



RACGP

## *RACGP Submission*

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GP prescribing rights for Isotretinoin

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The Royal Australian College of General Practitioners

## *Background*

The Royal Australian College of General Practitioners (RACGP) has identified a significant need to support General Practitioner (GP) prescribing rights for Isotretinoin. Currently, only dermatologists (upon referral by a GP) can prescribe Isotretinoin. The RACGP believes that extending prescribing rights to GPs will enhance timely and affordable access to patients (particularly in rural and remote areas), in a safely monitored environment, where GPs will be able to continue to provide holistic patient-centred care.

The RACGP approves of responsible prescribing through standards and clinical guidelines that support safety and the provision of quality clinical care. The RACGP believes that GPs have the appropriate training and education to safely prescribe a range of medications, including Isotretinoin.

GPs have comprehensive knowledge of a patient's medical history, including health problems, current medications and treatments. GPs also provide holistic patient-centred care and are therefore aware of a patient's social history and other emerging medical conditions and medications that may adversely affect a patient during Isotretinoin treatment.

Ensuring patient safety and the provision of quality care is of paramount importance. The RACGP believes that, with additional training, GPs can easily acquire sufficient, up-to-date knowledge of treatment options for acne and be competent to prescribe Isotretinoin. To address this issue and to ensure that patients have access to quality, safe and affordable healthcare, the RACGP recommends that GPs be granted prescribing rights for Isotretinoin as a matter of priority.

The RACGP's submission provides comment and feedback regarding the following key areas:

1. the role of the RACGP
2. the role of GPs
3. workforce shortages limiting access
4. affordable and accessible healthcare
5. the New Zealand experience
6. significant health risks to patients taking Isotretinoin
7. Recommendations.

### *1. The RACGP*

The RACGP is the specialty medical college for general practice in Australia and is responsible for defining the nature of the discipline, setting and maintaining the curriculum and standards for education, training and quality and for supporting general practitioners in their pursuit of clinical excellence and community service.

As the peak body for GPs, the RACGP is continually developing education, assessment and continuing professional development programs, including accreditation of appropriate learning modules and decision support tools.

As mentioned previously, GPs are competent to treat a wide range of conditions and to know whether, when and how to prescribe medicines with serious side effects. However, given GPs have not recently had experience with prescribing Isotretinoin, we would recommend prescribing is limited to those who undertake additional training. Given this, the RACGP is well placed to develop educational material and guidelines as well as provide communications for GPs regarding prescribing of Isotretinoin.

## ***2. The role of General Practitioners***

GPs have regular and honest conversations with young people about a diverse range of adolescent issues and undertake HEADSS (Home and Environment, Education and Employment, Activities, Drugs, Sexuality, Suicide/Depression) screening. GPs are then able to discuss these concerns with their patients in conjunction with possible treatment options.

As described earlier, GPs:

- are well positioned to provide holistic care for patients taking Isotretinoin
- are aware of the importance of preventing pregnancy
- can initiate appropriate contraception where needed
- are experienced in assessing the mental health of the patient.

GPs are also well positioned to follow up on all of the above issues within the same consultation.

Overall, GPs are at the forefront of medical care and are responsible for establishing and maintaining ongoing therapeutic relationships with their patients and prescribing of Isotretinoin is a logical extension of this care. They have the ability to monitor patients regularly, including the effectiveness of treatments (such as Isotretinoin) and any side effects and changes in a patient that may occur.

It is therefore recommended that prescribing rights for Isotretinoin be extended to GPs who have undertaken specific training.

## ***3. Workforce shortages limiting access***

The literature demonstrates that there is a workforce shortage of dermatologists in Australia. The Health Workforce 2025 report highlights there is difficulty in filling dermatology positions either through maldistribution or insufficient workforce, with minimal change predicted between 2012 and 2025.<sup>1</sup>

Such workforce shortages result in patients receiving delayed treatment. After receiving a referral from a GP, patients often experience long waiting periods to see a dermatologist.<sup>1</sup> These periods are even longer in rural and remote communities.<sup>1</sup>

The RACGP believes that all Australians should have access to quality and timely healthcare, and supports equitable and affordable access to Isotretinoin for patients with severe acne. Such workforce shortages mean that patients requiring Isotretinoin often experience unnecessary, lengthy delays.

The RACGP believes that extending Isotretinoin prescribing rights to GPs will improve patient access to appropriate, safe, affordable and timely care.

## *4. Affordable and accessible healthcare*

The Health Workforce 2025 report also highlights the significant shift of dermatologists to the private sector and sub-specialist areas such as skin cancer. This will contribute to higher out-of-pocket costs and less access to services for patients.

In accessing care via a dermatologist (as referred by the GP), patients incur two separate consultation fees resulting in out-of-pocket costs which can be avoided if GPs are granted prescribing rights. As outlined previously, there is also the necessity for a patient to come back to the GP to manage other aspects of the safe prescribing of Isotretinoin, such as contraception initiation or mental health assessment – resulting in additional but potentially unnecessary costs.

According to Bettering the Evaluation And Care of Health (BEACH) data for the year April 2012 to March 2013, there were 534 000 general practice encounters for the treatment of Acne. Close to 20% of all those encounters were outside of major capital cities.<sup>2</sup> Therefore, providing GPs with the ability to prescribe Isotretinoin will increase the accessibility of appropriate and affordable treatment for patients living in regional, rural, and remote areas.

The RACGP believes that all patients should have access to safe and affordable healthcare. Providing GPs with prescribing rights for Isotretinoin will ensure that patients are able to access appropriate and timely care/treatment with fewer out-of-pocket expenses.

## *5. The New Zealand experience*

In New Zealand, the access to subsidised oral Isotretinoin was widened on 1 March 2009, to allow vocationally registered GPs and Nurse Practitioners working in an appropriate field to prescribe the medicine, fully subsidised, subject to Special Authority criteria.<sup>3</sup>

GPs are now significant prescribers of Isotretinoin in New Zealand. From July 2011 – June 2012 there were a total of 46 531 dispensed prescriptions for Isotretinoin, of which 58% originated from a GP.<sup>4</sup>

Other feedback on the outcomes of GPs prescribing Isotretinoin in New Zealand suggests that it is cheaper for patients as long as they no longer have to pay a visit to the dermatologist. The ability for GPs to prescribe Isotretinoin has meant that it is now more accessible to those who previously weren't able to pay the cost of a dermatologist or skin specialist. GPs prescribing Isotretinoin has also led to a reduction in long waiting lists at hospitals and specialist clinics, has allowed the treatment to be more accessible for those living in remote areas and the side effects are better handled by their GP.

The New Zealand experience of GPs prescribing Isotretinoin subject to specific criteria has shown that it has been effective in providing affordable and accessible healthcare. The RACGP believes that providing Australian GPs the same prescribing abilities of Isotretinoin would provide the same benefits.

## 6. Significant health risks to patients taking Isotretinoin

Isotretinoin has been associated with a number of non dermatological adverse side effects including: liver problems, increased risk of cardiovascular disorders, increased triglyceride levels, increased depression and suicide rates, fetus abnormalities and inflammatory bowel disease.<sup>5</sup> As generalists, GPs are well positioned to detect and monitor such conditions and maximise safe prescribing.

The teratogenicity of Isotretinoin when prescribed to a woman who is, or becomes, pregnant is a significant concern. There is clear evidence that Isotretinoin is linked to an estimated 30%<sup>6</sup> risk of significant birth defects. Given that the majority of patients with acne are in the 15-24 age group, and given that familiarisation with adolescent sexual and mental health is a core GP skill associated with safe prescribing, it would be appropriate to consider prescribing rights for Isotretinoin to GPs.

A study on the teratogenicity effects and pregnancy in women prescribed Isotretinoin highlighted that in four years, 402 out of 124,216 women prescribed Isotretinoin became pregnant. 72% of these had terminations, and 16% miscarried, 3% had ectopic pregnancies, 8% had live births, and at least seven of the 32 infants were born with major or minor abnormalities<sup>7</sup>.

The establishment of trust, based on consultations with a GP, enables a more accurate assessment of pregnancy risk and therefore better management of contraception. The training undertaken by registered GPs and the continuity of care that is an inherent part of general practice, equip GPs with the skills and competencies to minimise the occurrence of adverse events.

Additionally, with a link between the use of Isotretinoin and risk of mood disorders and suicidal behavior,<sup>8</sup> GPs are well positioned to ensure those patients at risk and those who have already been diagnosed and treated for mental illness, are consulted and monitored as a priority while being treated with Isotretinoin. Ensuring patient safety is critical. Increasing GPs' access to prescribing Isotretinoin will enhance rather than compromise patient safety.

Below are real life case studies where GPs have documented the adverse affects to patient health while taking Isotretinoin. These case studies again highlight the potential advantages of GPs having prescribing rights to this drug:

- I. Case Study: A female patient had been treated by her GP for depression for approximately five (5) years and had been overall quite well. However, the patient developed severe acne that was unresponsive to topical therapy. Furthermore, her cosmetic appearance was also negatively impacting on her mental health. The patient was referred to a Dermatologist who prescribed Isotretinoin. During the course of the Isotretinoin the patient's mood was further negatively affected and the Dermatologist suggested that the patient cease taking the Isotretinoin immediately. After a consultation with her GP, involving a thorough suicide risk assessment and an assessment within the context of the impact of acne on the patient's mental health, the patient's antidepressant dosage was increased and her mood improved. The course of the Isotretinoin was successfully completed.

- II. Case Study: A 16 year old female patient with a history of Attention Deficit Hyperactivity Disorder (ADHD) was prescribed Isotretinoin by her Dermatologist. She saw her GP four (4) months later with symptoms of stomach upset and dizzy spells, and following a pregnancy test, was found to be pregnant. The situation could have been avoided if it had been recognised that, due to her ADHD, the patient may have been at high risk of pregnancy and therefore required:
- effective contraception (such as a contraceptive implant) in place prior to the commencement of Isotretinoin
  - regular counselling about the importance of avoiding pregnancy.
- III. Case Study: A young man presented with acute liver failure after taking Isotretinoin for approximately six weeks for severe acne. The patient ceased the treatment when he noticed he was jaundiced. However he presented with acute liver failure two months later and then had to undergo a liver transplant<sup>9</sup>. A second patient, a 17 year old female, was admitted to hospital following five days of treatment with Isotretinoin. She presented with bilateral flank pain, nausea, vomiting and acute interstitial nephritis due to Isotretinoin use. She was diagnosed and treated with intravenous fluids and Isotretinoin ceased.<sup>10</sup> Two weeks later her serum creatinine and urinary protein returned to normal values. Both cases demonstrate the importance of testing for kidney and liver function in patients who present as unwell on Isotretinoin. As the GP is often the first point of call for patients who become unwell, enhanced and more timely recognition of these complications may occur where the GP is the prescriber, rather than relying on the often adolescent patient to disclose that they are taking Isotretinoin.

## 7. Conclusion

The RACGP believes that there are many benefits of extending Isotretinoin prescribing rights to GPs. Changes to prescribing regulations for Isotretinoin will:

- ensure that adverse effects of Isotretinoin prescribing are kept to a minimum
- ensure that patients receive holistic, safe, quality healthcare
- improve patients' access to timely, affordable and equitable healthcare services
- provide economic efficiencies through reduced consultations.

Given the above, the RACGP strongly recommends that the Minister for Health, support the RACGP's request that changes be made to current prescribing regulations so that GPs can prescribe this medication in the near future.

## References

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- <sup>2</sup> Bettering the Evaluation And Care of Health (BEACH), (2014) *Acne in general practice April 2012 - March 2013*
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- <sup>5</sup> Wells. R, (2013), *Roaccutane induced acute liver failure*, Australian Journal of Medical Science, vol. 34(3), p. 82 - 85
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