licensed but not reimbursed, to commissioned prescribing centres, and to IPF patients who had no alternative licensed and reimbursed treatment available. Boehringer Ingelheim did not believe it had acted in breach of Clause 9 and its actions did not bring the industry in to disrepute as described in Clause 2. To the contrary, Boehringer Ingelheim believed that not providing such a discount, to enable availability of Ofev for this limited patient population, would be viewed as withholding treatment for patients with a significant need and no other option.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. Anonymous complaints were accepted and like all complaints, judged on the evidence provided by the parties. The Panel noted that every complainant bore the burden of proving his/her complaint on the balance of probabilities. As the complainant in this case had provided no contact details the Panel could not ask him/her for more information. Boehringer Ingelheim had not been able to identify from the information given, the interaction between the complainant and one of its employees that was alleged to have taken place.

The Panel noted that the supplementary information to Clause 18.1, Patient Access Schemes stated that such schemes were acceptable in principle under the Code provided they were carried out in conformity with its requirements.

The Panel noted that the commercial teams' briefing document provided stated that the Ofev Supply Programme would only be offered to specialist centres which had experience of prescribing Ofev via the Individual Patient Supply Programme and which had signed a new agreement for the Ofev Supply Programme. The programme was designed to address unmet clinical need by making Ofev available to those IPF patients for whom no other licensed and reimbursable treatment was available (Ofev was licensed but currently not reimbursable). The programme was to be led by the medical team and was not to be raised proactively with customers by the commercial teams. The only currently licensed and reimbursable treatment available was Esbriet which was restricted by NICE guidance to use in patients with a forced vital capacity (FVC) of 50-80%. The briefing explained that under the Ofev Supply Programme, Ofev could be offered for use in patients unable to take Esbriet and who had an FVC >50%. The programme would close to new patients when national guidance was agreed but that those already in the programme would continue to receive stock until local reimbursement was agreed. Patients who did not fulfil local reimbursement guidance would continue to receive free stock until they either became eligible for reimbursement or a clinical decision was taken to discontinue their treatment.

A 'Dear Doctor' letter appended to the briefing document and explaining the above was dated to be sent to eligible sites at the beginning of June 2015. The letter clearly stated that Ofev would only be supplied to patients that could not be treated with a licensed and reimbursable alternative and only to those who met the FVC inclusion criteria of the INPULSIS trial programme (the pivotal registration studies). The Panel noted Boehringer Ingelheim's submission that no promotional material was associated with the supply programme.

The Panel noted that the complainant had stated that the Ofev supply programme was aimed at those who had failed on another treatment (Esbriet). This was not so; Ofev would only be supplied under the programme to those patients who could not take Esbriet. There was no reference in either the briefing document or the 'Dear Doctor' letter to patients who had failed on Esbriet. In that regard the programme could not be a switch programme as alleged and the Panel ruled no breach of Clause 19.1.

The Panel noted the complainant's inference that the arrangements were not *bona fide*; that once the 'free programme' had finished the NHS would be charged for the medicine. The Panel noted the arrangements for the scheme as set out above; it considered that there was no evidence before it to show that the programme was such as to offer, supply or promise any gift, pecuniary advantage or benefit to health professionals or any other relevant decision makers, as an inducement to prescribe, supply, administer, recommend, buy or sell Ofev. No breach of Clause 18.1 was ruled.

The complainant appeared to be confused about the role of a member of the medical team at a meeting. As noted above, Boehringer Ingelheim was unable to identify the interaction. The Panel noted that the supply programme was led by the medical team; commercial teams could not raise the matter proactively with customers. There was no associated promotional material. In the Panel's view the programme was non-promotional and thus it could not be disguised promotion. No breach of Clause 12.1 was ruled. Further, the supply programme could thus not be a promotional activity disguised as a clinical assessment or the like. No breach of Clauses 12.2 was ruled.

The Panel noted its rulings above and considered that there was no evidence to show that Boehringer Ingelheim had not maintained high standards. No breach of Clause 9.1 was ruled

Given its rulings above, the Panel ruled no breach of Clause 2.

Complaint received **22 June 2015**

Case completed **15 July 2015**