5.1.1

Oral contraceptives – objection to the proposed reclassification from prescription medicine to restricted medicine (Royal New Zealand College of General Practitioners)

Purpose

This was an objection to the Committee’s recommendation at the 54th meeting to reclassify selected oral contraceptives (desogestrel, ethinylestradiol, norethisterone and levonorgestrel) from prescription medicine to restricted medicine, when sold in the manufacturer's original pack containing not more than six months' supply by a registered pharmacist who has successfully completed an approved training programme, when indicated for oral contraception in women who have previously been prescribed an oral contraceptive within the last 3 years from the date of an original medical practitioner's prescription.

The objection was upheld on the grounds of the process the Committee undertook to make their recommendation. Following the 53rd meeting, Green Cross Healthcare Ltd objected to the Committee's recommendation that oral contraceptives should not be reclassified. In the objection, Green Cross Healthcare Ltd included an alternative proposal to the original submission. This alternative proposal was considered at the 54th meeting, and the Committee made a recommendation based on this alternative proposal that selected oral contraceptives should be reclassified. However, at the time of its consideration, the Committee was under the impression that the alternative proposal had been made publicly available, which was incorrect. The Royal New Zealand College of General Practitioners (RNZCGP) objected on the grounds that proper process had not been followed as the alternative proposal had not been released to the public for consultation.

Background

At the 7th meeting on 31 July and 1 August 1990, the Committee confirmed that desogestrel, ethinylestradiol, levonorgestrel and norethisterone were all classified as prescription medicines.

At the 14th meeting on 2 November 1994, the Committee considered the safety issues related to the use of oral contraceptives and decided to produce an extensive public consultation plan before making any recommendation on the reclassification of oral contraceptives.

At the 15th meeting on 20 November 1995, the Committee recommended that further consideration of the reclassification of oral contraceptives should be deferred until the results of the several ongoing studies had been published and analysed. At the time several studies claimed that low dose oral contraceptive pills containing desogestrel and gestodene presented an increased risk of thromboembolism compared to other low dose oral contraceptive pills.

At the 51st meeting on 8 April 2014, the Committee recommended that desogestrel, ethinylestradiol, levonorgestrel, and norethisterone should not be reclassified from their current schedule entries.

At the 53rd meeting on 5 May 2015, Green Cross Healthcare Ltd made a submission to reclassify specific oral contraceptives from prescription medicines to restricted medicines to allow pharmacists who have completed a certified course approved by the Ministry of Health to prescribe to women who meet specific criteria. The submission included consideration of the specific points raised by the Committee at the 51st meeting. Each concern raised by the Committee was claimed to be addressed. The submission argued that the model of care it proposed had now been reviewed by primary healthcare professionals and a more conservative approach had been taken.

The Committee recommended that desogestrel, ethinylestradiol, levonorgestrel, and norethisterone should not be reclassified from their current schedule entries.

The major reason it was declined was that the submission was not supported by medical representative bodies.

Green Cross Healthcare Ltd objected to the decision made at the 53rd meeting. The original proposal was documented with the 53rd meeting minutes. The grounds for the objection were:

the criteria for reclassification were not followed

support from medical representative bodies is not a prerequisite for reclassification

minimising fragmentation of care is not a classification criterion

access via other medical visits is not a classification criterion

the Committee had not fully captured the benefit of increased access in preventing unintended pregnancy in its discussions

the Royal Australian New Zealand College of Obstetrics and Gynaecology (RANZCOG) partially supported the proposal. It supported the availability of oral contraceptives only to women who had previously been prescribed oral contraceptives i.e. oral contraceptive naïve patients were excluded.

At the 54th meeting on 24 November 2015, Green Cross Healthcare Ltd submitted a revised proposal for consideration if the objection was upheld. The alternative proposal requested the reclassification of desogestrel, ethinylestradiol, levonorgestrel, and norethisterone to restricted medicines when indicated for women who had been previously prescribed an oral contraceptive pill (OCP).

The alternative option proposed that oral contraceptives be available from trained pharmacists for women in the following five scenarios:

a NZ woman who has run out of her oral contraceptive

a woman visiting from overseas who has run out of her oral contraceptive

a woman receiving the emergency contraceptive pill who was a previous oral contraceptive user

a woman wanting to restart contraception who was a previous oral contraceptive user

a woman wanting post-partum contraception who was a previous oral contraception user.

The Committee made the following recommendations:

That selected oral contraceptives (desogestrel, ethinylestradiol, norethisterone and levonorgestrel) should be reclassified as restricted medicines, when sold in the manufacturer's original pack containing not more than six months' supply by a registered pharmacist who has successfully completed a training programme (endorsed or accredited by an organisation to be confirmed), when indicated for oral contraception in women who have previously been prescribed an oral contraceptive within the last 3 years from the date of an original medical practitioner's prescription; and

that Green Cross Healthcare Ltd should provide Medsafe with details of who will be responsible for accrediting the training programme and maintaining and enforcing the provisions under which a pharmacist with additional competencies could prescribe selected oral contraceptives; and

that Green Cross Healthcare Ltd should update Medsafe of the changes required to the training and monitoring procedures to reflect the Committee's recommendations; and

that market sales should be collected and analysed to monitor the success of the scheme in improving access to oral contraceptive pills.

Following the publication of the 54th meeting minutes, the Committee received an objection from the RNZCGP. The objection was upheld on the grounds of a process issue, that the alternative proposal put forward by Green Cross Healthcare Ltd had not been available for public consultation as recorded in the minutes.

The RNZCGP provided an alternative proposal as part of its objection (the RNZCGP proposal). The details of the RNZCGP proposal were that:

the prescribing pharmacist should ensure that there has not been a change to the woman's health, or that of her close relatives

with any changes to the woman's health, or that of her relatives, she should be advised that the OCP may no longer be the appropriate contraceptive option for her

she has been prescribed that OCP within the past year

she has been reviewed by an authorised prescriber at least once since starting the OCP for the first time (i.e. OCP naïve women would need to have to been reviewed by a general practitioner as a follow up appointment since starting the OCP, before repeats can be provided without a prescription).

The previous submissions, alternative proposal, amended alternative proposal and the RNZCGP proposal requested the reclassification of selected oral contraceptives (desogestrel, ethinylestradiol, norethisterone and levonorgestrel), which are currently classified as follows:

Desogestrel, ethinylestradiol and norethisterone are classified as prescription medicines.

Levonorgestrel is currently classified as:

prescription medicine; except when specified elsewhere in this Schedule; except in medicines for use as emergency post-coital contraception when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health

restricted medicine; in medicines for use as emergency post-coital contraception when in packs containing not more than 1.5 milligrams except when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health.

Comments

A total of 10 comments regarding the proposed reclassification of selected oral contraceptives were received for this meeting. One comment requested clarification on the recommendation made at the 54th meeting. Two comments were from individuals and organisations that did not support the amended alternative proposal. Five comments were from individuals and organisations that supported the amended alternative proposal, several of which proposed modifications. Two comments were from organisations that supported increased access to selected oral contraceptives (desogestrel, ethinylestradiol, norethisterone and levonorgestrel) but believed the amended alternative proposal did not capture this.

Discussion

The Chair introduced the objection with a summary of the record of events of the submissions and objections regarding the application for reclassification of selected oral contraceptives that was presented at the 51st, 53rd, 54th and the current meeting. The Chair went on to compare the reclassification of selected oral contraceptives process with the standard process for a submission that has been unsuccessful for reclassification, where the applicant (if they wish to do so) resubmits a submission with amendments.

The Committee acknowledged the confusion generated from a submission for which deliberations have extended over four meetings, particularly when several objections had been made. The Committee noted the accumulation of information spread across a number of different documents and meetings. The Committee noted it would be prudent and avoid confusion, to consider the submission for the reclassification of selected oral contraceptives (desogestrel, ethinylestradiol, norethisterone and levonorgestrel) in its entirety, by combining all of the information accumulated so far.

The Committee noted that the majority of comments received with respect to the alternative proposal were regarding the amended alternative proposal that the Committee put forward and not the alternative proposal put forward by the applicant. The Chair took this opportunity to discuss the role of the Committee in that they are to assess the risk-benefit profile of a medicine against the criteria in the 'Medicines Classification Committee Handbook' (agenda item 5.2.2) for reclassification and that they are able to propose amendments to a proposal to improve its alignment with the handbook criteria. He also explained that it is the applicant’s role to communicate with stakeholders, not the Committee's responsibility. Thus, the Chair and the members stand by the recommendation made at the 55th meeting.

The Committee noted that there were concerns surrounding the details of the accredited training programme. The concerns raised included

which organisation would be responsible for the training programme

whether pharmacists would be allowed to dispense any of the selected oral contraceptives to the woman who was previously prescribed an OCP (i.e. could pharmacists switch between selected oral contraceptives), or would pharmacists be limited to dispensing the oral contraceptive as previously prescribed.

The Committee compared the amended alternative proposal with the proposal put forward by the RNZCGP. They found various aspects of the two proposals warranted consideration. However, the Committee was concerned that the prolonged process this submission had followed meant that concerned parties remained confused about what was currently proposed. The Committee suggested that the submitters should submit a new, comprehensive proposal for consideration to ensure clarity, and that the proposed scheme provides assurance that the issues/ concerns raised had been considered.

Recommendation

The Committee invites Green Cross Healthcare Ltd and Natalie Gauld Ltd to make a new submission with complete background papers, and supporting documentation for consideration as an agenda item for the 57th meeting, for the reclassification of selected oral contraceptives (desogestrel, ethinylestradiol, norethisterone and levonorgestrel) as restricted medicines. The Committee considers that if a new submission is made, it should address all of the concerns raised to date by the Committee, the public, healthcare professionals and medical bodies including those from the New Zealand Medical Association and the Royal New Zealand College of General Practitioners, and that the submission should be in accordance with the updated guidance document titled ‘How to change the legal classification of a medicine in New Zealand’ (agenda item 5.2.1).

The Committee suggests that Green Cross Healthcare Ltd and Natalie Gauld Ltd could consider collaborating with a New Zealand medical organisation to produce the new submission