**CASE AUTH/3268/10/19**

# PHARMACIST v MERCK SERONO

## Homecare Service and conduct of a representative

**A homecare services pharmacist alleged that Merck Serono was involved in the aggressive promotion of Mavenclad (cladribine), a linked dispensing and delivery service and a patient support programme. Mavenclad was indicated for the treatment of adults with highly active relapsing multiple sclerosis (MS).**

**The complainant noted that on 1 October, the local Merck Serono representative emailed a named homecare service provider stating that the local provision of a clinical service to patients had been agreed and that that organisation should meet with employees of a named health board to implement it.**

**The complainant explained that although a homecare service for the provision of Mavenclad had been approved locally in September 2019, that decision had not officially been communicated to anyone. Without that official communication, Merck Serono could not state that a homecare service had been agreed. The complainant stated that before 1 October, he/she had not met anyone from Merck Serono, nor received any requests to discuss the implementation of such a service. Without such a meeting, no-one from Merck Serono could obtain any authority to contact an independent third party on either the complainant's or the health board's behalf to request the introduction of any clinical service. Such authority would always be given in writing, which was not done on this occasion.**

**The complainant noted that part of the discussion regarding the service focussed on the use of Mavenclad in a 17-year old patient. Mavenclad was used in a relatively small cohort of patients, and this was the only new patient potentially being considered for treatment at the time. As such use would not be in accordance with the terms of its marketing authorization, the complainant alleged that the promotional activities to implement the homecare service were in breach of the Code.**

**The complainant alleged that Merck Serono's actions were intended to circumvent local policies and procedures by influencing local stakeholders to implement a clinical service not in accordance with due process. The policies and procedures of the health board were designed to ensure that all medicines were prescribed appropriately, safely and effectively and that adequate governance procedures were always strictly adhered to. The complainant alleged that where a pharmaceutical company sought to impair the effectiveness of local policies, it necessarily followed that this might potentially prejudice patient care, in breach of Clause 2.**

**The complainant stated that commercial relationships between Merck Serono and the named homecare service provider should be clear and transparent and in that regard**

**he/she referred to the representative's email of 1 October. The complainant asked for the contents of any such contract to be disclosed.**

**The complainant noted that procurement of a medicine via a homecare service meant that VAT was not applied and at the current NHS list price that represented a saving of £409.45 per tablet. The complainant alleged that promotion of the homecare service constituted a substantial financial incentive to prescribe.**

**The complainant further alleged that the conduct of the Merck Serono representative was unethical, with the potential to damage the internal working relationships between health professionals within the health board.**

**Additionally, the homecare service was provided with an optional 'add-on' of a named patient support programme, an entirely separate service which was not dependent upon the 'dispense and deliver' service. Promotional material distributed by the homecare service provider referred specifically to Mavenclad not to Merck Serono's sponsorship. Likewise, on the website the large font gave the homecare service provider as a valid UK email contact point, and so an uninformed user might assume that this was the service provider's-managed service, despite the site being owned and managed by Merck Serono.**

**The complainant stated that he/she was currently only able to procure Mavenclad directly via wholesale dealing or via the homecare service provider. He/she did not consider it necessary for a pharmaceutical company to place restrictive commercial arrangements on procurement and supply which distorted the market, reduced competition and limited patient choice. The complainant referred to national good practice guidelines, which Merck claimed to follow, which stated that for homecare services, companies should offer at least two providers wherever possible and appropriate.**

**Mavenclad was an oral tablet which could be dispensed by any registered pharmacy contractor, of which the homecare service provider was but one of many. The complainant considered that the absence of any other dispensing and delivery service options was unacceptable and without any just rationale. The health board had requested Mavenclad to be made available via alternative providers, but this had not yet been implemented.**

**The complainant noted that the health board currently had a separate service level agreement with each homecare service provider under which it monitored performance and enforced quality improvements. However, a single procurement option removed market competition and the health board's ability to enact the sanction of changing provider in the event of a sub-standard service. That being the case, then the failing of any third-party in respect of delivering an acceptable clinical service would necessarily become a failing of the pharmaceutical company to adhere to the Code – including, in particular, Clause 2 by reducing confidence in the industry.**

**The detailed response from Merck Serono is given below.**

**The Panel noted Merck Serono's submission that as part of the promotion of Mavenclad, its representatives informed health professionals, where relevant, of the associated homecare dispense and delivery service and the patient support programme;**

**representatives did not tell health professionals about the homecare delivery service or the patient support programme in isolation from the promotion of Mavenclad. The Panel did not consider that the complainant had shown that Merck Serono was engaged in aggressive promotion as alleged. No breaches of the Code were ruled in that regard.**

**The Panel noted that in July, Merck Serono's representative met a local hospital pharmacist and in September medical information sent a letter to him/her about the use of Mavenclad in a 17-year old. The letter appeared to have been sent in direct response to the pharmacist's enquiry about such use. Meanwhile, the representative had also met a local consultant at a conference sometime in September. The Panel noted Merck Serono's submission that both the pharmacist and the consultant were interested in the homecare dispense and delivery service and the representative followed up on this by referring that interest to the homecare service provider in a short email of 1 October. That Panel noted, however, that the email stated that the two health professionals had agreed to go ahead with the homecare service rather than referring to them being interested in it; the representative asked the homecare service provider to meet with the pharmacist and the homecare pharmacist (assumed by the Panel to be the complainant) to make the necessary arrangements. Contact details were provided for the pharmacist and consultant but not for the complainant despite his/her overall responsibility for homecare and prescribing support. In a second email of 1 October the representative contacted a number of people at the health board, including the pharmacist and the consultant stating that he/she had asked the homecare service provider to contact the pharmacist and the complainant about the implementation of the homecare delivery service, but again did not copy in the complainant. The service provider however, contacted the complainant on the same day (1 October), forwarding the message from the representative and asking whether it and the complainant should meet. This appeared to be the first that the complainant knew about the conversations which had taken place between the representative and the two health professionals.**

**The Panel noted that, apparently separate to the conversations between the representative and the two health professionals, the local health board was deciding whether to officially approve the homecare service offered by Merck Serono. The service was approved at a meeting in September but, as of 1 October when the complainant received the email from the homecare service provider, that position had not been more widely communicated within the health board. In that regard, it appeared to the Panel that two conversations (the health board's and the representative's) were progressing in parallel without either knowing about the other. The Panel thus did not consider that the representative's reference to 'the homecare service' in his/her email to the homecare service provider was a reference to the health board's decision – it seemed coincidental given that from the complainant's account, the representative was unlikely to know about that decision. The representative did not refer to the health board or to an 'agreed homecare service', but to the pharmacist and consultant agreeing to go ahead with the homecare service. The Panel noted Merck Serono's submission that it did not receive confirmation from the homecare service provider until 31 October that the health board had signed up for the homecare service. On balance, the Panel did not consider that the representative's reference to the homecare service misleadingly implied that such a service had been approved or agreed by the health board as alleged – the service was referred to generically as the service available from Merck Serono. No breach of the Code was ruled. The Panel considered that high standards in that regard had been maintained and no breaches of the Code were ruled including of Clause 2.**

**The Panel was extremely concerned to note Merck Serono's submission that as its representatives did not usually interact with homecare pharmacists, it would not expect the complainant to know about their promotional activities. The Panel noted that the representative had not kept the complainant informed despite his/her role within the health board for homecare and prescribing support and responsibility for the implementation and monitoring of those services. The Panel queried how, by not interacting with those responsible for homecare services and the like, representatives would know about the relevant policies in place at any particular establishment. By not engaging with the complainant, the Panel considered that the representative had not maintained a high standard of ethical conduct, albeit an action apparently condoned by the company. A breach of the Code was ruled. On the balance of probabilities, the Panel thus considered that the representative had not complied with the local arrangements in force regarding the introduction of a homecare service; a breach of the Code was ruled. The Panel considered that by accepting that its representatives would not interact with homecare pharmacists, Merck Serono had not maintained high standards. A breach of the Code was ruled. The Panel considered that to ensure high quality patient care it was of utmost importance to comply with local policies and to keep key health professionals informed about ongoing discussions with staff which would impinge directly on their areas of responsibility; in accepting that its representatives would not usually interact with those with direct responsibility within a health service for homecare services, Merck Serono had brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.**

**The Panel noted the allegation that the discussion of the use of Mavenclad in a 17-year old promoted the medicine for use in an unlicensed patient population. The Panel noted, however, that the medical information letter to the pharmacist about the use of Mavenclad in an adolescent appeared to have been prompted by an enquiry from the pharmacist; it did not appear to be the proactive promotion of such use. The complainant had provided no evidence of off-licence promotion. No breaches of the Code were ruled including no breach of Clause 2.**

**The Panel noted the complainant's allegation that the commercial relationship between Merck Serono and the homecare service provider should have been clear and transparent in the representative's email of 1 October. The Panel assumed that the email in question was the one forwarded to the complainant by the homecare service provider and not the email provided by Merck Serono. The Panel noted that the representative's email of 1 October was written to the homecare service provider, not to the complainant and so no statement explaining the relationship between Merck Serono (the sender) and the service provider (the recipient) was necessary. No breaches of the Code were ruled including Clause 2.**

**In the Panel's view, there was no information before it to suggest that the arrangements between Merck Serono and the homecare service provider were inappropriate. No breach of the Code was ruled.**

**The Panel did not consider that the matter in question was a joint working project – it was the straightforward provision of a service by Merck Serono. The Panel ruled no breach of the Code related to joint working. No breaches of the Code were ruled including Clause 2.**

**The Panel noted the allegation that promotion of the homecare service constituted a substantial financial incentive to prescribe. The Panel noted, however, that the VAT position advantages in supplying Mavenclad through a homecare service (a saving of £409.45 per tablet) did not represent a personal advantage for any individual. No breaches of the Code were ruled including Clause 2.**

**The Panel noted the allegation that promotional material distributed by the homecare service provider referred to Mavenclad but not to Merck's sponsorship. The promotional literature provided by the complainant clearly referred to the homecare service provider and appeared to be material from it. The leaflet began by introducing 'our adveva Patient Support Programme for Mavenclad' followed by 'We are delighted to announce that [third party] has been selected as the UK distributor and homecare provider for Merck's Multiple Sclerosis (MS) drug, Mavenclad'. Who 'we' was, was not stated – given the reference to 'Merck's MS drug' it appeared to be an organisation other than Merck Serono and given the clear reference to the homecare service provider, readers would assume that the material was independently written by that organisation. The Code required all material relating to medicines and their uses which was sponsored by a pharmaceutical company to clearly indicate that it had been sponsored by that company. In the Panel view, the material provided implied that the service provider had been independently appointed by an unstated third party and was acting independently of Merck Serono which was not so. The only reference to Merck was as the manufacturer of Mavenclad. The Panel considered that readers would not immediately understand the relationship between Merck Serono and the homecare service provider and breaches of the Code were ruled including that high standards had not been maintained. The Panel considered that, on balance, the circumstances did not warrant a ruling of a breach of Clause 2 and ruled accordingly.**

**The Panel noted the complainant's reference to the website; neither party had provided relevant screenshots but Merck Serono provided details of the demonstration site. The only reference to Merck Serono was found in two statements in small, light grey font at the bottom of the landing page which stated that the service was a post-prescription service provided by Merck KGaA and that the material was the copyright of Merck Serono Limited. In the Panel's view, Merck Serono's involvement was not immediately obvious from the landing page – it was not sufficient for the relationship between the service provider and the company to be 'hidden' in the 'Privacy Policy'. Breaches of the Code were ruled including that high standards had not been maintained. The Panel considered, on balance, that the circumstances did not warrant a ruling of a breach of Clause 2 and ruled accordingly.**

**The Panel noted the complainant's reference to restrictive commercial arrangements on the procurement and supply of Mavenclad given that the homecare service was only available from one service provider; national good practice guidelines stated that 'Manufacturers should offer a minimum of two different Homecare Providers for each Manufacturer Funded Homecare Medicines Service wherever possible and appropriate'. In that regard, the Panel noted Merck Serono's submission that following discussions with the relevant national guidelines committee, it was agreed that because Mavenclad was only dispensed four times over two years, it was not chronic homecare and so Merck did not need to appoint another homecare service provider. The Panel considered**

**that high standards had been maintained; no breach of the Code was ruled. The Panel also ruled no breach of Clause 2 of the Code.**

A homecare services pharmacist complained about the promotion of Mavenclad (cladribine) by Merck Serono Limited. Mavenclad was indicated for the treatment of adults with highly active relapsing multiple sclerosis (MS).

**COMPLAINT**

The complainant noted that on 1 October, the local Merck Serono representative emailed a named homecare service provider, stating that the provision of a clinical service to patients had been agreed and that the organisation should meet with employees of a named health board to implement it.

The complainant listed the specific details of his/her complaint as follows:

1 Merck Serono was engaged in active and aggressive promotion of three separate and entirely distinct products:
   a) Mavenclad,
   b) a dispensing and delivery service provided by the homecare service provider and funded by Merck Serono or linked company, and
   c) a named patient support programme, known as adveva which included a website adveva.co.uk.

2 The health board had had Mavenclad available for prescribing since January 2019. As patients already had access to, and some were already on active treatment, and that there were no restrictions placed upon prescribing other than those contained within the summary of product characteristics (SPC) and in guidance from the National Institute for Health and Care Excellence (NICE), it was assumed that Merck Serono's promotional activities over the past few months were related primarily, although not exclusively, to 1(b) and (c) above.

3 Although a homecare service for the provision of Mavenclad had been approved by the relevant committee in late September 2019, that decision had not officially been communicated to any clinical team member or other person. Without this official communication, Merck Serono was not entitled to make any assertion that a homecare service had been agreed.

4 As a manager of all the homecare services provided to patients of the health board, the complainant stated that he/she was responsible for the implementation and monitoring of those services. The health board had clear policies regarding the introduction of new services, overseen by a named committee, so that it could meet its obligations and expectations under the Royal Pharmaceutical Society's Professional Standards for Homecare Services following the publication of the Hackett Report.

5 The complainant stated that before 1 October, he/she had not met anyone from Merck Serono, nor received any requests to discuss the implementation of such a service.

6 With no such meeting, no-one from Merck Serono could obtain any authority to contact an independent third party on either the complainant's or the health board's behalf to request the introduction of any clinical service. Such authority would always be given in writing, which was not done on this occasion.

7 Part of the local discussion regarding this service focussed on the use of Mavenclad in a 17-year old patient. Mavenclad was used in a relatively small cohort of patients, and this was the only new patient potentially being considered for treatment at the time. Such use would not be in accordance with the terms of its marketing authorization. Merck Serono (including, the complainant believed, the local representative) knew about these discussions yet was still keen to see the homecare service rapidly implemented. The complainant alleged that promotional activities to implement the homecare service were in breach of Clause 3.

8 The complainant submitted that the actions above, taken as a whole, were intended to circumvent local policies and procedures by influencing local stakeholders to implement a clinical service not in accordance with due process. The health board's policies and procedures were designed to ensure that all medicines were prescribed appropriately, safely and effectively and that adequate governance procedures were always strictly adhered to. The complainant alleged that where a pharmaceutical company sought to impair the effectiveness of local policies, it necessarily followed that this might potentially prejudice patient care, in breach of Clause 2.

9 The complainant alleged that the 1 October email showed that Merck Serono had promoted the business interests of a completely independent third party directly to health board employees, instead of marketing its own product. This was unacceptable and led to a conflict of interest. If the local Merck Serono representative was acting as a representative of the homecare service provider, then that should have been clearly stated – and any and all commercial relationships between Merck Serono and the service provider should be clear and transparent. The complainant asked that the contents of any such contract be disclosed in accordance with Clause 20.

10 Central to the promotion of the homecare service was that this procurement method exploited the ability to provide medicine at 0% VAT rather than the existing rate of 20%. At the current NHS list price, that represented a saving of £409.45 per tablet. Considering point 2 above, the promotion of this service constituted a substantial financial incentive to prescribe in breach of Clause 18.

11 The complainant alleged that the representative's conduct detailed above was unethical, with the potential to damage the internal working relationships between health professionals within the health board, in breach of Clauses 15 and 20.

12 Additionally, the homecare service was provided with an optional 'add-on' of a named patient support programme, an entirely separate service which was not dependent upon the 'dispense and deliver' service. Promotional material distributed by the homecare service provider referred specifically to Mavenclad but not to Merck's sponsorship, even though it owned the registered trademark – both breaches of Clause 18.

13 Likewise, on the website the large font gave the homecare service provider as a valid UK email contact point, and so an uninformed user might assume that this was a service provider-managed service, despite the site being owned and managed by Merck Serono.

14 Additionally, there was an ongoing analysis of the cost-impact of Mavenclad to the health board. Mavenclad was marketed with a highly complex confidential pricing agreement with the NHS of which the complainant did not yet have full details, but which would rely upon post-marketing non-interventional studies. The complainant stated that he/she had requested full details of this and might consider it necessary to update this complaint (or submit an additional one) in respect of Clause 13 since the promotional activities appeared to be linked to these studies.

The complainant stated that he/she was currently only able to procure Mavenclad directly via wholesale dealing, or via the homecare service provider. He/she did not consider it necessary for any pharmaceutical company to place restrictive commercial arrangements on procurement and supply. This distorted the market, reduced competition and limited patient choice. The complainant noted that Merck claimed to adhere to the National Homecare Medicines Committee (NHMC) Good Practice Principles which stated:

> 'Manufacturers should offer a minimum of two different Homecare Providers for each Manufacturer Funded Homecare Medicines Service wherever possible and appropriate.'

As an oral tablet, Mavenclad required no special dispensing arrangements and could be dispensed by any registered pharmacy contractor, of which the homecare service provider was but one of many. The complainant considered that the absence of any other dispensing and delivery service options was unacceptable and without any just rationale. The health board had asked that Mavenclad be made available via alternative providers, but this had not yet been implemented.

Principle 11 (a reference to the principles and overview of self regulation set out in the introduction to the Code) stated that companies were responsible under the Code for the activities of their staff and third parties. If this was taken as an absolute literal interpretation, it would mean that any service provided to either the NHS or directly to the patient via a third-party provider, would be governed by the Code. Currently, the health board would have a separate service level agreement with each homecare service provider under which it monitored performance and enforced quality improvements. However, if pharmaceutical companies developed restrictive marketing arrangements for a product and enforced a single procurement option, then this removed market competition and the health board's ability to change provider in the event of a sub-standard service. That being the case, then the failing of any third-party in respect of delivering an acceptable clinical service would necessarily become a failing of the individual pharmaceutical company to adhere to the Code – in particular Clause 2 (by reducing confidence in the industry) and Clause 20; additionally each employee of the homecare company would presumably be required to meet the requirements of Clauses 15 and 16. The complainant was not sure that adhering to this interpretation would be beneficial to any party involved, and was certainly not a change he/she would wish to see but where no alternative supplier was available this might become the only means of enforcing acceptable standards of patient care. The complainant noted that this would be in contrast to paragraph 1.10 of the NHMC Good Practice Principles.

When writing to Merck Serono, the Authority asked it to consider the requirements of Clauses 2, 3, 15, 16, 18 and 20 as cited by the complainant. In addition, the company was asked to consider the requirements of Clauses 7.2, 9.1, 9.10 and 21 and Clauses 2 and 9.1 in relation to each allegation.

**RESPONSE**

Merck explained that it had appointed the named homecare delivery provider to administer its homecare dispense and delivery service for Mavenclad as well as its named patient support programme (PSP) adveva. Both could be provided independently or together.

Merck stated that it supplied Mavenclad to the NHS via homecare through the named homecare service provider or directly through wholesale via a named supplier.

Merck submitted that it had a confidential commercial agreement with a named NHS region, and not with the individual health boards, for the supply of Mavenclad.

Merck noted that in Point 3 above, the complainant referred to a meeting of the health board committee in September during which the homecare service was approved. The complainant stated that that decision had not yet been officially communicated and so the local representative could not have known about it. At interview, the representative confirmed he/she was not aware of such a meeting or its outcome.

The representative's email to the homecare service provider was not a result of, or linked to, the outcome of such a meeting. It was sent following conversations between the representative, a local neuro pharmacist and a local neurology consultant which took place before, and independently from the meeting referred to by the complainant (details set out below). During these conversations the pharmacist and the consultant were both interested in the homecare service, and the representative followed up on this by referring the interest to the homecare service provider given that Merck had appointed the service provider to follow up on any enquiries relating to the provision of homecare dispense and delivery service.

Merck Serono submitted that in-depth interviews with several staff members revealed that the complainant had asked for information on how Merck had chosen the homecare service provider as its provider, what criteria were used and why a different named provider was not chosen; details of the confidential commercial agreement with the NHS region and clinical trial data. Further details of these discussions were outlined below.

The outcome of the interviews was that Merck did not consider that any of its staff had behaved inappropriately or in breach of the Code. They acted in good faith following up on the various requests received.

**Point 1**

The complainant stated that 'Merck Serono was engaged in active and aggressive promotion of three separate and entirely distinct products:

a) Mavenclad - a licensed medicine
b) A dispensing and delivery service provided by the named homecare service provider and funded by Merck Serono or linked company

c) A patient support programme, known as adveva which included the website www.adveva.co.uk.

Merck submitted that, as part of their focus on the promotion of Mavenclad, its representatives informed health professionals, where relevant, of the existence of the associated homecare dispense and delivery service, and the adveva patient support programme. They did not tell health professionals about the delivery service or the patient support programme in isolation from the promotion of Mavenclad. Merck thus disagreed with the complainant's allegation that it promoted three distinct products.

Merck noted that with no specific details, it was unable to investigate the allegation that it was engaged in aggressive promotion. As a company it endeavoured to always ensure that the conduct of its representatives was appropriate, it did not encourage such behaviour and had no reason to believe that its representatives had acted in such a way. Merck denied breaches of Clauses 2 and 9.1.

**Point 2**

Merck noted the complainant's assumption that the company's promotional activities over the past few months were related primarily, although not exclusively, to the dispensing and delivery service and the patient support programme given that the health board had had Mavenclad available for prescribing since January 2019.

As referred to in Point 1 above, the representatives' main activity was to promote Mavenclad. This was not a one-off activity undertaken by the field force, it was an ongoing activity. Representatives did not usually interact with the homecare pharmacists and as such Merck would not expect the complainant to know about the promotional activities of its representatives. These activities were all conducted in line with the Code and the company denied any breach of Clauses 2 or 9.1.

**Point 3**

Merck noted that the complainant had stated the although a homecare service for the provision of Mavenclad had been officially approved by the health board in September 2019, that decision had not been communicated to any clinical team member or other person. Without this official communication, Merck Serono was not entitled to state that a homecare service had been agreed.

As stated above, Merck did not know about the decision to approve the homecare service; the only communication that it received was confirmation from the homecare delivery provider on 31 October 2019 that the health board had signed up for homecare and for the wholesale.

Merck submitted that it never asserted that the health board had agreed to engage with the homecare service. When the representative wrote to the homecare service provider, this was based on conversations with the pharmacist during a face-to-face meeting in July 2019 and with the consultant during an MS congress that ran from September 11-13. During those conversations, both health professionals expressed interest in having access to the homecare dispense and delivery service. (See Points 5 and 6 below for further details on this conversation and the context within which the representative's email was sent.)

Merck stated that it appeared that the complainant had misunderstood or misinterpreted the representative's email. Under no circumstances did the representative try to circumvent the process, he/she merely followed up on his/her discussions with the aforementioned health professionals. Merck apologised for any misunderstanding this might have caused. The company denied any breaches of Clauses 2, 7.2, 9.1 and 15.2.

**Point 4**

Merck noted that the complainant stated that he/she was responsible for the implementation and monitoring of homecare services and that the health board had clear policies in place regarding the introduction of new services, overseen by a named committee, so that it could meet its obligations and expectations under the Royal Pharmaceutical Society's Professional Standards for Homecare Services following the publication of the Hackett Report.

Merck stated that it respected policies and procedures of all health boards across the UK and would never seek to interfere with such policies and processes. As mentioned above, the representative's email was based on discussions with individual health professionals and was not intended to interfere with the decision of any health board committee. Merck denied breaches of Clauses 2 and 9.1

**Point 5 and 6**

In Points 5 and 6, the complainant stated that before 1 October, he/she had not met anyone from Merck Serono, nor received any requests to discuss the implementation of a [homecare] service. The complainant had added that without such a meeting, no-one from Merck Serono could obtain any authority to contact an independent third party on either the complainant's or the health board's behalf to request the introduction of any clinical service. Such authority would always be given in writing, which was not done on this occasion.

Merck explained that it had appointed the home care delivery provider to deliver a homecare dispense and delivery service for Mavenclad and its patient support programme. The homecare service provider was not an independent third party to Merck. The representative did not contact this organisation on behalf of the complainant or the health board, but as Merck's service provider.

Merck reiterated that the representative contacted the homecare delivery service following the interest in the dispense and delivery service shown by two health professionals. Such interest was expressed during a face-to-face meeting on in July 2019 with the pharmacist and at a conference 11-13 September with the consultant. Both of those meetings took place before the health board meeting in September referred to by the complainant. Merck provided a copy of an email from the representative to the neuro consultant, dated 1 October 2019, following up on the conversation they had had at the conference. As stated above, Merck considered that this was a misunderstanding and as such it did not believe it had breached Clauses 2 and 9.1, 15.2 or 15.4.

**Point 7**

Merck noted that the complainant had referred to local discussions regarding the use of Mavenclad in a 17-year old patient and that that use would not be in accordance with the terms of its marketing authorization. The complainant had added that Merck was aware of these

discussions but was still keen to see the homecare service implemented rapidly. The complainant had alleged that the promotional activities to implement the homecare service were in breach of Clause 3.

Merck explained that the representative received an enquiry from the neuro pharmacist about the use of Mavenclad in a 17-year-old patient. That query was passed to medical information and a letter was sent to the pharmacist which was included in the complaint. The representative was not involved with this communication and did not receive a copy of the letter.

Merck had discovered that the complainant also requested information on its clinical trial data. His/her request was referred to a medical science liaison employee (MSL) who met with him/her in late October. During that meeting, the complainant noted concerns about off-licence promotion. On three separate occasions during the meeting the MSL told him/her that if the Merck representative had engaged in off-licence promotion, he/she needed to report it immediately. The MSL asked the complainant to provide details but the complainant indicated that his/her concern was not with Merck's representative but with his/her clinicians prescribing off-label, at which point the complainant referred to prescribing Mavenclad for a 17-year old. Merck stated that it assumed that the complainant's concern arose from the neuro pharmacist's request for information on whether Mavenclad could be used in a 17-year old with relapsing remitting MS. As it seemed that the complainant's concerns related to the actions of consultants, rather than those of Merck, which appropriately followed up on the medical information request, the company refuted any allegation that it had engaged in off-label promotion and it denied a breach of Clauses 2, 3 or 9.1.

**Point 8**

Merck noted the complainant's reference to circumvention of local policies and procedures in order to implement a clinical service not in accordance with due process, and his/her allegation that where a pharmaceutical company sought to impair the effectiveness of local policies, it necessarily followed that this might potentially prejudice patient care, in breach of Clause 2.

Merck denied that it had tried to circumvent local policies and procedures by influencing local stakeholders. It had no reason to believe that its local representative, or any of its representatives, had not acted in compliance with the Code. As stated above, and as shown by the email from the representative, he/she had simply followed up on legitimate conversations he/she had had with the neuro pharmacist and the consultant. Merck thus denied a breach of Clauses 2, 9.1, 15.2 and 15.4.

**Point 9**

Merck noted that the complainant had queried the relationship between Merck and homecare service provider and that any and all commercial relationships between Merck and the homecare service provider should be clear and transparent. The complainant had suggested that the content of the contract between the parties should be disclosed.

Merck submitted that the representative was employed to promote Mavenclad which had an associated homecare dispense and deliver service and patient support programme. The representative did not work for the homecare service provider and he/she simply referred enquiries from health professionals to it. The homecare service provider was not an independent third party to Merck but was its preferred service provider for the delivery of its

homecare services and patient support programme. Merck submitted that as this was not a joint working arrangement within the meaning of the Code, Clause 20 did not apply. The contract between Merck and the homecare service provider was confidential and Merck did not consider that it was relevant to the complaint. Merck denied any breach of Clauses 2, 9.1, 9.10, 20 and 21.

**Point 10**

Merck noted that the complainant alleged that the £409.45 saving made per tablet, if Mavenclad was procured via a homecare service, constituted a substantial financial incentive to prescribe in breach of Clause 18.

Merck explained that if a medicine was bought and dispensed in a hospital it was subject to VAT whereas community pharmacies were not. Therefore, many hospitals now outsourced this to third parties running on a community pharmacy basis. Homecare companies operated under community pharmacy so were therefore not subject to VAT.

Hospital trusts/health boards decided, independently of Merck and of the prescriber, whether prescriptions were dispensed in hospital or via a homecare or community pharmacy. Any VAT related issues should be raised with the Her Majesty's Revenue and Customs. Merck understood that a consultant would prescribe what he/she considered was the most appropriate treatment for the patient and it was highly unlikely that he/she would consider VAT when making treatment decisions.

Merck therefore did not consider that promoting Mavenclad and its associated homecare delivery service or a patient support programme to a prescribing health professional could constitute an inducement to prescribe in breach of Clause 18, including 18.1. Any potential savings made by the hospital were independent from the prescribing decision and related only to a dispensing decision made by a different stakeholder. Merck denied breaches of Clauses 2 and 9.1.

**Point 11**

Merck noted the allegation that the conduct of the representative was unethical, with the potential to damage the internal working relationships between health professionals within the health board, in breach of Clauses 15 and 20.

Merck stated that, as demonstrated above, it had no reason to believe that it had not maintained high standards or that its representative's conduct was unethical. The representative had followed up on enquires from two health professionals, which took place before, and completely independently from, any health board decision. Merck stated that it always worked to maintain high standards; the company denied breaches of Clauses 2, 9.1, 15, 15.2 and 20.

**Point 12**

Merck noted that the complainant referred to the optional 'add-on' of a patient support programme (adveva) and that promotional material distributed by the homecare service provider referred specifically to Mavenclad but not to Merck's sponsorship, even though the service provider did not own the registered trademark.

Merck submitted that the material distributed by the homecare service provider outlined that the service would be provided by it on behalf of Merck. Merck's involvement was described in the first paragraph of the material, ie 'We are delighted to announce that [named homecare service provider] has been selected as the UK distributor and homecare provider for Merck's multiple sclerosis (MS) drug, Mavenclad'. The material outlined what the health professional/trust could expect from the service provider's offering.

Merck offered health professionals the option to prescribe Mavenclad alone, or in combination with the dispense and delivery service and/or with the patient support programme. This gave health professionals and trusts flexibility to decide which services they would like to choose.

Merck denied any breach of Clauses 2, 9.1, 9.10 or 18.

**Point 13**

Merck noted the complainant's concern that as the website gave the homecare service provider as a valid UK email contact point, an uninformed user might assume that this was the service provider's managed service, despite the site being owned and managed by Merck.

Merck reiterated that the named organisation was the provider contracted to deliver homecare and the adveva patient support programme to those trusts which wished to avail of it. These services were delivered and managed by the service provider separately from Merck to ensure patient confidentiality. Therefore, it was the service provider's email address that would be used for contact with any questions related to these services.

It was noted at the bottom of the website page that 'adveva is a post-prescription service provided by Merck KGaA'. In addition, Merck and the service provider's involvements were clearly explained and set out in the website's privacy policy, which was accessible without the need to log in or sign-up to the website. The privacy policy stated 'The adveva patient support program is set up by Merck and delivered to you by [named homecare service provider]…for patients in the UK and by [an alternative provider] for patients in the Republic of Ireland ….'.

Although the website was a Merck website and the patient support programme was sponsored by Merck, the patient support programme was managed by the service provider and Merck had no access to any patient information so as to protect patient confidentiality. To further guarantee patient confidentiality, the website was managed and hosted on behalf of Merck by a third-party provider and this was stated in the website's terms of use and privacy policy.

Merck considered that its materials, in particular those related to the patient support programme, clearly indicated its sponsorship or involvement, in compliance with Clause 9.10.

**Point 14**

Merck noted that the complainant referred to the ongoing analysis of the cost-impact of Mavenclad and that it was marketed with a highly complex confidential pricing agreement with the NHS which would rely on post-marketing non-interventional studies.

Merck noted that the complainant's comment regarding the reliance upon post-marketing non-interventional studies was incorrect; the agreement between Merck and NHS region did not rely on any such studies.

Upon request for further information from the complainant, a member of Merck's value, access & engagement team had proposed some dates to discuss the agreement. As this was a confidential commercial agreement he/she would only be able to discuss aspects that were publicly available.

The MSL met the complainant on 30 October 2019 and it had been agreed that medical information would send him/her details of clinical trials.

Merck submitted that Clause 13 was therefore entirely irrelevant. In addition, the company denied a breach of Clauses 2 and 9.1.

Merck noted that the complainant had referred to restrictive commercial arrangements and, in that regard, had cited the NHMC Good Practice Principles on the provision of Manufacturer Funded Homecare Medicines Services, ie that where possible and appropriate, manufacturers should offer at least two different homecare providers. In this context, Merck noted that in order for it to put a homecare service in place, it had to have that service approved by the NHMC before it could be rolled out.

Merck stated that it was very transparent when it sought approval from the NHMC and only included a single homecare service provider. Following discussions with the NHMC, it was agreed that because Mavenclad was only dispensed 4 times over the course of two years, it was not chronic homecare and so Merck did not need to appoint another homecare service provider. Ultimately, Merck considered that this was a commercial decision, outside the scope of the Code. By engaging early with the NHMC in accordance with the Good Practice Principle, Merck considered that it had maintained high standards and it denied breaches of Clauses 2 and 9.1.

**Summary**

Merck stated that compliance with the Code was taken very seriously across the organisation. The explanation above and the supporting documentation provided clear reasons as to why the Code had not been breached with regard to the allegations relating to Clauses 2, 3, 7.2, 9.1, 9.10, 15, 16, 18, 20 and 21.

**PANEL RULING**

The Panel noted that the complaint was wide-ranging and that there was some overlap in the points raised. The Panel further noted that the complainant had the burden of proving his/her complaint on the balance of probabilities.

The Panel noted Merck Serono's submission that as part of their focus on the promotion of Mavenclad, its representatives informed health professionals, where relevant, of the existence of the associated homecare dispense and delivery service, and the adveva patient support programme; representatives did not tell health professionals about the homecare delivery service or the patient support programme in isolation from the promotion of Mavenclad. In the Panel's view, companies were entitled to tell health professionals about services or support which they could offer for the benefit of patients provided it was done in a manner which complied with the Code. The Panel, however, did not consider that the complainant had shown

that Merck Serono was engaged in active and aggressive promotion of three separate and entirely distinct products as alleged. No breach of Clauses 9.1 and 2 were ruled in that regard.

The Panel noted that on 24 July, Merck Serono's representative met the neuro pharmacist and in mid September medical information sent a letter to the pharmacist regarding the use of Mavenclad in a 17-year old. The letter appeared to have been sent in direct response to the pharmacist's enquiry about such use. Meanwhile, the representative had also met the neuro consultant at a conference sometime between 11 and 13 September. The Panel noted Merck Serono's submission that both the pharmacist and the consultant were interested in the homecare dispense and delivery service and the representative followed up on this by referring that interest to the homecare service provider in a short email of 1 October. The Panel noted, however, that the email stated that the two health professionals had agreed to go ahead with the homecare service rather that referring to them being interested in it; the representative asked the homecare service provider to meet with the neuro pharmacist and the homecare pharmacist (assumed to be the complainant) to make the necessary arrangements. Contact details were provided for the neuro pharmacist and neuro consultant but not for the complainant despite his/her overall responsibility for homecare and prescribing support. In a second email of 1 October (copy provided by Merck Serono), the representative contacted a number of people at the health board, including the neuro pharmacist and the neuro consultant stating that he/she had asked the service provider to contact the neuro pharmacist and the complainant about the implementation of the homecare delivery service, but again did not copy in the complainant. The homecare service provider however, contacted the complainant on the same day (1 October), forwarding the message from the representative and asking whether the service provider and the complainant should meet. This appeared to be the first that the complainant knew about the conversations which had taken place between the representative and the two health professionals.

The Panel noted that, apparently separate to the conversations between the representative and the two health professionals, the local health board was deciding whether to officially approve the homecare service offered by Merck Serono. The service was approved at a meeting in late September but, as of 1 October when the complainant received the email from the service provider, that position had not been more widely communicated within the health board. In that regard, it appeared to the Panel that two conversations (the health board's and the representative's) were progressing in parallel without either knowing about the other. The Panel thus did not consider that the representative's reference to 'the homecare service' in his/her email to the service provider was a reference to the health board's decision – it seemed coincidental given that from the complainant's account, the representative was unlikely to know about that decision. The representative did not refer to the health board or to an 'agreed homecare service', but to the pharmacist and consultant agreeing to go ahead with the homecare service. The Panel noted Merck's submission that it did not receive confirmation from the service provider until 31 October that the health board had signed up for homecare and for the service provider wholesale. On balance, the Panel did not consider that the representative's reference to the homecare service misleadingly implied that such a service had been approved or agreed by the health board as alleged – the service was referred to generically as the service available from Merck. No breach of Clause 7.2 was ruled. The Panel considered that high standards in that regard had been maintained and no breach of Clauses 15.2 and 9.1 were ruled. It followed that there was thus no breach of Clause 2 and the Panel ruled accordingly.

The Panel was extremely concerned to note Merck Serono's submission that as its representatives did not usually interact with homecare pharmacists, the company would not expect the complainant to know about the promotional activities of its representatives. The Panel noted that the representative had not kept the complainant informed despite his/her central role within the health board for homecare and prescribing support and responsibility for the implementation and monitoring of those services. The Panel queried how, by not interacting with those responsible within a health organisation for homecare services and the like, local representatives would know about the relevant policies in place at any particular establishment. The Panel noted that in its document setting out Good Practice Principles, the NHMC stated, at Section 2.5 regarding local communication, that 'Manufacturers, and their contracted Homecare Providers, should aim to discuss any available Manufacturer Funded Homecare Medicines Services or Patient Support Programmes with the Pharmacy Homecare Team prior to any engagement with Clinical Teams at the Clinical Referring Centre'. By not engaging with the complainant, the Panel considered that the representative had not maintained a high standard of ethical conduct, albeit an action apparently condoned by the company. A breach of Clause 15.2 was ruled. The Panel further noted the complainant's submission that the health board had policies regarding the introduction of new services, overseen by a named committee. No copy of the policies had been provided and Merck made no reference to them. On the balance of probabilities, the Panel thus considered that the representative had not complied with the local arrangements in force regarding the introduction of a homecare service; a breach of Clause 15.4 was ruled. The Panel considered that by accepting that its representatives would not interact with homecare pharmacists, Merck Serono had not maintained high standards. A breach of Clause 9.1 was ruled. The Panel considered that to ensure high quality patient care it was of utmost importance to comply with local policies and to keep key health professionals informed about ongoing discussions with staff which would impinge directly on their areas of responsibility; in accepting that its representatives would not usually interact with those with direct responsibility within a health service for homecare services, Merck Serono had brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel noted the allegation that the discussion of the use of Mavenclad in a 17-year old promoted the medicine for use in a patient population for which it was not licensed. Mavenclad was only indicated for the treatment of certain adults with MS. The Panel noted, however, that the medical information letter to the pharmacist about the use of Mavenclad in an adolescent appeared to have been prompted by an enquiry from that pharmacist – it did not appear to be the proactive promotion of such use. The complainant had provided no evidence of off-licence promotion. No breach of Clause 3.2 was ruled. In that regard, the Panel considered that high standards had been maintained; no breach of Clause 9.1 was ruled. The Panel also ruled no breach of Clause 2.

The Panel noted the complainant's submission that the commercial relationship between Merck Serono and the homecare service provider should have been clear and transparent in the representative's email of 1 October – If the representative was acting as a representative of the homecare service provider, then that should have been clearly stated. The Panel assumed that the email in question was the one forwarded to the complainant by the service provider and not the email provided by Merck Serono. The Panel noted that the representative's email of 1 October was written to the service provider, not to the complainant and so in that regard, no statement explaining the relationship between Merck Serono (the sender) and the service provider (the recipient) was necessary. The Panel ruled no breach of Clause 9.10. High

standards had been maintained and so no breach of Clause 9.1 was ruled. It followed that there was no breach of Clause 2 and the Panel ruled accordingly.

In the Panel's view, although Merck Serono had been asked to consider the requirements of Clause 21, there was no information before it to suggest that the arrangements between Merck Serono and the service provider were inappropriate. No breach of Clause 21 was ruled.

The Panel noted the complainant's reference to Clause 20 but did not consider that the matter in question was a joint working project, defined as a situation where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery. In this case there was no pooling of skills – it was the straightforward provision of a service by Merck Serono. The Panel thus ruled no breach of Clause 20. In that regard, the Panel considered that high standards had been maintained; no breach of Clause 9.1 was ruled. The Panel also ruled no breach of Clause 2.

The Panel noted the allegation that promotion of the homecare service constituted a breach of Clause 18. Clause 18.1 stated that no gift, pecuniary advantage or benefit might be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicines, subject to the provisions of Clauses 18.2 and 18.3. Clause 18.2 allowed companies to provide health professionals with patient support items to pass on to patients and Clause 18.3 allowed the provision of inexpensive pens/pencil/notepads to health professionals when such were required for use at meetings. The Panel noted that the VAT position in supplying Mavenclad through a homecare service - 0% vs 20% - represented, according to the current NHS list price, a saving of £409.45 per tablet. The Panel noted, however, that such a saving did not represent a personal advantage for any individual and so it ruled no breach of Clause 18.1. In that regard, the Panel considered that high standards had been maintained; no breach of Clause 9.1 was ruled. The Panel also ruled no breach of Clause 2.

The Panel noted the allegation that promotional material distributed by the homecare service provider referred specifically to Mavenclad but not to Merck's sponsorship. The Panel noted Merck's submission that it had appointed a service provider to deliver the homecare dispense and delivery service for Mavenclad and its patient support programme adveva and that organisation was not an independent third party to Merck. The promotional literature provided by the complainant clearly referred to the homecare service provider and appeared to be material from that organisation. The leaflet began with 'Introducing our adveva Patient Support Programme for Mavenclad (cladribine 10mg tablets)' followed by, 'We are delighted to announce that [homecare service provider] has been selected as the UK distributor and homecare provider for Merck's Multiple Sclerosis (MS) drug, Mavenclad'. Who 'we' was, was not stated – given the reference to 'Merck's MS drug' it appeared to be an organisation other than Merck Serono and given the clear reference to the homecare service provider, readers would assume that the material was independently written by that organisation. The Panel noted that Clause 9.10 required all material relating to medicines and their uses which was sponsored by a pharmaceutical company, to clearly indicate that it had been sponsored by that company. In the Panel view, the statement in the material provided implied that the homecare service provider had been independently appointed by an unstated third party and was acting independently of Merck Serono which was not so. The only reference to Merck was as the manufacturer of Mavenclad. The Panel considered that readers would not immediately

understand the relationship between Merck Serono and the homecare service provider and a breach of Clause 9.10 was ruled. High standards had not been maintained; a breach of Clause 9.1 was ruled. The Panel noted its concerns but considered that, on balance, the circumstances did not warrant a ruling of a breach of Clause 2 which was seen as a sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

The Panel noted the complainant's reference to the adveva website; neither party had provided relevant screenshots but Merck Serono provided details of the demo site and how to login. The Panel noted that the only reference to Merck Serono was found by scrolling to the bottom of the landing page to two statements in small, light grey font which informed the reader that adveva was a post-prescription service provided by Merck KGaA and that the material was the copyright of Merck Serono Limited. The Panel noted that Clause 9.10 required all material relating to medicines and their uses, which was sponsored by a pharmaceutical company, to clearly indicate that it had been sponsored by that company. In the Panel's view, Merck Serono's involvement was not immediately obvious from the landing page – it was not sufficient for the relationship between the homecare service provider and the company to be 'hidden' in the 'Privacy Policy'. A breach of Clause 9.10 was ruled. High standards had not been maintained; a breach of Clause 9.1 was ruled. The Panel noted its concerns but considered that, on balance, the circumstances did not warrant a ruling of a breach of Clause 2 which was seen as a sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

The Panel noted the complainant's reference to Clause 13 which set out the requirements for, among other things, non-interventional studies of marketed medicines. The Panel noted the complainant's submission that he/she might consider it necessary to update this complaint (or submit an additional one) in respect of Clause 13. In that regard, the Panel did not consider that it had before it an allegation of a breach of Clause 13 and so no ruling was made in that regard.

The Panel noted the complainant's reference to restrictive commercial arrangements on the procurement and supply of Mavenclad given that the homecare service was only available from one organisation; the NHMC Good Practice Principles: Provision of Manufacturer Funded Homecare Medicines Service, stated at paragraph 1.2 that 'Manufacturers should offer a minimum of two different Homecare Providers for each Manufacturer Funded Homecare Medicines Service wherever possible and appropriate'. In that regard, the Panel noted Merck Serono's submission that following discussions with the NHMC, it was agreed that because Mavenclad was only dispensed four times over the course of two years, it was not chronic homecare and so Merck did not need to appoint another homecare service provider. The Panel considered that high standards had thus been maintained; no breach of Clause 9.1 was ruled. The Panel also ruled no breach of Clause 2.

**Complaint received** **24 October 2019**

**Case completed** **14 August 2020**