|  |
| --- |
| Notice of amendments to the current Poisons Standard in relation to New Chemical Entities (NCEs), January 2024 |
| 25 January 2024 |
|  |

**Copyright**

© Commonwealth of Australia 2024
This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>.

Contents

[Amendments to the Poison Standard in relation to New Chemical Entities (NCEs) 4](#_Toc155258468)

[Palovarotene 4](#_Toc155258469)

## Amendments to the Poison Standard in relation to New Chemical Entities (NCEs)

The NCE listed below will be included in the new Poisons Standard that will come into effect on 1 February 2024.[[1]](#footnote-1)

### Palovarotene

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Schedule 4 – New Entry**PALOVAROTENE.**Index – New Entry****PALOVAROTENE**Schedule 4Appendix F, clause 4Appendix L, clause 2**Appendix F, clause 4 – New Entry****Poisons that must be labelled with warning statements and safety directions**

|  |  |  |  |
| --- | --- | --- | --- |
| Item | Poison | Warning statement item number | Safety direction item number |
| 255a | PALOVAROTENE | 7, 62, 76, 111 |  |

**Appendix L, clause 2 – New Entry**Additional warning statements for certain human medicines

|  |  |  |
| --- | --- | --- |
| Item | Poison | Warning statement item number |
| 25a | PALOVAROTENE | 7, 62, 76, 111 |

 |

|  |
| --- |
| Therapeutic Goods Administration |
| PO Box 100 Woden ACT 2606 AustraliaEmail: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605[**https://www.tga.gov.au**](https://www.tga.gov.au) |
|  |

1. Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard. [↑](#footnote-ref-1)