CASE AUTH/2743/12/14

COMMUNITY PHARMACIST v AMDIPHARM MERCURY

Yellow card follow-up

A community pharmacist complained about the conduct of Amdipharm Mercury in relation to the follow-up to a yellow card report. The complainant explained that a patient asked for levothyroxine tablets from, *inter alia*, Teva UK as he had previously had issues with those made by Amdipharm Mercury. The pharmacy spoke to Teva which explained that it no longer made this medicine but outsourced it to Amdipharm Mercury and that it wanted to issue a yellow card warning based on the patient's account of 'issues'.

The pharmacy subsequently received a follow-up call from Amdipharm Mercury citing the call from Teva about the patient and requesting personal information about him such as contact details, date of birth etc. The pharmacy refused to answer despite the caller's insistence that he/she had to ask for this information. The complainant stated that the company should not have pressurised the pharmacy to supply this information which it felt unable to supply without the patient's prior permission.

The detailed response from Amdipharm Mercury is given below.

The Panel noted that the complaint had arisen following an exchange between the complainant, a superintendent pharmacist, and a pharmacovigilance (PV) associate from Amdipharm Mercury's PV provider. The PV associate was following up a report of a possible adverse event which had occurred in the patient who had taken levothyroxine manufactured by Amdipharm Mercury. The patient had told the pharmacist that he had had 'issues' with the medicine from Amdipharm Mercury. This information had been passed to Amdipharm Mercury via Teva and in line with Amdipharm Mercury's PV procedures, had been taken up as an adverse drug reaction report. The PV associate had tried unsuccessfully on two successive days to contact the pharmacist for details before he/she was able to speak to him on the third. The adverse event report had been given high priority by Amdipharm Mercury and in his/her conversation with the pharmacist it appeared that the the PV associate was anxious to collect as much information as possible and in that regard mistakenly asked for personal data about the patient which required the patient's prior consent. The Panel noted the complainant's reference to the PV associate's insistence in that regard and that in his view he should not have been put under pressure to provide such information without first gaining the patient's permission. Neither party had commented on whether the pharmacist had offered to get such permission during his conversation with the PV associate or to otherwise help with the collection of data. Overall, the Panel considered that the outcome of the exchange between the complainant and the PV associate was unfortunate – co-operation between the two should have been such that the patient's best interests were uppermost. Nonetheless, the Panel acknowledged that in his/her efforts to collect comprehensive data, the PV associate had asked a third party for the patient's personal details which could not be provided without the patient's consent as acknowledged by Amdipharm Mercury. The Panel noted its comments above and considered that, on the very narrow point of asking for too much personal data without prior consent from the patient, high standards had not been maintained. A breach of the Code was ruled.

The Panel noted that the PV associate had been trained in PV requirements. It was unfortunate that in following up one adverse event report the PV associate had asked a third party for more personal information than he/she should have done. Amdipharm Mercury referred to the incident as an isolated case but acknowledged that it had highlighted gaps in explicitly covering patient confidentiality. Given Amdipharm Mercury's submission in this regard the Panel considered that the PV associate's mistake meant that, on the balance of probabilities, he/she was not fully conversant with PV requirements in relation to patient confidentiality relevant to his/her work. A breach of the Code was ruled.

The Panel noted that the Code required companies to comply with all applicable codes, laws and regulations. As breaches of the Code had been ruled, the Panel also ruled a futher breach of the Code.

A community superintendent pharmacist complained about the conduct of Amdipharm Mercury Company Limited in relation to the follow-up to a yellow card report.

COMPLAINT

The complainant stated that the pharmacy took a query from a patient on 11 December 2014 about the brand of levothyroxine to be dispensed. The patient indicated that he had had issues previously with certain brands including Amdipharm Mercury and asked for tablets manufactured by others including Teva UK Limited. The pharmacy spoke to Teva which explained that it no longer made this medicine but outsourced it to Amdipharm Mercury and it wanted to issue a yellow card warning based on the patient's query.

On 18 December the pharmacy received a follow-up call from Amdipharm Mercury citing the call from Teva about the patient and requesting personal information about the patient such as his home

contact details, date of birth etc. The pharmacy refused to answer despite the caller's insistence that he/she had to ask for this information. The complainant stated that the company should not have put the pharmacy under pressure to supply this information which it felt unable to supply without the patient's prior permission.

When writing to Amdipharm Mercury, the Authority asked it to respond to Clauses 1.9, 9.1 and 16.2 of the Code.

RESPONSE

Amdipharm Mercury explained that it had outsourced its pharmacovigilance (PV) function to a provider for over 6 years. The dedicated teams responsible for pharmacovigilance and drug safety within both Amdipharm Mercury and the PV provider worked together in close partnership with well defined roles and responsibilities. Amdipharm Mercury provided details of the PV provider's role and responsibilities and stated that a technical agreement between Amdipharm Mercury and its PV provider detailed all of the contractual arrangements.

1 Process for handling adverse drug reactions (ADRs)

The main relevant features of receiving and processing an ADR in Amdipharm Mercury and its PV provider were as follows:

i Handling ADRs by Amdipharm Mercury:

ADRs were reported to the medical information (MI) team in Amdipharm Mercury which gathered as much information as it could about a particular ADR from the reporter. The ADR was logged in the MI database with a reference number generated in-line with Amdipharm Mercury's relevant standard operating procedure (SOP). This ADR was then shared with the PV team at the PV provider which was responsible for further follow-up.

ii Handling ADRs by the PV provider:

The follow-up of spontaneous ADRs received by Amdipharm Mercury was done in-line with its SOP 'Medical Information and Processing Medical Queries' and once an ADR was received from Amdipharm Mercury an ADR form and follow-up sheet were completed.

After receipt of initial information for a spontaneous ADR, follow-up activity was undertaken by the PV provider. At least three telephone follow-up attempts for a spontaneous ADR should be made, if initial attempts were not successful. Thereafter, an e-mail/fax/letter should be sent providing a response to a spontaneous ADR case if contact details were available. A list of data elements that determined what follow-up information was needed for particular types of ADR cases was included. These included as a minimum, an identifiable reporter, an identifiable patient, a suspect drug or drugs, one or more ADR, source type and country in which the event occurred. In the case of a patient, personal details such as name and address were not considered as identifier details. In cases of higher priority ie serious expected/serious unexpected cases, further details were also sought. Details were provided. The process for follow-up of a spontaneous ADR received from health professionals was provided.

iii Training

The PV provider ensured that all of its employees responsible for following up ADR reports were trained on the following SOPs: 'Medical Information and Processing Medical Queries' and 'Case Processing of Medical Inquires'.

iv Quality control measures at Amdipharm Mercury and its PV provider

Amdipharm Mercury audited annually; the last audit was in April 2014. Amdipharm Mercury self-inspection audits also look at various responsibilities that its PV provider performed on its behalf. The PV provider could record all telephone conversations related to ADRs for quality and training purposes. Details of this complaint were readily available through playing these recordings. Since July 2014 the PV provider managers had listened to 10% of all recordings. There was no record of any issues pertaining to patient confidentiality deviations in any of these recordings.

2 Details of events pertaining to this complaint

An adverse event was received by Amdipharm Mercury MI team via Teva on 12 December 2014, which was logged in the MI database. This case was then passed to the PV provider to gather further follow-up information as per the Amdipharm Mercury process for handling ADRs.
In line with the process for handling ADRs by the PV provider, follow-up attempts were made by one of the PV associates from at the PV provider to the reporting pharmacist. First and second follow-ups were made on 16 December 2014 and 17 December 2014. Contact could not be established with the pharmacist (reporter) and on both occasions a message was left requesting a call back. At the third follow-up attempt the same PV associate established contact and spoke with the pharmacist on 18 December 2014 to obtain the required information. During the call, the PV associate tried to obtain the patient's contact details for follow-up information. The reporter refused to give any contact details or information about the patient without the patient's consent as he was concerned about patient confidentiality. Call recordings supported the view of the reporting pharmacist that 'during a follow-up call from Mercury Pharmaceuticals the caller began requesting personal information about the patient, in particular his home contact details, date of birth etc. We refused to supply them despite the insistence from the caller that they had to ask for this information'.

Amdipharm Mercury provided details of the induction training and SOP training given to the PV associate at issue. Training records were provided.

Amdipharm Mercury submitted that in-line with the process of follow-up at the PV provider, the PV associate had tried to gather as much information as possible about the ADR because this was a high priority case. It had been identified that he/she should not have tried to obtain the patient's personal details and instead should have sought further information from the health professional. If vital information was still lacking, then the PV associate should have asked the health professional for help to get consent from the patient to disclose his personal details to the PV provider. Furthermore, the PV associate should have waited for patient consent from the health professional, if he agreed to have helped.

Amdipharm Mercury noted that the following measures had been undertaken both in-house and by the PV provider to avoid the recurrence of such instances in future:

- This case raised the need for specific training on patient confidentiality especially in this particular situation.
- All relevant SOPs in Amdipharm Mercury and the PV provider would be redrafted to explicitly cover this point.
- Importantly, once the SOPs were rewritten, they would be retrained to the entire team.
- In the interest of timely response, the entire PV provider team had been briefed and trained on patient confidentiality matters at an *ad hoc* training session. Re-training on the PV provider's SOPs for the entire team responsible for performing follow-ups for Amdipharm Mercury had been completed, with added attention to patient confidentiality. The record of this training was provided.
- Although 10% of all follow-up calls were reviewed for quality and training purposes by the PV provider, following this instance a further 15 were randomly reviewed. In none of these calls had an issue of patient confidentiality arisen.
- Amdipharm Mercury monitored the quality of MI calls by regular and independent 'mystery shopping exercises'; the last exercise was conducted in December 2014. The PV provider had previously been included in such independent activities and would continue to do so.

In conclusion, Amdipharm Mercury submitted that both it and its PV provider had robust PV processes and procedures in place, underpinned by training and quality control measures. This meant that the company had complied with the local requirements whilst keeping abreast of PV regulations. In doing so the company had maintained the necessary high standards.

However, this case had highlighted gaps in explicitly covering patient confidentiality which had led to a deviation by an individual. This had been manifested by falling short of necessary high standards in this particular case. Although there was no evidence (despite Amdipharm Mercury actively looking) to suggest anything more than a single isolated case, immediate and appropriate actions had been taken to strengthen processes and procedures, with more long-term definitive actions to follow soon.

Amdipharm Mercury therefore submitted there was no breach of Clauses 1.9 and 16.2, but acknowledged an isolated breach of Clause 9.1, where relevant actions had been undertaken already.

PANEL RULING

The Panel noted that the complaint had arisen following an exchange between the complainant, a superintendent pharmacist, and a pharmacovigilance (PV) associate from a PV provider. The PV associate was following up a report of a possible adverse event which had occurred in a patient who had taken levothyroxine manufactured by Amdipharm. The patient had told the pharmacist that he had had 'issues' with the medicine from Amdipharm Mercury. This information had been passed to Amdipharm Mercury via Teva and in line with PV procedures at Amdipharm Mercury, had been taken up as an adverse drug reaction report. The PV associate charged with following up the report had tried twice, on successive days, to contact the pharmacist for details but he/she had been unavailable and he/she had received no response to his/her request for him/her to return his/her calls. On the third day the PV associate was able to speak to the pharmacist. The adverse event report had been given high priority by Amdipharm Mercury and in his/her conversation with the pharmacist it appeared that the the PV associate was anxious to collect as much information as possible and in that regard made a mistake by asking for personal data about the patient which required the patient's prior consent. The Panel noted the complainant's reference to the PV associate's insistence in that regard and that in his view he should not have been put under pressure to provide such information without first discussing this with and gaining the patient's prior permission. Neither party had commented on whether the pharmacist had offered to get such permission during his conversation with the PV associate or to otherwise help with the collection of data. Overall, the Panel considered that the outcome of the exchange between the superintendent pharmacist and the PV associate was unfortunate – co-operation between the two should have been such that the patient's best interests were uppermost. Nonetheless, the Panel acknowledged that in his/her efforts to collect comprehensive data, the PV associate had asked a third party for the patient's personal details which could not be provided without the patient's consent as acknowledged by Amdipharm Mercury. The Panel noted its comments above and considered that, on the very narrow point of asking for too much personal data without prior consent from the patient, high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that the PV associate had been trained in PV requirements and that training records had been kept. It was unfortunate that in following up one adverse event report the PV associate had asked a third party for more personal information than he/she should have done. Amdipharm Mercury referred to the incident as an isolated case but

acknowledged that the incident had highlighted gaps in explicitly covering patient confidentiality which had led to a deviation by the PV associate. Given Amdipharm Mercury's submission in this regard the Panel considered that the PV associate's mistake meant that, on the balance of probabilities, he/she was not fully conversant with PV requirements in relation to patient confidentiality relevant to his/her work. A breach of Clause 16.2 was ruled.

The Panel noted that Clause 1.9 required companies to comply with all applicable codes, laws and regulations. As breaches of Clauses 9.1 and 16.2 had been ruled, the Panel also ruled a breach of Clause 1.9.

Complaint received **19 December 2014**

Case completed **12 February 2015**