PAU Ref: 17646

CONSULTATION RESPONSE

REFORMS TO THE GENERIC MEDICINE MARKET AUTHORISATION PROCESS

Orion Laboratories Pty Ltd T/A Perrigo Australia | www.perrigo.com.au **|** ABN 56 009 293 136
Head Office, Perth: 25-29 Delawney Street, Balcatta WA 6021 Australia I Phone: +61 8 9441 7800 I Fax: +61 8 9441 7888
Sydney Office: PO Box 602, Terrey Hills NSW 2084 | Suite 14, Level 1, 13a Narabang Way, Belrose NSW 2085 Australia I Phone: +61 2 9847 7999 I Fax: +61 2 9847 7977
Brisbane Office: PO Box 2504, Fortitude Valley QLD 4006 | Unit 3, 236 Arthur Street, Newstead QLD 4006 Australia
Customer Service: Toll Free Phone: 1800 805 546 I Toll Free Fax: 1800 004 110 I Email: customerservice@perrigo.com.au

About Perrigo Australia:

Orion Laboratories Pty Ltd. was founded in 1985 as a privately owned company. Orion grew rapidly into one of Australia's few pharmaceutical and medical device manufacturers and suppliers, particularly focused on hospitals. In March 2010 Perrigo acquired Orion. Perrigo, headquartered in Ireland, is one of the world's largest manufacturer of OTC pharmaceutical products for the Private Label market and an industry leader in pharmaceutical technologies. Perrigo provides "Quality Affordable Selfcare Products" across a wide variety of product categories and geographies. Perrigo Australia markets in excess of one hundred quality affordable healthcare products throughout Australia, New Zealand and beyond. Our presence as a medical device manufacturer is primarily in the cost effective, low risk medical device market, with health care professionals and hospitals as our target consumers. The majority of these products manufactured in Australia and Perrigo Australia is proud of its ongoing commitment to Australian made products.

Introduction:

Perrigo Australia appreciates the opportunity to provide feedback on the Department of Health's Therapeutic Goods Administration (TGA) consultation on the proposed reforms to the generic medicine market authorisation process.
Perrigo Australia supports the main themes of this consultation, and

Response to Questions:

Q1. Would changes to our requirements for demonstrating that Australian and overseas reference products are identical reduce barriers for applicants seeking to register new generic medicines?
Perrigo Australia unconditional believes this would be the case.

Q2. Are there any potential unintended consequences of changing the data requirements when using an overseas reference product in a bioequivalence study submitted to the TGA?
Perrigo Australia has not been able to identify any potential issues with the proposal.

Q3. Are there any other ways that we could reduce barriers through increased international alignment in the processes for obtaining market authorisation for generic medicines?
Perrigo Australia would like the TGA to consider arrangements to recognise generic registration in comparable regions with the view to streamlining the approval locally without submission of a currently required dossier.

Q4. Would early advice from the TGA on biowaiver justifications be useful in compiling a dossier?
Early advice from TGA would be the greatest benefit from this proposal. The ability to consult with the TGA and to have binding specific advice provided from the TGA would be of great assistance in registering generic medicines. This could potentially allow generic medicine producers to develop a plan to register and avoid unnecessary financial burden.
Perrigo Australia fully supports this portion of this consultation.

Q5. In what other ways can we increase transparency and clarity of regulatory requirements for generic medicine applications?
There would be benefit to the industry if the TGA published guidelines for demonstrating bioequivalence on other dosage forms and drug delivery routes, as well as extended release products.

Q6. Will adopting these international templates improve opportunities for joint submissions to multiple agencies and hence work sharing?
We feel that any change that facilitates work sharing with regulatory comparable regions will benefit the industry.

Q7. Are there other ways of improving the generic medicines market authorisation process to support work sharing?

Orion Laboratories Pty Ltd T/A Perrigo Australia | www.perrigo.com.au | ABN 56 009 293 136
Head Office, Perth: 25-29 Delawney Street, Balcatta WA 6021 Australia I Phone: +61 8 9441 7800 I Fax: +61 8 9441 7888
Sydney Office: PO Box 602, Terrey Hills NSW 2084 | Suite 14, Level 1, 13a Narabang Way, Belrose NSW 2085 Australia I Phone: +61 2 9847 7999 I Fax: +61 2 9847 7977
Brisbane Office: PO Box 2504, Fortitude Valley QLD 4006 | Unit 3, 236 Arthur Street, Newstead QLD 4006 Australia
Customer Service: Toll Free Phone: 1800 805 546 I Toll Free Fax: 1800 004 110 I Email: customerservice@perrigo.com.au

No comment at this time.

Q8. Is it appropriate to offer incentives to medicine sponsors to bring more generic medicines to Australia?
Perrigo Australia has reservation regarding incentives. We are concerned that this may lead to a rash of unsustainable applications with no intention to provide continuous supply. We feel that there are suitable facilities to supply medically appropriate but potentially financially non-viable products in the Australian market.

Q9. Should we offer incentives to medicine sponsors to address medicine shortages and medicine expenditure?
We feel that this measure would be inappropriate at this time.

Q10. Are there any other examples where a more robust supply of generic medicines may be beneficial to patients and the Australian health system?
No comment at this time.

Q11. What incentives should we pursue in order to create a more robust supply of medicines?
No comment at this time.

Q12. Are there any other options for improvements to generic medicines market authorisation processes that would:

- •reduce regulatory barriers through greater international alignment with comparable overseas regulators
- •increase clarity and transparency of regulatory requirements
- •support international work sharing for generic medicines
- •support a more robust supply of medicines?

No comment at this time.

Orion Laboratories Pty Ltd T/A Perrigo Australia | www.perrigo.com.au | ABN 56 009 293 136
Head Office, Perth: 25-29 Delawney Street, Balcatta WA 6021 Australia I Phone: +61 8 9441 7800 I Fax: +61 8 9441 7888
Sydney Office: PO Box 602, Terrey Hills NSW 2084 | Suite 14, Level 1, 13a Narabang Way, Belrose NSW 2085 Australia I Phone: +61 2 9847 7999 I Fax: +61 2 9847 7977
Brisbane Office: PO Box 2504, Fortitude Valley QLD 4006 | Unit 3, 236 Arthur Street, Newstead QLD 4006 Australia
Customer Service: Toll Free Phone: 1800 805 546 I Toll Free Fax: 1800 004 110 I Email: customerservice@perrigo.com.au