Australian Government

Australian Pesticides and Veterinary Medicines Authority

Earlier guidance

COVID-19: advice for veterinary medicine manufacturers and holders

Comments and enquiries regarding copyright:

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001 Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au.

This publication is available from the APVMA website.

Contents

Earlier guidance: advice issued 7 August 2020 1
Background 1
Overseas manufacturers 1
Domestic manufacturers 1
Automatic extension – the majority of manufacturers 1
Interim report – medium and high-risk manufacturers 2
New premises 2
Notification 2
Review of this advice 2
More information 3
Earlier guidance: advice issued 1 April 2020 4
Background 4
Overseas manufacturers 4
Domestic manufacturers 4
Automatic extension – the majority of manufacturers 4
Interim report – medium and high risk manufacturers 5
New premises 5
Notification 5
Review of this advice 5
More information 6

Earlier guidance: advice issued 7 August 2020

Date of current advice: 7 August 2020

Date range for affected audits: 1 April 2020 through 31 March 2021

Background

Following the World Health Organization's 11 March 2020 declaration of the novel coronavirus (COVID-19) pandemic, the Australian Pesticides and Veterinary Medicines Authority (APVMA) is providing support to holders and manufacturers of veterinary medicines.

The COVID-19 pandemic has resulted in travel restrictions and guidelines for social distancing that have affected the ability to perform Good Manufacturing Practice (GMP) inspections in Australia and overseas.

The APVMA has developed the following guidance to allow veterinary manufacturers audited by the APVMA to demonstrate compliance with GMP while social distancing measures and travel restrictions are in place. This advice was first published on 1 April 2020, and has been updated in August 2020.

This guidance applies during the time that physical audits cannot be carried out due to COVID-19. Further extensions may be made if the relevant restrictions are still in place. Manufacturers should note that audits should be conducted as soon as practical; the extended audit due date is the last date by which the audit must be conducted.

Due to the evolving nature of the pandemic, this advice may change. Where necessary, this may involve extension to relevant timeframes in locations where COVID-19 remains a relevant consideration.

Overseas manufacturers

All overseas manufacturers with an audit scheduled before 31 March 2021 (whether this was the original or the extended date) will receive an automatic six-month extension to their current GMP compliance letter expiry date.

There are no changes to the terms of recognition of evidence of overseas GMP compliance.

Domestic manufacturers

For domestic manufacturers with an audit due date before 31 March 2021 (whether this was the original or the extended date) the following advice applies.

Automatic extension – the majority of manufacturers

Domestic manufacturers with two or less major non-conformances will receive an automatic six-month extension to their audit due date.

For example, if an audit was due by 1 November 2020, it would now be due by 1 May 2021.

These extensions will be automatically granted without the need to apply for them. Further extensions may be made if the relevant restrictions are still in place.

Interim report – medium and high-risk manufacturers

Domestic manufacturers with three or more major non-conformances identified in their last routine audit will be asked to provide the completed, signed COVID-19 Corrective Action Progress Review Form to the MQL Team.

These manufacturers will be required to provide details of the actions they have implemented to address the non-conformances identified in their previous GMP audit, as well as any other information relevant to their GMP operations. Unless otherwise advised by the APVMA, the evidence specified will be required 14 days before their audit due date or by 30 December 2020, whichever comes first.

Pending consideration of the material submitted, manufacturers with this risk rating will be eligible for up to a six-month extension to their audit date if the APVMA is satisfied that non-conformances have been, or are being, effectively addressed. Further extensions may be made, if the relevant restrictions are still in place.

New premises

Manufacturers with domestic or overseas premises that are not part of a current licence or letter of GMP compliance should contact the APVMA via MQL@apvma.gov.au to discuss their situation.

Notification

Manufacturers and holders are reminded of their obligations to notify the APVMA of any adverse experience reports or recalls, and their responsibilities under s 161 of the Code.

Notification of any Quality Management System (QMS) failure must occur via email to MQL@apvma.gov.au, within one day for critical non-conformances and five days for major non-conformances, from when the manufacturer or holder becomes aware of the problem.

Notification of recalls must occur via email to recalls@apvma.gov.au when the manufacturer or holder becomes aware of the problem.

Notification of adverse experiences must occur via the online portal or to aerp@apvma.gov.au, within one day for serious adverse experiences, from when the manufacturer or holder becomes aware of the problem.

Review of this advice

Given the evolving nature of the COVID-19 situation worldwide, it is not possible to predict accurately when normal business, travel and auditing activities will be able to resume.

The APVMA will review the above plan before September 2020 and, in consultation with stakeholders, will advise whether an extension of these arrangements will be necessary. If you would like to be added to the consultation list please contact MQL@apvma.gov.au.

More information

Manufacturers and holders are encouraged to monitor the advice for their products and to contact the APVMA if they have questions or concerns.

There are no anticipated changes to the process for export certificates issued under s 70.

Manufacturers who undergo an audit for the purposes of the EC-MRA or under PICS should contact the Therapeutic Goods Administration Manufacturing Quality Branch with questions regarding audit scheduling.

COVID-19 Corrective Action Progress Review Form (FM_MQL_COVID-19).

Phone: +61 2 6770 2301

Email: MQL@apvma.gov.au

More information: Find out more about Good Manufacturing Practice.

Earlier guidance: advice issued 1 April 2020

Date of current advice: 1 April 2020

Date range for affected audits: Through 30 September 2020

Background

Following the World Health Organization's 11 March 2020 declaration of the novel coronavirus (COVID-19) pandemic, the Australian Pesticides and Veterinary Medicines Authority (APVMA) is providing support to holders and manufacturers of veterinary medicines.

The COVID-19 pandemic has resulted in travel restrictions and guidelines for social distancing that have affected the ability to perform Good Manufacturing Practice (GMP) inspections in Australia and overseas.

The APVMA's Manufacturing Quality and Licensing (MQL) Team has developed the following guidance to allow veterinary manufacturers audited by the APVMA to demonstrate compliance with GMP while social distancing measures and travel restrictions are in place.

This guidance applies during the time that physical audits cannot be carried out due to COVID-19. Further extensions may be made if the relevant restrictions are still in place.

Due to the evolving nature of the pandemic, this advice may change. Where necessary, this may involve extension to relevant timeframes in locations where COVID-19 remains a relevant consideration.

Overseas manufacturers

All overseas manufacturers with an audit scheduled before 30 September 2020 will receive an automatic six-month extension to their current GMP compliance letter expiry date.

There are no changes to the terms of recognition of evidence of overseas GMP compliance.

Domestic manufacturers

For domestic manufacturers with an audit due date before 30 September 2020 the following advice applies.

Automatic extension – the majority of manufacturers

Domestic manufacturers with two or less major non-conformances will receive an automatic six-month extension to that date.

For example, if an audit was due by 15 April 2020, it would now be due by 15 October 2020.

These extensions will be automatically granted without the need to apply for them. Further extensions may be made if the relevant restrictions are still in place.

Interim report – medium and high risk manufacturers

Domestic manufacturers with three or more major non-conformances identified in their last routine audit will be asked to provide the completed, signed COVID-19 Corrective Action Progress Review Form (41.06 KB) to the MQL Team.

These manufacturers will be required to provide details of the actions they have implemented to address the non-conformances identified in their previous GMP audit, as well as any other information relevant to their GMP operations. Unless otherwise advised by the APVMA, the evidence specified will be required 14 days before their audit due date or by 30 June 2020, whichever comes first.

Pending consideration of the material submitted, manufacturers with this risk rating will be eligible for up to a six-month extension to their audit date if the APVMA is satisfied that non-conformances have been, or are being, effectively addressed. Further extensions may be made, if the relevant restrictions are still in place.

New premises

Manufacturers with domestic or overseas premises that are not part of a current licence or letter of GMP compliance should contact the APVMA via MQL@apvma.gov.au to discuss their situation.

Notification

Manufacturers and holders are reminded of their obligations to notify the APVMA of any adverse experience reports or recalls, and their responsibilities under s 161 of the Code.

Notification of any Quality Management System (QMS) failure must occur via email to MQL@apvma.gov.au, within one day for critical non-conformances and five days for major non-conformances, from when the manufacturer or holder becomes aware of the problem.

Notification of recalls must occur via email to recalls@apvma.gov.au when the manufacturer or holder becomes aware of the problem.

Notification of adverse experiences must occur via the online portal or to aerp@apvma.gov.au, within one day for serious adverse experiences, from when the manufacturer or holder becomes aware of the problem.

Review of this advice

Given the evolving nature of the COVID-19 situation worldwide, it is not possible to predict accurately when normal business, travel and auditing activities will be able to resume.

The APVMA will review the above plan before September 2020 and, in consultation with stakeholders, will advise whether an extension of these arrangements will be necessary. If you would like to be added to the consultation list please contact MQL@apvma.gov.au.

More information

Manufacturers and holders are encouraged to monitor the advice for their products and to contact the APVMA if they have questions or concerns.

There are no anticipated changes to the process for export certificates issued under s 70.

Manufacturers who undergo an audit for the purposes of the EC-MRA or under PICS should contact the Therapeutic Goods Administration Manufacturing Quality Branch with questions regarding audit scheduling.

COVID-19 Corrective Action Progress Review Form (FM_MQL_COVID-19)

Phone: +61 2 6770 2301

Email: MQL@apvma.gov.au

More information: Find out more about Good Manufacturing Practice.