Medicines Australia

Better health through research & innovation

COMPLAINT OUTCOME

1170 - Patient communication re Revlimid®

DETERMINATIONS OF THE MEDICINES AUSTRALIA CODE OF CONDUCT AND APPEALS COMMITTEES

The administration of the Code is supervised by the Code of Conduct Committee. The Code of Conduct Committee has the power to make a determination as to a breach of the Code and impose sanctions. The right of appeal is available to both the Complainant and Subject Company. An appeal is heard by the Appeals Committee which has the power to confirm or overturn the decision and to amend or remove any sanctions.

The decisions of the Code of Conduct and Appeals Committees are relevant to the date of publication of the materials subject to complaint and approved Product Information (PI) at that time. A complaint is not deemed finalised until the Subject Company has advised Medicines Australia that they will not appeal the outcome of the Code of Conduct Committee decision (following circulation of the Code minutes) or, in the case of an appeal, the minutes of the Appeals Committee meeting have been provided to both parties.

This report is an extract of the minutes of the complaint heard on 19 June 2023.

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DOWNLOAD THE CODE

The Code of Conduct and all associated materials are available on the Medicines Australia Website

COMPLAINT 1170 - Patient communication re Revlimid®

SUBJECT COMPANY	PRODUCT	COMPLAINANT
Celgene, a BMS Australia company	Revlimid® (Lenalidomide)	A provider of pharmacy services (de-identified on request)

COMPLAINT

This complaint concerns written communication sent by Celgene Pty Ltd to patients on Revlimid. The complainant believes the communication constitutes inappropriate promotion of a pharmaceutical drug to a consumer, inducing them to stay with the Celgene brand of Lenalidomide.

The complaint alleges that the communication has the intended effect to persuade patients to stay on the originator brand Revlimid® rather than changing to a generic molecule (noting generic molecules were listed on the PBS in February 2023), which therefore constitutes promotional material targeting consumers.

In addition, the complaint alleges the communication implies superiority of the originator brand as opposed to the generics now available and implies that generic companies' safety programs do not ensure the same level of safety as the i-access® program. As a result, this has caused confusion with patients and concerns about using the generic brands and encourages patients to move away from what could be their usual place of dispensing should they not dispense the originator brand Revlimid®.

The complaint alleges the communication is unsolicited information from a pharmaceutical company to consumers, and questions whether those recipients have consented to being contacted directly by Celgene. Letters "may have been sent to all patients including those that have already decided to change to a generic brand of Lenalidomide."

SECTIONS OF THE CODE

- **Principle 2:** Companies are committed to transparency in their interactions with healthcare professionals and other stakeholders, to maintain trust and confidence in the industry.
- **Principle 5**: Consistent with our ethical undertakings, nothing is offered or provided by a Company in a manner or with conditions that would have an inappropriate influence on the approval, recommendation, prescribing, and/or use of a product
- **Principle 6**: Companies' interactions with all stakeholders are at all times professional, consistent with all legislative requirements, and appropriate to the information needs of the respective audience.
- **Section 13.2**: The tone of the material must not be presented in a way that unnecessarily causes alarm or misunderstanding in the community nor stimulate the demand for prescription of a particular product.
- **Section 14**: A Company may use individual patient data to report on whether the program delivers any improvement in compliance, for safety monitoring or to otherwise increase positive health outcomes, so long as the appropriate consents have been provided and all data is used in a de-identified manner… and ….data from a PSP should never be used for promotional purposes.

COMPLAINT 1170 - Patient communication re Revlimid®

RESPONSE TO THE COMPLAINT

Celgene Pty Ltd is the sponsor for Revlimid® products. Celgene Pty Ltd is a Bristol Myers Squibb company, both are Medicines Australia members, and they have responded to this complaint jointly.

Revlimid® contains an active ingredient lenalidomide which is structurally related to 'thalidomide', which has serious risks and require specific pregnancy prevention management for persons prescribed lenalidomide products. Because of this, and in the interest of patient safety, prescription and use of Revlimid® products are closely monitored and only available to patients who agree to participate in and continue to be monitored under the Bristol Myers Squibb Australia's i-access® Pregnancy Prevention Program. Where a patient changes to a generic brand lenalidomide, the patient would no longer be monitored under the i-access® Pregnancy Prevention Program and would need to transfer to the generic specific program.

As part of a safety and education initiative led by their pharmacovigilance department, Bristol Myers Squibb Australia wrote to physicians, pharmacists and current Revlimid® patients to inform them about the need to continue appropriate monitoring under an applicable patient safety program (noting if a patient changed brand, they would no longer be monitored by the BMS safety program). Bristol Myers Squibb Australia asserts these communications were educational and solely for the purpose of ensuring patients maintain appropriate safety monitoring when receiving Revlimid® or other lenalidomide treatment.

Bristol Myers Squibb Australia consider these to be important communications about the ongoing safe use of lenalidomide products, consistent with pharmacovigilance requirements, conditions of registration for Revlimid®, and all aspects of the Medicines Australia Code of Conduct.

CODE COMMITTEE DECISIONS

Overarching Principle 2	**No breach (unanimous decision)**
Overarching Principle 5	**No breach (majority decision)**
Overarching Principle 6	**No breach (majority decision)**
Section 13.2	**No breach (majority decision)**
Section 14	**No breach (majority decision)**

SANCTION

As no breach was found, no sanction was levied

CONSIDERATION OF THE COMPLAINT

The Committee discussed the unique context of risk relating Revlimid®, being that the active ingredient is lenalidomide, which is structurally related to 'thalidomide' and now well known to cause severe life-threatening human birth defects and/or death to an unborn baby if taken during pregnancy. Within this context, the Committee shared the view that it was reasonable to communicate with patients for the purposes of informing them that any changes to their dispensed medicine will also result in changes to their access to the Revlimid® Patient Safety Program. This was particularly poignant given the fact that prior to 2023, there was only one brand available, and the recent availability of generic brands created the need for clarity around the Patient Safety Program registration. The Committee acknowledged the material may also have the effect of maintaining their product market share, but it was not the intent of the material, and nor did any such effect, potential or otherwise, preclude Bristol Myers Squibb Australia from communicating directly to patients enrolled in their Revlimid® Patient Safety Program to alert and inform them of current changes and access consequences.

In coming to this view, the Committee also considered whether the patient would also share in the responsibility to be registered in a patient safety program, or whether this responsibility was fully covered by the prescriber and the dispenser (and therefore communication to the patient was inappropriate). The patient information uses the term “you will need to register…” when the responsibility for registration is that of the prescriber and the dispenser. Overall, the Committee shared the view that the three parties (prescriber, dispenser and the patient) are all key mandatory stakeholders in ensuring the patient is registered on an appropriate patient safety program. Keeping the patient informed about changes to the program to which they registered is likely to build their capacity in making informed choices and potentially increases their health literacy.

The Committee addressed the complainant’s concern that patient material may have been sent to all patients registered on the Revlimid® Patient Safety Program, which is likely to have included patients that have already decided to change to a generic brand of lenalidomide. Whilst this may be true, the Committee took the view that Bristol Myers Squibb Australia, had sound and reasonable rationale for determining who should receive the material. It was sent to patients who were enrolled in the Revlimid® Patient Safety Program and had a status of "active" for Revlimid® (as defined by the patients themselves) who had been dispensed Revlimid® products within the last 6 months. Further to this, the Committee acknowledged that Bristol Myers Squibb Australia could not have further segmented the recipients because they are not informed if a patient who has previously been prescribed Revlimid® products has switched to an alternative brand, or later dispensed an alternative brand, or been prescribed an alternative brand. The letter’s first paragraph supports this by stating clearly “If you are no longer receiving this medication, please ignore this letter”. On this basis, and under these circumstances, the Committee did not share the same concerns as the complainant.

The Committee also considered whether the communication elevated the ‘right to choose’ message inappropriately to patients, and in doing so, undermined the doctor-to-patient relationship and was promoting direct to the patient. The wording “Your treatment remains your choice and you have the right to decline being switched to a generic medicine if you do not wish to change” could imply that the decision is not a choice made in collaboration with their healthcare professional. However, this was prefaced by references on multiple occasions for the patient to speak to their treating physician, and therefore the Committee was not overly concerned. It was

likely that patients with multiple myeloma would have a good relationship with their practitioner, and that this decision (of medicine brand) was not an initial prescribing decision. The patient material repeatedly refers to the patient choice, which alludes to the patient being at the heart of decision-making, whilst also referring in multiple places to the decision being made between the patient and the doctor. It was also noted that this decision was not an initial prescribing decision. This is consistent with a patient-centric approach and material produced by the TGA. Under these circumstances, references to patient choice were not interpreted as promotional in the context they were presented.

At the heart of the complaint is whether the patient material is classified as promotional; if it encouraged the use of that product, or had the purpose, actual or likely effect to induce the use of the product. The patient material consisted of a letter informing of "changes to the prescribing of your Revlimid® treatment, and implications for your registration on the Revlimid® Patient Safety Program", followed by a 2-page leaflet explaining to patients about how to ensure they can stay on Revlimid® and receive the brand medicine, if that was their choice. Overall, the Committee were comfortable with the letter in its purpose and wording, and was not of the view that the letter was promotional. Whilst the decision on the material was that no breach had occurred (on all counts), there were aspects of the accompanying leaflet that did concern the Committee. Should the leaflet be provided out of the context, or without the accompanying letter, or to a different recipient, it would have likely been considered promotional, and construed as a marketing strategy to keep patients on Revlimid® rather than switching to a generic brand. Also, the Committee would expect this communication to be a one-time interaction and not repeated, or it would likely tip the balance to being classified as promotional. Context is key and played an important part in the Committee's decision.

The choice of words in the leaflet, namely "Your REVLIMID treatment. Your treatment. Your choice." and "Plan ahead to ensure you receive REVLIMID" were concerning. On face value, and if considered in isolation, would likely be considered promotional. In addition, the layout, graphics, imagery and the way the information was presented as a whole may have contributed to it being understood as a promotional piece. However, the material did make clear that it was only intended for patients who had been prescribed Revlimid® and who, in decision with their doctor, wished to continue with REVLIMID®, and it was only under those circumstances that the leaflet would be useful. On balance, and given the context, purpose and accompanying letter, the Committee agreed the material was not promotional.

In its consideration of the leaflet specifically, the Committee questioned its purpose and whether this was warranted. An alternative and conservative approach could have been informing the patient they need to be on a patient safety program corresponding to their lenalidomide medicine, and focusing on how they can do that, rather than informing them how they can remain on Revlimid®. In assessing this aspect, the Committee considered the wider context of pharmacies and their dispensing behaviours, noting that dispensing generic medicines usually provides a greater financial margin to the pharmacist, and this contributes to pharmacies choosing to supply a generic rather than the originator brand. Given the arrival of generic brands for lenalidomide, the Committee understands some pharmacies will have switched and therefore will only be dispensing the generic brand. Given this context, coupled with the fact that this is a highly specialised drug requiring a strict patient safety program, the Committee took the view that there

is a legitimate need to inform the patient on how they can continue "to ensure they receive this medicine from their pharmacy", and "have the right to decline being switched to a generic medicine if they do not wish to change". Without explicit information on how to manage this, the patient may not be automatically informed on what steps and options are available to them, and the leaflet ultimately addresses this.

The Committee acknowledged that it is likely to be true that some hospital pharmacies may no longer dispense Revlimid®, and therefore stating this in the letter, along with instructions on how to find a pharmacy that does stock Revlimid®, does not necessarily represent an "encouragement for patients to move away from their usual place of dispensing", whether or not this may be a hospital pharmacy. It was also acknowledged that choice (of medicine) is important for patients, and also consistency and familiarity (with their medicine) are especially important to the older patient populations on lenalidomide medicines.

Building on the Committee's review and analysis of the issues, as outlined above, the Committee then considered each aspect of the complaint.

Complaint related to Overarching Principle 2:
The Committee considered the complainant's perspective that the communication sent to patients was misleading and that the subject company is not being transparent with consumers as to the real reasons they want patents to stay on Revlimid®. The Committee also considered whether the communication lead to mistrust and diminished confidence in the pharmaceutical industry.

The Committee resolved that the information was not misleading, nor did it contradict the principle of transparency. The company had been sincere in its educational initiative by engaging directly with physicians and pharmacists as well as current Revlimid® patients and had been transparent about the fact there were now generic choices available to patients.

Complaint related to Overarching Principle 5:
The Committee considered the complainant's perspective that the communication sent to patients inappropriately influenced the consumer to remain on Revlimid®. The Committee considered whether the patient material was likely to cause behavioural change; namely whether it had the effect to persuade the patient to stay on Revlimid®, or to return to Revlimid® if they had already changed to a generic brand. The Committee determined that any such possible influence was not inappropriate, given the requirement for patients to be registered in an accompanying patient safety program.

The Committee considered whether the letter implied that safety programs provided by generic brands did not ensure the same level of safety as the Revlimid® Patient Safety Program. The Committee examined the wording "You are enrolled in the program to ensure the highest level of safety while you are treated with Revlimid®", and did not believe this implied the Revlimid® Patient Safety Program was superior over those provided by the generic companies, and nor was this supported by any claims or comparisons in the material provide to patients. The Committee was satisfied the intent of this wording related to the TGA requirement and the likelihood that Bristol Myers Squibb Australia owed the patient the utmost duty of care whilst on their medicine Revlimid® whilst fulfilling their obligations of the TGA's risk management plan.

The Committee considered whether the patient material implied superiority of the originator brand, as opposed to the generics that are now available via the PBS. The Committee could not identify how this was implied, and noted this was not made explicit in the complaint.

Complaint related to Overarching Principle 6:
The Committee considered the complainant's perspective that the communication sent to patients was against the legislative requirements around promotion and advertising of pharmaceutical goods.

The Committee expressed some difficulty in adjudicating consistency "with all legislative requirements" when the specific legislative requirements were not spelled out in the complaint. The Medicines Australia Code is not considered a legislative requirement, but rather compliance with the Code is a condition of registration. In the absence of any specificity, they understood this to reference the prohibition in the Therapeutic Goods Act that advertising of prescription products must not be made to anyone who is not a healthcare professional. The definition of advertising in the Act was referenced, as were the definitions of promotion and promotional material as per the Medicines Australia's Code of Conduct's Glossary, which is consistent with the Act's definition.

Whilst there were concerns raised about possible promotional aspects of the leaflet complying with the legislative requirement to not advertise prescription products to the general public, the Committee remained satisfied the material was educational in nature and intent, was appropriate to the information needs of the patient and did not constitute promotion to the public. As such, the Committee did not share the view that the patient material was 'against the legislative requirements'.

Complaint related to Section 13.2:
The Committee considered the complainant's perspective that the communication sent to patients has caused concern, confusion and alarm for patients, particularly those that had already switched to a generic before being contacted by Celgene in regard to the safety program that accompanies Revlimid®.

The Committee did note the timing of the letter was unfortunate and would have been more useful to patients if communicated prior to generics being made available. This may have minimised any 'confusion for patients' who 'have already decided to change to a generic brand'.

The Committee acknowledged that the patient material may have been given to patients who had already switched to a generic brand as there was no mechanism for Bristol Myers Squibb Australia to be informed of which patients had already switched. The Committee agreed it was not sufficient a concern to override the need to communicate with patients under these circumstances.

Overall, the Committee determined the material would not cause alarm or misunderstanding in the patient community, nor did it stimulate any increase in demand for an already prescribed product.

Complaint related to Section 14:
The Committee considered the complainant's query that patients may not have provided consent about being contacted by Bristol Myers Squibb Australia when signing up to the Revlimid®

Patient Safety Program and the allegation the company has used the program for promotional purposes of their therapeutic product.

Bristol Myers Squibb Australia argued that the Revlimid® Patient Safety Program is defined as a risk management program mandated by the TGA, and not a patient support program within the meaning of the Code. In doing so, they asserted that Section 14 does not apply. The Committee disagreed, referencing the Code's definition of a patient support program being "a company-developed program that is intended to assist patients in gaining benefit from their prescribed medical treatment, to improve health outcomes and promote the quality use of medicines". In the broader understanding of a principles-based Code, the patient safety program fits this definition, as deduced by an average person especially a consumer. The Committee cautioned against segmenting Code sections based on technical or definitive arguments and encouraged consideration of the Code's broader principles in determining ethical conduct. Even though the program was mandated by the TGA, the company had agreed to developing and implementing the program, which effectively makes it a company-developed program.

The Committee considered information consent and privacy issues. Without being provided with the exact terms and conditions under which a patient agreed to when registering on the Revlimid® Patient Safety Program, they acknowledged there were limitations in adjudicating on this issue. Given the context, Bristol Myers Squibb Australia may have had a moral obligation to contact patients registered on their patient safety program. On the balance of the material before them, the Committee was of the view that Bristol Myers Squibb Australia did have consent to contact current patients to issue the patient material, and therefore it follows there was no breach in relation to Section 14.

In addition, because the Committee determined the material was not promotional, the Committee similarly found that data used from the patient safety program (names and contact details) was not used for promotional purposes.

- end -