CASE AUTH/3808/08/23

COMPLAINANT v SUN PHARMA

Ability to contact the company

CASE SUMMARY

This case was in relation to a Sun Pharma telephone number and website that were allegedly not functional.

The outcome under the 2021 Code was:

No Breach of Clause 5.1 (x2)	Requirement to maintain high standards at all times
NO DIEACH OF CIAUSE 5.1 (XZ)	Requirement to maintain nigh standards at an times
[1x Panel's breach ruling	
overturned at appeal]	

This summary is not intended to be read in isolation. For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received from an anonymous, contactable complainant about Sun Pharma UK Limited.

COMPLAINT

The complaint wording is reproduced below:

"I have been trying to contact Sun pharma for the past two weeks and have been unable to reach them as no phone numbers listed for them work and their website blocks you as soon as you click on anything. I think it would appropriate if they were contactable and their website worked as patients may need to report side effects or problems with their medication."

FURTHER INFORMATION FROM THE COMPLAINANT

The complainant's response to a request for further information by the case preparation manager is reproduced below:

"The phone numbers did not connect as they were found online as the leaflet found in the medication did not have any phone numbers on it. The first call was made at about 2:45pm on the 26th of July 2023 after I received the medication as I have a query about the medication that I need answered before I can use them. After that I have been trying intermittently a couple of times a day apart from Saturday and Sunday as I didn't think anyone would be there on the weekend.

[Telephone number provided] – the number goes straight through to a Vodafone voicemail every time I have tried calling.

There was also another number that we tried but the number was unavailable.

I need information as I have severe OCD [Obsessive Compulsive Disorder] and have to know the country of origin of every product I use due to the OCD. Usually the pharma companies are extremely helpful, this is the first time we've had a problem."

When writing to Sun Pharma, the PMCPA asked it to consider the requirements of Clause 5.1 of the Code.

SUN PHARMA'S RESPONSE

The response from Sun Pharma is reproduced below:

"Our organisation recently experienced disruptions to our phone systems due to an IT Security Incident. While our medical information and customer service lines had continued to work, our UK office phone line, which operates on a Voice over Internet Protocol (VoIP) system, was temporarily affected. However, we are pleased to inform you that we took swift action to rectify the situation. On the 17th of August, a qualified engineer addressed the issues, and extensive testing has been conducted to ensure that all our phone lines, including our medical information and customer service lines, are in full working order.

Regarding the issue with accessing our website, we sought assistance from our global IT department, which has indicated that the problem may be related to the SIM service provider of the patient. Subsequently, we conducted thorough testing, and we can confirm that the website is fully accessible. Furthermore, we have asked our communications team to enhance our website by adding further contact information to assist patients.

To address the issue of how people can contact us, we are committed to ensuring that reaching our company is straightforward and efficient. We can confirm that we have our contact information on the PIL as well as the yellow card system, we provide medical information numbers, full contact details are available on the EMC and our office number is readily accessible through internet searches.

Concerning after-hours communication, we have implemented clear procedures. When contacting our UK office numbers outside of our standard business hours (09:00 – 17:00), the following messages are relayed:

- When dial[I]ing the UK office number at [number provided], you will hear: 'Thank you for calling Sun Pharma, our offices are currently closed. For the medical information line, please dial [number provided]. For all other enquiries, please leave a message after the tone, and we will get back to you when our offices reopen.'

- When contacting the UK Customer Service number at [number provided] outside of regular business hours, you will hear: 'Our offices are currently closed. For the medical information line, please ring [number provided]. For all other enquiries, please leave a message after the tone, and we will get back to you when our offices re-open.'
- When reaching out to the Medinfo line at [number provided], you will hear: 'Welcome to the medical information department at Sun Pharma company. Please be informed that this call is being recorded for the purposes referred to in the privacy policy on our website. By continuing with this call, you agree with the data processing. If you do not wish to be recorded, please contact us via email at [email address provided]. Please leave a message after the tone.'

In accordance with our previous email correspondence, we welcome the patient to contact me directly to address any questions or potential concerns they may have."

PANEL RULING

This case was in relation to a Sun Pharma telephone number and website that were allegedly not functional.

The Panel noted that the complainant was concerned that they were unable to contact Sun Pharma to ascertain the country of manufacture of a medicine; they could not access the website and the telephone numbers found online either repeatedly went to a voicemail or were not available. The complainant queried whether patients would be able to report side effects and stated that there was no contact telephone number in what appeared to be the patient information leaflet (PIL).

The Panel noted Sun Pharma's submission that contact details were on the PIL and that the complainant bore the burden of proof in this regard. The Panel noted that it did not have the PIL in question nor details of the medication but noted on the Electronic Medicines Compendium, accessed on 10 September 2024, that the Sun Pharma PIL accessed did have contact details and a medical information number.

In relation to contacting Sun Pharma by telephone, Sun Pharma submitted that it recently experienced disruptions to its phone systems due to an IT Security Incident and that whilst its medical information and customer service lines had continued to work, its UK office phone line was temporarily affected. The Panel understood that the difficulties appeared to have been present two weeks prior to the submission of the complaint on 1 August 2023 and the matter was resolved on 17 August 2023, totalling at least four and a half weeks. Whilst the Panel was reassured that the medical information telephone number remained operative throughout this period, it queried whether disruption to the main telephone line had been treated with sufficient urgency. In this regard, the Panel noted that some patients might not necessarily be aware that companies had a medical information telephone number and thus might be directed to the main telephone line by sources such as the Internet. Overall and on balance, whilst the Panel acknowledged that the IT security incident may have been outside of the company's control, the Panel considered, in relation to telephone line accessibility, that it took at least four and a half weeks to resolve the matter meant that high standards had not been maintained. A **breach of Clause 5.1 was ruled**.

With regard to website accessibility, the Panel noted that patients and the public with questions about medicines might use various routes to contact companies including via the company website. It was important that websites were accessible and contact details were clearly signposted.

The complainant had provided a screenshot of an error message from 01 August 2023, coinciding with the IT security incident, which stated the complainant's access was 'rate limited' and that the owner of the website had temporarily banned them from accessing Sun Pharma's website. The Panel noted Sun Pharma's submission that according to its global IT department, the problem may have been related to the SIM service provider of the complainant and that it had subsequently conducted thorough testing and the website was fully accessible. Sun Pharma had not specifically commented on the image but the Panel generally understood that the rate limiting error was a response strategy for limiting excessive network traffic from an IP address, amongst other security matters.

It was unclear to the Panel whether the issue was related to the complainant's device or Sun Pharma's website security settings. Noting the complainant bore the burden of proof and that all complaints had to be judged on the evidence provided by the parties, the Panel considered it had not been established that high standards had not been maintained in relation to the website's accessibility. **No breach of Clause 5.1 was ruled**.

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During its consideration of this case, the Panel considered it was important that contact details for patients, including how to contact the company, were easy to find and clearly signposted. It was important that companies had robust monitoring and processes in place to regularly review such matters. The Panel requested that Sun Pharma be advised of its concerns in this regard.

APPEAL BY SUN PHARMA

Sun Pharma's written basis for appealing is reproduced below.

"We are writing to formally appeal the PMCPA ruling, dated 20 September 2024, regarding Complaint Case AUTH/3808/8/23, which pertains to an anonymous complaint dated 2 August 2023 received under the Code of Practice for the Pharmaceutical Industry (the "**Code**"). Sun Pharma UK Limited ("**Sun Pharma UK**") was given an extension to appeal the PMCPA's ruling up until 11 October 2024. Following the Panel's ruling, Sun Pharma UK Limited was found in breach of Clause 5.1 of the Code, which relates to a "failure to maintain high standards." However, we respectfully submit this appeal based on the following merits:

1. Access to Contact Information

As outlined in our initial response letter dated 22 August 2023, the phone number in question, which the complainant was reportedly unable to reach, pertains to Sun Pharma UK's general office line. This line is used for all day-to-day business matters regarding the functioning of the Sun Pharma UK office. In the event a customer contacts the Sun Pharma UK office line requesting product-related information, they are redirected to the medical information line accordingly. Additionally, the Patient Information Leaflet ("**PIL**") which is included with the product, directs all queries

regarding product-related matters to the medical information line. Sun Pharma UK also utilizes a customer service line which can be reached for any queries, which is available on the Sun Pharma UK website. Both the medical information and customer service lines were fully operational at the time of the complaint. We are fully aware that our patients may have certain queries regarding our products, which is why Sun Pharma UK has two dedicated contact numbers that were fully operative, which would assist a patient with their queries.

In the complainant's complaint dated 2 August 2023, the complainant states: "the number goes straight through to a Vodafone voicemail every time I have tried calling". If the complainant had continued listening to the voicemail in question, they would have been redirected to the appropriate medical information line. As already stated in our initial response letter, the following is played for a caller in the voicemail in the event of calling outside of our standard office hours or in the event the Sun Pharma UK office line is temporarily down: "Thank you for calling Sun Pharma, our offices are currently closed. For the medical information line, please dial 02088485052. For all other enquiries, please leave a message after the tone, and we will get back to you when our offices re-open."

We would also like to note that the complainant in question did not leave a voicemail, which Sun Pharma UK would have responded to timeously if it had been left correctly.

Further, while the complainant was unable to access the Sun Pharma UK website due to network issues on their particular device, the Sun Pharma UK website would have had alternative contact information in the form of an email address.

2. Response to the Complaint

Upon receipt of the complaint, the Head of Sun Pharma UK offered his personal contact information to assist the complainant's queries, though this offer was not taken up by the complainant.

3. Technical Issues with Office Line

During the downtime of the office line, Sun Pharma was attempting to resolve the issue with urgency. The delay in restoration and was beyond Sun Pharma's reasonable control. While our previous response mentioned that the technical issues were resolved on 17 August 2024, personnel from our offices were attempting to fix the issue immediately after the complaint was registered. Notably, during this time there was a critical fault in the Ethernet lines, which required replacement, as well as the ordering of a new router. During such time, we were at the disposal of our third-party connectivity provider and were following up on regular basis.

4. Internal Processes

Sun Pharma has rigorous internal processes for managing communications and patient inquiries. These processes are regularly reviewed and updated to ensure that we meet the highest standards of care and compliance. In our previous response letter, we highlighted the various steps taken to ensure continued compliance with Code of Practice for the Pharmaceutical Industry.

5. High Standards Maintained and Interpretation of Clause 5.1

We do not agree with the Panel's decision that Sun Pharma UK failed to maintain high standards. Sun Pharma UK sold 27.3 million packs in the 2023/24 financial year and this was the sole complaint regarding our contactability or access to information in the recent years and during the relevant period, underscoring the robustness of our systems. The issue pertained only to the office line, not the customer service or medical lines. If the complainant had consulted the PIL, EMC, yellow card system, the Sun Pharma UK voicemail system or Sun Pharma's website, they would have located the necessary contact information of our operational medical and customer service lines. We respectfully submit that the Panel's interpretation of Clause 5.1 in this case may have overlooked the comprehensive measures Sun Pharma has in place to ensure access to essential information. We maintain that we acted with diligence and in good faith to address the complainant's concerns.

We trust that this letter adequately addresses all of the PMCPA's concerns. Nonetheless, should you require any additional information or documents or if you have any further inquiries, please do not hesitate to contact us."

RESPONSE FROM THE COMPLAINANT

There was no response from the complainant.

APPEAL BOARD RULING

The Appeal Board observed that the complainant's allegation subject to appeal was that they were unable to contact Sun Pharma and the telephone numbers found online either repeatedly went to a Vodafone voicemail or were not available.

Sun Pharma had acknowledged it had experienced disruptions to its phone systems and that while its medical information and customer service lines had continued to work, its UK office phone line was temporarily affected.

In its appeal, Sun Pharma had given more information about some of its procedures. Sun Pharma had submitted if the complainant had continued listening to the voicemail in question, they would have heard "Thank you for calling Sun Pharma, our offices are currently closed. For the medical information line, please dial [number]. For all other enquiries, please leave a message after the tone, and we will get back to you when our offices re-open". Both the medical information, referred to in the patient information leaflet, and customer service lines were fully operational at the time of the complaint according to Sun Pharma. Sun Pharma had further submitted the complainant in question did not leave a voicemail, which it would have "responded to timeously if it had been left correctly".

The Appeal Board considered that it was very important for patients, amongst others, to be able to contact pharmaceutical companies for questions relating to their medicines. The Appeal Board also bore in mind that an individual would usually have to be extremely dissatisfied before they were moved to actually submit a complaint.

However, the complainant had the burden of proving their complaint on the balance of probabilities and a judgement had to be made on the available evidence. There had been no further submissions from the complainant, and the Appeal Board accepted Sun Pharma's description of its communication procedures.

The Appeal Board took account of the submissions and evidence before it, including that the voicemail directed listeners to its medical information line. The Appeal Board decided that despite the prolonged issue with the main office number there appeared to have been adequate ways for the public to contact Sun Pharma. The Appeal Board therefore did not consider that Sun Pharma had failed to maintain high standards in relation to the availability of its phone line as alleged. The Appeal Board ruled **no breach of Clause 5.1**. The appeal on this point was successful.

Complaint received	01 August 2023
Case completed	11 December 2024