HEALTH PROFESSIONAL v BIOGEN IDEC

Imraldi Mailing

A hospital doctor complained that he/she had been inconvenienced by having to collect from the post office an Imraldi (adalimumab) mailing sent by Biogen Idec because the postman was unable to deliver the package to his/her home address as a signature was required. The complainant stated that this was unacceptable and an inappropriate marketing practice which constituted harassment. At least one other of his/her colleagues had also been put to considerable inconvenience by this practice.

The complainant stated that he/she had tried to ask the mailing company to remove him/her from its database and was awaiting a reply.

The detailed response from Biogen Idec is given below.

The Panel noted the complainant's submission that the Imraldi mailing was sent to his/her home address and that he/she had received information from pharmaceutical companies over the years to home and work addresses. The Panel noted Biogen Idec's submission that it had confirmed with the third-party mailing house that the addresses held on its database were those which had been provided by health professionals' themselves. The Panel noted the complainant's concern that the Imraldi mailing required a signature on receipt and he/she had to collect it from the post office which was considerably inconvenient.

Based on Biogen Idec's submission, it appeared to the Panel that the Imraldi mailing at issue was non-promotional additional Risk Management Materials (aRMMs) which Biogen Idec was required to send to targeted health professionals based on its legal and regulatory obligations. The Panel noted Biogen Idec's submission that the relevant pharmacovigilance guideline required it to track dissemination of the aRMMs and that by sending the materials by recorded delivery it allowed Biogen Idec to monitor whether the material at issue was actually received by the health professional.

The Panel acknowledged that extreme dissatisfaction was usually necessary on the part of an individual before he or she was moved to submit a complaint. The Panel noted it might be inconvenient for an individual to have to collect a package from the post office during office hours. However, in the Panel's view, that Biogen Idec wanted to track its dissemination of risk minimisation materials to ensure that it was received for compliance purposes was not unreasonable in this particular case. Taking everything into consideration, and noting its comments above, the Panel did not consider that sending the Imraldi mailing at issue by recorded delivery was inappropriate marketing practice that constituted harassment as alleged. The Panel considered that Biogen Idec had not failed to maintain high standards in this regard and ruled no breach of the Code.

The Panel noted the complainant's comment that he/she had asked the mailing company to remove him/her from its database and was awaiting a reply. The Panel noted that the complainant wished to remain anonymous to Biogen Idec and had not provided details of when he/she had submitted the request to be removed from the mailing list. The Panel considered that the complainant had not discharged the burden of proof that Biogen Idec had failed to maintain high standards in this regard and no breach of the Code was ruled.

A hospital doctor complained that he/she had been inconvenienced by having to collect from the post office an Imraldi (adalimumab) mailing. Samsung Bioepis was the marketing authorisation holder for Imraldi. Biogen International GmbH was partnered with Samsung Bioepis for all Imraldi commercial activities, including required national regulatory activities. Biogen Idec Limited confirmed that it was responsible for the Imraldi mailing at issue which solely featured the Biogen company logo.

COMPLAINT

The complainant submitted that his/her complaint was prompted by the receipt of a packet of commercial/marketing information from a company that used a database (kept by a named mailing company) to access his/her details. A photograph of the Imraldi material at issue was provided by the complainant. The postman was unable to deliver the package to the complainant's home address as a signature was required. The complainant stated that he/she then had to go to considerable inconvenience to pick the package up from the post office five miles away on a busy high street in office hours. This was unacceptable; at least one other of his/her rheumatology colleagues had also been put to considerable inconvenience by this practice.

The complainant noted that he/she had received information from pharmaceutical companies over the years to both his/her home and work addresses in this way, but the post labels originating from the mailing company now stated as a special instruction that the package 'cannot be left without a signature'. This was the case for a recent package delivered to work which put busy secretaries under unnecessary pressure.

The complainant considered that this was an inappropriate marketing practice which constituted harassment.

The complainant stated that he/she had tried to ask (by telephone and email) the mailing company to remove him/her from its database and was awaiting a reply.

When writing to Biogen Idec, the Authority asked it to consider the requirements of Clause 9.1 of the Code.

RESPONSE

Biogen Idec explained that the materials at issue were additional Risk Management Materials (aRMMs) that were required as a condition of the Imraldi marketing authorisation to be disseminated to health professionals before launch. The mailing was carried out on behalf of Biogen by a third-party medical mailing specialist.

Biogen Idec stated that it understood that the complaint did not relate to the content of the mailing, but rather the method by which the mailing was sent, in particular, that it required a signature upon receipt which caused inconvenience due to the complainant having to collect it from the post office.

Biogen Idec noted that the complainant referred to information from other pharmaceutical companies being delivered using recorded delivery/courier and had referred to another recent example delivered to the complainant's work which required a signature and appeared unrelated to the Imraldi mailing. As such, Biogen Idec submitted that the mailing method it used for the Imraldi mailing at issue was, at the very least, not unique practice and that this was not surprising considering the published guidelines on good pharmacovigilance practices.

Biogen Idec noted that the complainant referred to receipt of 'commercial/marketing information'. Biogen Idec submitted that the Imraldi mailing in question was neither commercial nor marketing information, but legally mandated information concerning aRMMs.

Biogen Idec submitted that the launch of Imraldi required the company to post aRMMs to relevant health professionals with information about the medicine. It was a condition of the product licence to provide these risk mitigation materials to target health professional specialities who would use the product, and this was mandated by the European Medicines Agency (EMA). The aRMMs were agreed with the Pharmacovigilance Risk Assessment Committee under the EU Risk Management Plan, and subsequently approved by the EMA's Committee for Medicinal Products for Human Use.

The content of the aRMMs also must be, and was, approved nationally by each National Competent Authority, such as the Medicines and Healthcare products Regulatory Agency (MHRA) and distributed to the target health professionals before launching the product. Furthermore, a list of health professional specialities to be targeted with the aRMMs information, based on the approved indications for use, was sent to the MHRA for its review, modification and approval at national level. The MHRA approved the aRMMs for the UK on 31 July 2018 and requested that the target list included the following: homecare providers and hospital pharmacists, rheumatology, dermatology, gastroenterology, ophthalmology, and specialist rheumatology paediatric clinical nurse specialists and nurse consultants.

Biogen Idec noted that the Imraldi mailing was thus not a form of advertising (and not direct marketing materials under the Privacy and Electronic Communications (EC Directive) Regulations 2003), but legally mandated materials that were sent to targeted health professionals in compliance with the company's regulatory obligations. It also clearly did not constitute harassment, although this specific allegation appeared to concern receipt of mailings generally and was not a complaint about the Imraldi mailing specifically.

As noted above, Biogen Idec engaged a medical mailing specialist, to administer the mailing of the aRMMs across Europe. The mailing company administered a database of practising health professionals' contact information, which it updated and checked regularly. The mailing company identified the health professionals in its database to whom the aRMMs should be disseminated, based on the MHRA approved target list, and printed and disseminated the materials on behalf of Biogen Idec.

In relation to the specific complaint that the aRMMs were sent by recorded delivery rather than ordinary mail, Biogen Idec noted that the relevant pharmacovigilance guideline required it to track dissemination of the aRMMs. In particular, the Heads of Medicines Agencies and EMA's Guideline on good pharmacovigilance practices (GVP) Module XVI – Risk minimisation measures: selection of tools and effectiveness indicators (Rev 2) effective as at 31 March 2017, specifically provided as follows:

> 'XVI.B.4.1.1. Reaching the target population
>
> When risk minimisation measures involve the provision of information and guidance to healthcare professionals and/or patients by means of educational tools, measures of distribution **and receipt** should be used to acquire basic information or implementation. These metrics should focus on assessing whether the materials were delivered to the target audience and **whether they were actually received by the target population** (emphasis added).'

Biogen Idec submitted that sending the aRMMs by recorded delivery allowed it to track its compliance with providing this information to health professionals and confirming whether they were actually received. It also allowed Biogen Idec in the future, should it be necessary, to prove compliance with its regulatory obligations and best practice guidelines to any regulatory authority (such as the MHRA) which might request information/proof in this regard.

In Biogen Idec's view, distribution of aRMMs information by recorded delivery was wholly consistent with the maintenance of high standards in the pharmaceutical industry, and in any event,

could not reasonably be considered to be in breach of maintaining high standards under Clause 9.1 of the Code.

Biogen Idec stated that it was not its practice to send materials to home addresses and if it happened on this occasion, Biogen Idec confirmed with the mailing company that the addresses held on its database were those which had been provided by the health professionals themselves. Biogen Idec was committed to compliance with the General Data Protection (GDPR) regulations and ensuring that any supplier or vendors it used were GDPR compliant. Accordingly, if the complainant wished to amend his/her mailing address or be removed from any mailing list, Biogen Idec recommended that he/she contacted the mailing company directly to carry out such changes.

Biogen Idec stated that it would be unlikely that the complainant would have known that the letter was from a pharmaceutical company before he/she went to pick it up as the third-party medical mailing specialist used plain envelopes. The packages included return addresses however, it was unlikely that the sender or nature of the materials would be known prior to receiving them.

For the reasons outlined above, Biogen Idec considered that it had upheld high standards as per Clause 9.1 and denied that a breach of the Code had been identified.

PANEL RULING

The Panel noted that Samsung Bioepis was the marketing authorisation holder for Imraldi and according to Biogen Idec's submission it was partnered with Samsung Bioepis for all commercial activities for Imraldi, including required national regulatory activities. The Panel noted that Biogen Idec Limited confirmed that it was responsible for the Imraldi mailing at issue.

The Panel noted the complainant's submission that the Imraldi mailing was sent to his/her home address and that he/she had received information from pharmaceutical companies over the years to home and work addresses. The Panel noted Biogen Idec's submission that it had confirmed with the third-party mailing house that the addresses held on its database were those which had been provided by health professionals' themselves. The Panel noted the complainant's concern that the Imraldi mailing required a signature on receipt and he/she had to collect it from the post office which was considerably inconvenient.

The Panel noted that the complainant had referred to the instruction 'cannot be left without a signature' on the labels used by the third-party mailing house in question and in this regard referred to another recent package delivered to his/her work address which also required a signature and put busy secretaries under unnecessary pressure. It appeared to the Panel that this package was unrelated to the Imraldi mailing at issue; the complainant had provided no further information regarding the content of the other package and the Panel had no information before it with regard to which medicine it related to and subsequently whether Biogen Idec was the responsible pharmaceutical company. The Panel therefore could make no ruling on the package delivered to the complainant's work and considered only the Imraldi mailing delivered to his/her home.

Based on Biogen Idec's submission, it appeared to the Panel that the Imraldi mailing at issue was non-promotional additional Risk Management Materials (aRMMs) which Biogen Idec was required to send to targeted health professionals based on its legal and regulatory obligations. The Panel noted Biogen Idec's submission that the relevant pharmacovigilance guideline required it to track dissemination of the aRMMs and that by sending the materials by recorded delivery it allowed Biogen Idec to monitor whether the material at issue was actually received by the health professional.

The Panel acknowledged that extreme dissatisfaction was usually necessary on the part of an individual before he or she was moved to submit a complaint. The Panel noted it might be inconvenient for an individual to have to collect a package from the post office during office hours. However, in the Panel's view, that Biogen Idec wanted to track its dissemination of risk minimisation materials to ensure that it was received for compliance purposes was not unreasonable in this particular case. Taking everything into consideration, and noting its comments above, the Panel did not consider that sending the Imraldi mailing at issue by recorded delivery was inappropriate marketing practice that constituted harassment as alleged. The Panel considered that Biogen Idec had not failed to maintain high standards in this regard and ruled no breach of Clause 9.1.

The Panel noted the complainant's comment that he/she had asked the mailing company to remove him/her from its database and was awaiting a reply. The Panel noted that the complainant wished to remain anonymous to Biogen Idec and had not provided details of when he/she had submitted the request to be removed from the mailing list. The Panel considered that the complainant had not discharged the burden of proof that Biogen Idec had failed to maintain high standards in this regard and no breach of Clause 9.1 was ruled.

Complaint received **7 November 2018**

Case completed **28 March 2019**