

Statement of Reasons

in respect of an exclusive dealing
notification lodged by

Equestrian Australia

in relation to the supply of equestrian event services
on condition that horses are vaccinated against the Hendra virus

Date: 18 December 2015

Notification no. N98410

Summary

Equestrian Australia (EA) lodged a notification on 30 July 2015 seeking to address the risks that may arise from horses from Hendra virus affected areas attending equestrian events.

The notification is intended to enable EA, or event Organising Committees acting as its agents, to require that horses are vaccinated against the Hendra virus as a condition of entry into particular events (the Entry Condition). In accordance with the notification, such a condition of entry would only be imposed when an event specific biosecurity risk assessment has been undertaken that indicates it is appropriate. Legal protection under the *Competition and Consumer Act 2010* (the CCA) conferred by the notification commenced automatically on 13 August 2015.

The notification does not impose a general requirement that participants in equestrian events vaccinate their horses against the Hendra virus. Nor does it oblige Organising Committees of particular events to impose such a requirement. Similarly, the notification does not affect any existing legal rights, other than removing the ability for EA to be challenged under the competition law for third line forcing.

The Australian Pesticide and Veterinary Medicines Authority (the APVMA), which is the government authority responsible for the assessment and registration of pesticides and veterinary medicines, has recently approved registration of the Hendra vaccine. The ACCC understands that before granting registration the APVMA was satisfied that the vaccine—used in accordance with the approved instructions on the label—would:

- not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues
- not be likely to have an effect that is harmful to human beings
- not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment
- be effective.

Nevertheless, a large number of people have expressed significant concerns about the notified conduct, including:

- that there have been a large number of adverse reactions to the vaccine and boosters, with people not wanting to continue to vaccinate their horses and those horses being excluded from participating in equestrian events
- the impact on the value of elite competition and breeding horses from not being able to compete, either because of an adverse reaction to the vaccine or because the horse cannot or will not be vaccinated
- that there is negligible risk of Hendra transmission at equestrian events
- that there are less intrusive methods available that would equally reduce the spread of the Hendra virus
- that other equestrian organisations do not require horses to be vaccinated against the Hendra virus
- the practical impact/imposition of six monthly boosters and the view that adverse reactions increase in severity with ongoing boosters
- the cost of the vaccine and boosters

- a range of allegations including alleged conflicts of interest involving veterinarians, EA and Zoetis.

The ACCC understands that the APVMA is aware of these concerns and presently remains satisfied with the vaccine's registration and that the level of "probable" and "possible" adverse reactions remains within a normal range for a relatively new vaccine.

Further, Biosecurity Queensland, the Queensland Department of Health and Queensland Workplace Health & Safety advise that vaccination is the single most effective way to address the risk of Hendra infection. These agencies support individual equestrian Organising Committees being able to decide, based on an informed risk assessment, to only allow horses to compete if vaccinated.

The ACCC also received a number of submissions in support of the Notification, including from Equestrian clubs, veterinarians and equestrian event organisers. In general terms, these submissions suggest the notified conduct will result in public benefits, including by reducing the risk of people or horses contracting the virus, the risk of exposure for equine veterinarians at equestrian events and concerns about the liability, cost and welfare implications for Organising Committees associated with a suspected case of Hendra at an event.

After carefully considering the large number of submissions in this matter, and for the reasons outlined in this document, the ACCC considers that having the Hendra vaccination required as a condition of entry to particular equestrian events (after an event specific biosecurity risk assessment has been undertaken) is likely to result in public benefits by reducing the risk of transmission of the Hendra virus to other horses or to humans. This is particularly so in circumstances where the appropriate Government veterinary medicine regulatory approval body has recently completed a detailed assessment of the Hendra vaccine and found it to be generally safe to use and effective against the Hendra virus.

The ACCC accepts that there are strong concerns from many parties in relation to the notification, and that there are detriments associated with only allowing vaccinated horses to compete in particular events including as a result of any adverse reactions to the vaccine and associated financial implications. However, the ACCC does not consider that these detriments outweigh the benefits. Accordingly the ACCC does not intend to take any further action on this notification. As a result, the statutory protection afforded to EA by the notification continues.

1. Background

- 1.1 The ACCC is the Commonwealth agency responsible for administering the *Competition and Consumer Act 2010* (CCA). The object of the CCA is to enhance the welfare of Australians, including through the promotion of competition and fair trading.
- 1.2 Section 47 of the CCA prohibits exclusive dealing conduct, including conduct commonly referred to as 'third line forcing'. Broadly speaking, third line forcing involves the supply of goods or services on condition that a buyer acquires other goods or services from another person, or a refusal to supply because the buyer will not agree to that condition.
- 1.3 Businesses may obtain protection from legal action to engage in exclusive dealing conduct by lodging a 'notification' with the ACCC. The protection from legal action that is provided by a notification for third line forcing commences automatically 14 days after the day on which the notification is lodged.
- 1.4 The ACCC may issue a notice which has the effect of revoking a third line forcing notification at any time if it is satisfied that the likely benefit to the public from the notified conduct will not outweigh the detriment to the public from the notified conduct.¹
- 1.5 The ACCC is not required to provide a statement of reasons where it has decided to take no further action in relation to a notification. However, where, as in this case, significant consultation has occurred the ACCC will prepare a statement of reasons to provide greater transparency in respect of its decision.
- 1.6 This statement of reasons outlines the basis on which the ACCC has decided not to take any further action in relation to the notification lodged by Equestrian Australia Limited (EA).

2. The notified conduct

- 2.1 On 30 July 2015, EA lodged third line forcing notification N98410 (the Notification) with the Australian Competition and Consumer Commission (ACCC).
- 2.2 The Notification relates to third line forcing conduct under sections 47(6) and (7) of the CCA.
- 2.3 The legal protection from the Notification took effect on 13 August 2015.
- 2.4 Amongst other things, the ACCC understands that EA administers equestrian sports in Australia in relation to eight internationally recognised equestrian disciplines, Eventing, Show-jumping, Dressage, Carriage Driving, Show Horse, Vaulting, Endurance and Para-equestrian, and one national discipline, Show Horse.

¹ The ACCC conducts a comprehensive and rigorous public consultation process before making a decision to revoke a notification, which includes issuing a draft notice advising the notifying party and interested parties of its intention to revoke the notification.

2.5 The Notification is stated to relate to:

- equestrian sports events services (**Event Services**), including the control, management, conduct and official recognition of equestrian sports competitions, exhibitions, events, demonstrations and displays (**Events**) to owners and/or riders of equestrian sports horses (**Entrants**) who are members of EA and
- the supply and administration to horses of a vaccine against Hendra virus (**HeV**), a zoonotic (i.e. transmittable to humans) paramyxovirus that causes serious illness and death to horses and humans.

2.6 The notified conduct is described in the Notification as follows:

- (i) EA supplies and/or offers, through local and state based organising committees, to supply Events Services to Entrants, on the condition that Entrants comply with and/or satisfy certain conditions (**Entry Conditions**)
- (ii) EA may refuse to supply Events Services to a person for the reason that the person has not complied with or does not satisfy relevant Entry Conditions
- (iii) EA does not have a general rule or policy that relates to the vaccination status of horses in relation to the HeV. EA does, however, encourage the bodies responsible for organising Events on behalf of EA (**Organising Committees**) to take measures to manage biosecurity risks in accordance with the “Horse Venue Biosecurity Workbook” published by Animal Health Australia
- (iv) Where an Organising Committee so determines in its discretion (having regard to its assessment of the biosecurity risks of the specific Event), the Entry Conditions for an Event may include that all horses or any horse that has lived or been in or transited through one or more specified geographic areas (**Endemic Regions**) within a specified period must have a current vaccination against HeV (**Vaccination Condition**)
- (v) Although the necessary HeV vaccine may be acquired from and administered by any suitably qualified veterinarian, there is currently only one supplier of a HeV vaccine: Equivac HeV is manufactured and supplied through an Australian subsidiary of Zoetis, Inc (**Zoetis**).

2.7 A copy of the Notification and the EA’s supporting submissions are available on the ACCC website and are also discussed in the ACCC’s assessment below.

3. **Validity**

3.1 Some interested parties have questioned the validity of the Notification. In particular two potential grounds raised are whether the conduct can properly be considered to be third line forcing and whether it is in fact Organising Committees rather than EA that will be the parties engaging in the conduct notified.

3.2 After careful consideration, the ACCC has confirmed its view that the Notification is valid. However, the ACCC notes that the question of the validity of a notification is ultimately a matter to be determined by a Court.

Framework for assessment of validity

3.3 In order to be valid, a notification under s 93(1) of the CCA must, amongst other things, relate to conduct or proposed conduct which is:

- to be engaged in by the corporation giving the notification, and
- of a kind referred to in s 47(2) to (9) of the CCA – i.e. is exclusive dealing conduct.

3.4 The ACCC does not take a narrow or restrictive approach when considering whether a notification is valid. That is, in making this assessment the ACCC takes the view that if there is any risk that conduct proposed to be entered into by an entity could be found to be third line forcing, that entity is entitled to seek to address that risk by lodging a notification.

Is EA engaging in the notified conduct?

3.5 EA is the corporation which lodged the Notification. However, it is not clear to the ACCC, having regard to the nature of EA's relationship with EA state branches, Organising Committees and Entrants, that EA is the only supplier of Event Services to Entrants. For example, it appears possible that Organising Committees may supply Event Services other than as EA's agents. However, it appears likely that EA, including through Organising Committees, supplies at least some Event Services, or may do so in the future. For example, as the only Australian entity with authority from the Fédération Equestre Internationale and Australian Olympic Committee to sanction events to allow the results to count towards international rankings and participation in Olympic and World Games, it appears arguable that EA supplies the 'official recognition of equestrian sports competitions' services referred to in the Notification.

Is the notified conduct exclusive dealing conduct?

3.6 There is a real argument that the conduct proposed to be engaged in by EA through Organising Committees as described in the Notification does not constitute third line forcing or exclusive dealing at all. As noted above, in general terms, third line forcing involves the supply of goods or services on condition that a buyer acquires other goods or services from another person.

3.7 In this case, the Notification relates to the supply of Event Services on condition that relevant horses have a current vaccination against the Hendra virus.

3.8 While it is the case that Zoetis is currently the only manufacturer and distributor of the Hendra virus vaccine, as the ACCC understands it Entrants would not be required to (and, indeed, could not) acquire the vaccine directly from Zoetis. Rather, it appears that:

- an unrestricted number of suitably qualified veterinarians would acquire the vaccine from Zoetis, and
- Entrants could choose any of those veterinarians to administer the vaccine when vaccinating their horse.

3.9 In any event, notwithstanding doubts as to whether the notified conduct would be found by a court to constitute third line forcing, the ACCC is unable to rule out the possibility that, absent the Notification:

- EA could face legal action in respect of the notified conduct taken by a person other than the ACCC, and

- a court may ultimately decide that the conduct does constitute third line forcing in contravention of section 47 of the CCA.

3.10 For example a person may seek to argue that the Vaccination Condition requires Entrants to indirectly acquire the vaccination from Zoetis, given that Zoetis is currently the only manufacturer and distributor of the Hendra virus vaccine.

3.11 For this reason, the ACCC confirms its view that the Notification was validly lodged.

4. Chronology

Date	Event
30 July 2015	Notification lodged.
13 August 2015	Public consultation process begins.
13 August 2015	Immunity commences.
4 September 2015	Closing date for submissions.
14 October 2015	Public Forum – Brisbane.
21 October 2015	Further submissions – closing date.
18 December 2015	Statement of Reasons Issued.

5. Submissions

Equestrian Australia submissions

5.1 In support of the Notification, EA submitted that the notified conduct will result in the following public benefits:

- improved protection of public and occupational health and safety of persons attending equestrian events
- improved protection of the health and safety of horses
- improved control of the spread of the Hendra virus
- contribution to the preservation of Australia’s biosecurity
- preservation of the integrity of the Australian equestrian sports system
- preservation or enhancement of Australia’s international reputation with respect to equestrian sports and their administration and with respect to responsible control of infectious and fatal disease generally
- mitigation of upward pressure on costs of insurance for equestrian sports organisations, relevant veterinarians and owners of equestrian sports horses
- avoidance of a significant disincentive for individuals to participate on Organising Committees as a result of increased risk of uninsured liability

- mitigation against a significant disincentive for equine veterinarians to provide professional services at equestrian events (at all or without indemnification against any legal liability).

Submissions raising concerns about the notified conduct

- 5.2 The ACCC also received a large number of submissions from interested parties (many of which are confidential), primarily owners/trainers and riders of horses but also Equestrian clubs and event organisers, objecting to the Notification on the basis that it would not give rise to public benefits and would result in significant public detriment.
- 5.3 In general terms, and having regard to the framework within which the ACCC is required to assess notifications, these submissions can be generally summarised as follows.

Limited Benefits

- 5.4 Interested parties argue that the notified conduct provides limited, if any, benefits because:
- the risk of contracting the Hendra virus is extremely low (particularly at equestrian events where it has never occurred) and vaccination is therefore unnecessary
 - the potential for a vaccinated horse to pass on the Hendra virus cannot be ruled out and therefore vaccination appears to be insufficiently effective²
 - there are less harmful methods for managing any risk that may exist, including by applying a biosecurity plan and wearing personal protective equipment
 - EA's position is inconsistent with other horse bodies/codes which do not require that horses be vaccinated against the Hendra virus
 - relevant state and federal government bodies have not made the vaccine mandatory.

Significant detriments

- 5.5 Many submissions argue that the Hendra vaccine has not been sufficiently tested and is unsafe for horses. Parties refer to the statements printed on the product label and the number and severity of adverse reactions experienced by horses to support their claim.

² The Equivac HeV product label states: *The potential for a vaccinated horse to pass on the Hendra virus cannot be ruled out. As a precaution, it is recommended people take the same steps to protect vaccinated horses from exposure to infection—and to prevent humans being infected by horses—as are recommended for unvaccinated horses. Personal protective equipment should be worn whenever infection is suspected even in vaccinated horses.*

5.6 The Equivac HeV label includes the following statements:

- The effect of the vaccine on pregnant mares or on horses intended for breeding is not known.
- The product should not be used in sick or immunocompromised horses.
- The potential for interactions when administered with other vaccines and veterinary medicines is not known.

5.7 Many submissions argue that there are adverse reactions to the Hendra vaccine, for example:

- interested parties claim there are significant numbers of horses that have experienced severe adverse reactions to the Hendra vaccine, including sterility and death, and
- some parties also claim that the severity of the adverse reactions appear to increase with the ongoing six monthly boosters required to maintain an appropriate level of immunity.

5.8 Other submissions are concerned about the financial impacts of a vaccination requirement, for example:

- Because of the impact on the value of elite competition and breeding horses if they are unable to compete either because of an adverse reaction to the vaccine or because the owner cannot or chooses not to vaccinate their horse
- horses vaccinated against the Hendra virus are unable to compete or be sold in many countries³
- the cost of treating a horse that has had an adverse reaction to the vaccine and the ongoing costs of vaccination.

Other matters

5.9 Interested parties argue that the notified conduct is based on a flawed decision making process because:

- there is a lack of scientific evidence about the risk of the Hendra virus at equestrian events
- there was a failure to undertake a proper risk assessment to determine the risk
- of perceived conflicts of interest between Zoetis, veterinarians and EA Board members who all have an alleged financial incentive to promote the vaccine.

5.10 In addition, parties argue that the Entry Condition:

- discriminates against horses and riders based on geography
- impedes an owners' autonomy in relation to their horse and

³ The ACCC understands that a number of countries will not accept horses that test positive for the Hendra virus. Vaccinated horses can potentially show a false positive and hence are unable to be sold or compete in those countries.

- the conduct may result in more veterinarians refusing to treat unvaccinated horses.

Submissions in support of the notified conduct

5.11 The ACCC also received submissions in support of the Notification, including from Equestrian clubs, veterinarians and event organisers. In general terms, these submissions refer to the notified conduct as giving rise to public benefits, including that:

- for a number of reasons it is not easy or quick to diagnose whether a horse has the Hendra virus, so in these circumstances requiring horses to be vaccinated before participating in an equestrian event reduces the risk that people or horses may contract the virus
- equine veterinarian numbers are small and dwindling and the number of veterinarians willing to attend an unvaccinated sick horse is decreasing because of the risk of exposure
- vaccination is the single most effective way of reducing the risk of Hendra virus in horses (quoting Biosecurity Queensland and NSW Department of Primary Industries)
- horse owners that choose not to vaccinate their horse not only potentially affect themselves but also risk affecting other people that may come into contact with that horse
- veterinarians are at risk of being prosecuted either because of accidental poor choices or lack of knowledge with some veterinarians currently being prosecuted because of their handling of Hendra cases
- the only way to protect staff and businesses is not to attend unvaccinated horses
- EA has an obligation to keep horses, competitors, volunteers and the general public safe
- Organising Committees are concerned at the liability, cost and welfare implications associated with a suspected case of Hendra at an equestrian event
- Organising Committees should be able to decide to minimise the risk of the above by only accepting Hendra vaccinated horses at events.

Key government organisations

5.12 The ACCC met with representatives from Biosecurity Queensland, Queensland Workplace Health and Safety and the Queensland Department of Health that specialise in Hendra response.

5.13 To address the risks created by a zoonotic disease such as the Hendra virus, these agencies suggest that a multi-pronged approach is desirable. This could include event organisers preparing and following biosecurity management plans, veterinarians adopting biosecurity and infection control practices including wearing appropriate personal protective equipment for contact with horses with possible Hendra virus infection, and vaccination of horses against the Hendra virus.

5.14 These agencies have publicly stated that vaccination is the single most effective way to prevent Hendra virus infection in horses and provides a public health and work health and safety benefit. The ACCC understands these agencies support individual equestrian Organising Committees being able to decide, based on an informed risk assessment, to only allow horses to compete if vaccinated. The agencies do not, however, have jurisdictional authority to require mandatory vaccination at specific events or more broadly. The agencies also advise that appropriate biosecurity and infection prevention practices should continue to always be adopted regardless of the vaccination status of the horse.

6. ACCC Assessment

6.1 As noted above, the ACCC may issue a notice which has the effect of revoking a third line forcing notification at any time if it is satisfied that the likely benefit to the public from the notified conduct will not outweigh the detriment to the public. When undertaking this assessment in respect of the Notification, the ACCC considered the information provided by EA and interested parties, including that provided on a confidential basis, as well as information it obtained itself in the course of its inquiries, including information provided by participants at the public forum held in Brisbane on 14 October 2015.

Market definition

6.2 The relevant markets appear to be those for the supply of:

- Event Services that qualify competitors for national and international competitions
- veterinarian services
- a Hendra vaccine.

The future without the notified conduct

6.3 The ACCC considers that in the absence of the notified conduct, EA and its Organising Committees would seek to continue to run equine events, but that it is likely that increasing numbers of equine veterinarians will be unwilling to attend these events due to a perceived higher risk of being exposed to the Hendra virus, and people will be less willing to volunteer to participate on Organising Committees due to a perceived higher risk of liability.

6.4 The ACCC considers it is unlikely that governments would introduce legislation to require mandatory Hendra vaccination of horses.

Public benefits

6.5 It is well recognised that the Hendra disease is serious and that the mortality rate for both horses and humans who contract the Hendra virus is very high. Further, horses that have the Hendra virus can be contagious without showing any obvious signs or symptoms.

6.6 Accordingly, while the risk of horse to horse or horse to human transmission of the Hendra virus at an equestrian event appears to be low, such transmission is possible and the consequences were it to occur can be severe.

- 6.7 The ACCC also acknowledges, as many interested parties submitted, that employing appropriate precautions including veterinarians wearing full personal protective equipment when attending horses in or from Hendra affected areas can significantly reduce the risk of horse to human transmission.
- 6.8 However, a low likelihood of transmission of the virus does not mean there is no risk. Given the serious consequences of infection if transmission does occur, the overall risk faced by event organisers (and participants, volunteers, horses, veterinarians and attending members of the public) can still be significant. The fact that Hendra transmission may not have occurred yet at an event does not mean that there is no risk of it happening in the future. Accordingly, the ACCC considers that addressing this risk will result in public benefits.
- 6.9 The ACCC considers that where a risk assessment undertaken by an Organising Committee indicates implementing the Entry Condition is appropriate, doing so is likely to result in public benefits from:
- improved safety for persons attending equestrian events, including the public
 - reduced risk of horses contracting the Hendra virus
 - avoiding a significant disincentive for equine veterinarians to provide professional services at equestrian events
 - avoiding a significant disincentive for individuals to participate on Organising Committees as a result of a perceived increased risk of liability.

Public detriments

- 6.10 When assessing third line forcing notifications, the ACCC must also consider the potential public detriments. These may relate to the impact the notified conduct is likely to have on competition in relevant markets but can include broader detriments.

Possible competition related detriments

- 6.11 The ACCC considers that the notified conduct would not reduce competition in the market for the provision of Event Services that qualify competitors for national and international competition, since EA is the only Australian entity with authority from the Fédération Equestre Internationale and Australian Olympic Committee to sanction Events and this is not changed by the Notification.
- 6.12 Given that the notified conduct does not specify that event attendees acquire vaccination services (including the vaccine itself) from particular veterinarians, the ACCC considers that the notified conduct will not have a significant impact on competition in the market for the provision of veterinarian services. Indeed the conduct is likely to encourage more veterinarians to be willing to offer their services to support equestrian events.
- 6.13 While it is the case that government requires that only accredited veterinarians who have undertaken specific education (provided by Zoetis) on the proper use of the vaccine can administer the vaccine, the ACCC understands that it is open to all veterinarians to undertake the relevant training.

- 6.14 The ACCC recognises that there is currently only one supplier of a Hendra virus vaccine to veterinarians and that it is unlikely another supplier will emerge in the short to medium term. However, the notified conduct is not limited to the existing vaccine and will not discourage or prevent potential competition from occurring in the future.
- 6.15 Accordingly, the ACCC does not consider there are any material detriments arising from a reduction in competition in relevant markets.

Other possible detriments

- 6.16 Many interested parties have raised concerns that there have been a significant number of adverse reactions to the Hendra vaccine. Reactions have been described as ranging from minor to severe.
- 6.17 Parties submit the vaccine has resulted in lameness and other conditions that prevent horses from competing, sterility and death. Further, interested parties have noted that even where a horse recovers from an adverse reaction, the fact that the horse is unable to continue a program of vaccination via six monthly boosters means that it will not be able to participate in events where the Entry Condition is imposed.
- 6.18 In light of the concerns raised about possible adverse reactions to the vaccine, the ACCC has consulted with the Australian Pesticide and Veterinary Medicines Authority (the APVMA) on issues related to the safety and effectiveness of the Hendra vaccine.
- 6.19 The APVMA is the government authority responsible for the assessment and registration of pesticides and veterinary medicines.
- 6.20 In August 2015, the APVMA approved registration of the Hendra vaccine. The ACCC understands that before granting registration the APVMA was satisfied that the vaccine—used in accordance with the approved instructions on the label—would:
- not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues
 - not be likely to have an effect that is harmful to human beings
 - not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment
 - be effective.
- 6.21 The APVMA has an ongoing role in monitoring feedback about adverse reactions to the animal vaccines it has registered. The APVMA assesses this information to ensure those products continue to be safe and effective and may take regulatory action if it determines that it can no longer be satisfied these requirements are met. The APVMA website indicates that certain side effects may be expected and are typical of many vaccines.⁴ The ACCC understands that the APVMA presently

⁴ The ACCC notes that the APVMA publishes a list of reported adverse reactions to the Hendra vaccine on its website. As at 31 March 2015 there had been a total of 125 Possible, 633 Probable and 72 Unlikely adverse

remains satisfied with the vaccine's registration and that the level of "probable" and "possible" adverse reactions remains within a normal range for a relatively new vaccine.

- 6.22 The ACCC understands that should substantiated adverse reactions to the vaccine reach a certain level, it will trigger a review of the vaccine's registration by the APVMA. If at any time the APVMA were to form the view that the Hendra vaccine should no longer be registered due to the nature or level of adverse reactions that were occurring, the ACCC would expect EA to cease requiring vaccination as a condition of entry to events.
- 6.23 The ACCC has carefully considered the submissions from many concerned parties to the effect that there have been a significant number of adverse reactions to the Hendra vaccine. The ACCC considers that potential adverse reactions to the vaccine are a relevant public detriment in circumstances where, as a result of the notified conduct, unvaccinated horses may otherwise be excluded from participating in equestrian events. The ACCC notes that participation in some events may be critical to the accumulation of points required for qualification for international competitions and hence owners may feel compelled to vaccinate their horse when they otherwise might not.
- 6.24 Submissions have also expressed concern at the significant cost of vaccination – particularly where some interested parties consider it, at best, unnecessary and, at worst, potentially harmful. Concerns have been raised that the current six monthly booster requirements are unnecessary and that significant costs could be avoided by moving to annual boosters. The ACCC understands that there is research being undertaken to determine whether booster requirements can be effective at twelve monthly intervals rather than six.
- 6.25 The ACCC considers that the cost imposed on Entrants by any requirement that horses be vaccinated, as a condition of entry to particular equestrian events, including any financial impact from a decrease in the value of an elite competition or breeding horse, is also likely to be a material public detriment.

7 Weighing the benefits and detriments

- 7.1 In determining whether to revoke the notification the ACCC must determine whether it is satisfied that the likely benefit to the public from the notified conduct will not outweigh the public detriment.
- 7.2 The ACCC notes that EA, as the representative body for equestrian event participants, is responsible for ensuring an appropriate balance between minimising the risks of potential transmission of the Hendra virus at EA events and the needs of its members to participate in Fédération Equestre Internationale recognised events to qualify for international competitions.

reactions from approximately 340,000 doses of the vaccine. The APVMA assesses adverse reaction reports in terms of the likelihood that the adverse reaction is caused by the vaccine and classifies reports accordingly. The classifications range from 'Possible' to 'Unlikely', with the Possible classification indicating that there is a reasonable association between the vaccine and the adverse reaction, and 'Unlikely' indicates that there is sufficient information to establish that the adverse reaction was not likely to be associated with the vaccine. See <http://apvma.gov.au/node/15786>

- 7.3 The ACCC further notes that the Entry Condition will only be imposed if supported by a biosecurity risk assessment consistent with the *Horse Venue Biosecurity Workbook* published by Animal Health Australia.
- 7.4 The Notification does not impose any general requirement that participants in equestrian events vaccinate their horses against the Hendra virus. Nor does it oblige Organising Committees of particular events to impose such a requirement. Similarly, the Notification does not affect anyone's existing legal rights, other than removing the ability for EA to be challenged under the competition law for third line forcing.
- 7.5 Accordingly, after considering the many submissions in relation to this matter, the ACCC has concluded that in light of the serious consequences for people and horses in the event of contracting the Hendra virus, the likely benefits of the notified conduct will outweigh the likely detriments.
- 7.6 In reaching this conclusion the ACCC has relied on the fact that the appropriate Government veterinary medicine regulatory approval body has recently completed a detailed assessment of the Hendra vaccine and found it to be generally safe to use and effective against the Hendra virus.
- 7.7 This is also consistent with advice from Biosecurity Queensland, the Queensland Department of Health and Queensland Workplace Health & Safety that vaccination is the single most effective way to address the risk of Hendra infection.
- 7.8 The ACCC understands that EA has committed to consider applications for horses to be exempt from the Entry Condition to Events – particularly where a horse has been determined by a veterinarian to be unable to receive further vaccinations due to adverse reactions or the significant risk of them occurring. Some interested parties have expressed concern that this exemption process is not workable and that no exemptions would ever be granted.
- 7.9 The ACCC encourages EA to ensure that its process for assessing applications for exemption from an Entry Condition seeks to appropriately balance the impact the condition would otherwise have on horses (and their riders) with the need to properly address the risks associated with the Hendra virus. The fact that there is insufficient research yet undertaken to determine the impact of the vaccine on breeding mares, for example, could be a reasonable basis for seeking exemption.
- 7.10 Based on the above analysis, the ACCC considers the likely detriments will not outweigh the likely benefits, and as such is not proposing to take any further action on this notification at this time.
- 7.11 As a result, the statutory protection afforded by the notification continues.

Scope of protection

- 7.12 As noted above, the notification applies only to conduct engaged in by EA. This includes where EA engages in the conduct through others, such as organising committees, acting as its agents.
- 7.13 On the information available about the relationships between EA, its state branches and organising committees, it appears to the ACCC to be possible that organising

committees (or others) might supply Event Services to Entrants other than on behalf of EA.

- 7.14 In this context, it is important to note that any statutory protection afforded by this notification does not cover an organising committee supplying or offering to supply Event Services on condition that horses have been vaccinated against the Hendra virus unless that committee is acting as an agent of EA in doing so.