Research Director Agriculture and Environment Committee Parliament House George Street Brisbane Qld 4000



Equestrian Queensland submission to the committee's inquiry into the Hendra virus (HeV) Equivac vaccine and its use by veterinary surgeons in Queensland, including the potential efficiency and effectiveness of options to mitigate the risk of infection with HeV and its consequences.

22 April 2016

# **Background**

Equestrian Queensland (EQ) is the peak body for the administration of equestrian sports in Queensland. It is the entity through which participation in equestrian activities under the Federation Equestre International (FEI) is conducted, promoted, regulated and administered in Queensland.

EQ is an incorporated association in Queensland and one of six state peak organisations that exist to promote, develop and grow the sport within their respective jurisdictions, but also collectively represent the stakeholders of the national body under the Equestrian Australia (EA) constitution.

EQ represents 15,000 participants, including more than 300 affiliates, across the Olympic sports of dressage, eventing, showjumping and para equestrian, along with show horse, vaulting, carriage driving and interschool sports. There are presently 5407 performance horses registered with EQ.

Horse riding can be a dangerous activity and equestrian sports are classified as extreme sports. EQ aims to conduct the safest equestrian events possible for all involved including competitors, horses, event organisers, volunteers and visitors, including constantly assessing hazards and implementing controls to mitigate risks.

Hendra virus is endemic in flying foxes, not horses. EQ's professional assessment of the risks associated with equestrian competitions rates the transmission of Hendra virus at a competition as among the lowest of all hazards. Travelling to and from competitions and falls from or with horses during competitions are the two most extreme.

EQ believes that in the absence of Government legislation requiring mandatory vaccination, individual horse owners should be free to make their own choice whether or not to Hendra vaccinate their horses based on their individual circumstances.

EQ's biosecurity policy was developed in consultation with a diverse range of stakeholders including equine veterinarians and is based on a revise and review approach. It acknowledges the advice of Workplace Health and Safety Queensland,

Queensland Health, and Biosecurity Queensland, that vaccination is the single most effective way of reducing the risk of Hendra virus infection in horses and provides a workplace health and safety and public health benefit. Strategic vaccination of horses is encouraged and horse owners are advised to discuss their individual risk with their private veterinarian.

EQ has been at the forefront of development of a comprehensive suite of biosecurity policies, plans and supporting documents that have been endorsed by all relevant government departments and the Australian Horse Industry Council, and adopted by event organisers across Australia.

### **Context**

In 2011 - almost a year before the first Hendra virus vaccine permit was issued  $^{\rm 1}$  - the Australian Veterinary Association (AVA) began lobbying the Australian and State governments to mandate vaccination of all Australian horses against Hendra virus.  $^{\rm 2}$ 

In 2013 the then Equine Veterinarians Australia (EVA) President and EA Deputy Chair also sought a mandate from the FEI.

I have written to the FEI veterinary department to seek their assistance with amending rules in Australia that will mandate HEV vaccination for all FEI events in Australia. <sup>3</sup>

Dr Warwick Vale

Despite no agreement from government, industry or the FEI, in July 2014 EA unilaterally introduced a national by-law that imposed mandatory Hendra vaccination of horses from its self-defined endemic regions in parts of Queensland and New South Wales as an entry requirement for participation in events.

EVA fully supports EA's implementation of the Hendra Vaccination Bylaw... EVA does not support Equestrian Queensland's intention to repeal the Hendra Vaccination Bylaw.<sup>4</sup>

Dr Nathan Anthony- President EVA

The bylaw was repealed by EA in January 2015 following EQ's pro-choice representations on behalf of its members, 80 per cent of whom disagree with mandatory Hendra vaccination.<sup>5</sup>

EQ also shared with EA its legal advice from December 2014 that mandatory vaccination was in breach of section 47(6) and (7) of the Competition and Consumer Act 2010. In December 2015, the ACCC decided to uphold an application for immunity against prosecution for event organisers who chose to mandate Hendra vaccination of horses.

<sup>&</sup>lt;sup>1</sup> Australian Pesticides and Veterinary Medicines Authority (APVMA) PER13510 10 August 2012-3 August 2014

<sup>&</sup>lt;sup>2</sup> Hendra virus response, AVA policy briefing 5 July 2011

<sup>&</sup>lt;sup>3</sup> Email to EQ CEO and Chair 7 March 2013

<sup>&</sup>lt;sup>4</sup> EVA Letter to Equestrian State Association Chair 4 September 2014

<sup>&</sup>lt;sup>5</sup> EQ member surveys conducted in January 2015 and August 2015

Since the repeal of the by-law members of the EVA have systematically contacted equestrian event organising committees advising that mandatory Hendra vaccination of horses was a condition of vet attendance at competitions, citing their reason as fear of Workplace Health and Safety prosecution.

Faced with the prospect of having to cancel competitions because they could not source FEI accredited vets, or in fact any vet, many organising committees have mandated Hendra vaccination.

# EQ response to terms of reference

EQ welcomes the committee's inquiry. On behalf of our members, this submission presents comments each of the terms of reference, and presents three recommendations. These comments and recommendations are based on our own knowledge and experience, supported by examples that have been shared with us by our members.

1. The development, trials and approval processes: the incidence and impact of adverse reactions by horses following vaccination and the reporting of adverse reactions and economic impacts of the HeV Equivac vaccine.

Queensland horse owners have paid an estimated \$19 million to participate in clinical trialling of the Hendra vaccine.  $^6$ 

## Vaccine development and trial

The Equivac HeV vaccine is the first of its kind ever developed in the world or to undergo registration in Australia. The vaccine development approach means that the horse owners have effectively funded the clinical trial of the vaccine from November 2012 to its registration in August 2015, with minimal or no feedback other than receiving booster reminders, and no compensation for adverse reactions.

The Australian Pesticides and Veterinary Medicines (APVMA) recorded 367,759 doses of vaccine administered to 30 June 2015.<sup>7</sup> At a conservative average of \$100 per dose including vet fees that means horse owners outlaid more than \$36 million to trial the vaccine. In Queensland, this represents 57,647 horses or 52 per cent of the total number of 110,358 vaccinated horses registered on the Zoetis database at March 2015.<sup>8</sup>

The preliminary data that was gathered from research animals (including those belonging to Zoetis) was the same as required by APVMA for any other vaccine. However data on duration of immunity and advice on booster intervals can only be gathered over time, and perhaps one difference with this vaccine is that kind of information is normally known by the time a vaccine becomes available to the Australian animal industries, because typically it has already been used elsewhere in the world.<sup>9</sup>

Dr Deborah Middleton Senior Veterinary Pathologist CSIRO Australian Animal Health Laboratory

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<sup>&</sup>lt;sup>6</sup> 367759 doses x 52 percent x \$100 = \$19.123m

<sup>&</sup>lt;sup>7</sup> http://apvma.gov.au/node/15786 (accessed 31 March 2015)

<sup>&</sup>lt;sup>8</sup> Zoetis report to HBALG confirmed at QHIA March 2015

<sup>&</sup>lt;sup>9</sup> Email to EQ member 2 June 2015

### Incidence and impact of adverse reactions

The APVMA classified 900<sup>10</sup> possible or probable adverse reactions to the 367,759 doses of vaccine administered during the trial period to 30 June 2015.11

Of particular concern to EQ members are:

- the number of horse deaths recorded
- the themes of presenting signs
- the stated risks associated with booster vaccines, and
- the accuracy of reporting and recording of reactions.

The APVMA's figures that show seven horse deaths as a possible or probable result of the vaccine, 10 per cent of horses with adverse reactions presented with lethargy, eight per cent experienced pain, six per cent had pyrexia and five per cent had anorexia, are of major concern to our members as owners of performance horses.

EQ considers that seven horse deaths from reactions to a vaccine against a virus that infects approximately three horses a year is excessive and unacceptable.

In registering the vaccine on 4 August 2015 the APVMA said it was:

satisfied that the product - when used as instructed - would be effective as an aid in the prevention of disease caused by Hendra virus. That is when it is administered with a booster dose every six months after the primary vaccination course. 12

EQ is not aware of any other human or animal vaccine in Australia that requires six-monthly boosters. Our members are further concerned about the potential risks of adverse reactions from over-vaccination arising from inconsistent interpretation of the duration of immunity.

It is not unusual for booster shots for any vaccine to result in more severe reactions. 13

APVMA

For horses which have received the first series of three injections there is no evidence that a further booster (at 12mths) will add significant value in terms of protection...<sup>14</sup>

Dr Deborah Middleton

A report extracted from the Zoetis database in April 2016 indicates that there has been a substantial increase in the number of EQ registered horses whose HeV vaccination status is no longer current. A total of 74 per cent of horses registered since the vaccine was introduced in 2012 have been vaccinated. Of these, 36 per cent are no longer current, compared with 13 per cent that were not current at December 2014 when 54 per cent had been vaccinated.

<sup>14</sup> Email to EQ member 2 June 2015

<sup>&</sup>lt;sup>10</sup> A further 77 reported reactions were classified as unlikely

http://apvma.gov.au/node/15786 (accessed 31 March 2016) http://apvma.gov.au/node/12881 (accessed 31 March 2016)

In the context of horse owner concerns about safety, what is perceived to be an excessive and costly booster regime, and a low level of perceived risk to horses (and more so to people, given no human cases since 2009) it would be prudent to reconsider blanket measures to mandate or compel horse owners to vaccinate until these situations are resolved. The actions of horse associations and some veterinary practices to force vaccination are driving a ground swell of mistrust and are alienating horse owners and mobilising collective resistance to undermine the vaccine. Neutralising negativity and regaining trust are substantial challenges that will be costly to resolve in the future if allowed to continue unabated. This situation could also lead to poor or delayed engagement and cooperation in any future emergency animal disease situation.<sup>15</sup>

HHALTER<sup>16</sup>

(Horse Owners and Hendra virus: A Longitudinal study To Evaluate Risk)

Furthermore, an agreed definition on 'current vaccination status' has still not yet been resolved.

At this time there is no agreed definition of a vaccinated horse. <sup>17</sup> EA Hendra Working Group

...I think it may be possible to implement a "Hendra Vaccination Requirement" with conditions that provide flexibility so that the riders who are apposed (sic) to vaccinating for genuine reasons can still compete....Reasonable and fair conditions of entry could include;

1. Booster dose administered within the last 12 months (not 6)...<sup>18</sup>

Dr Nathan Anthony FEI Veterinarian

The conflicting interpretations between APVMA, government departments, vets and the Zoetis database further undermines the emphasis on vaccination status as a determination of treatment, particularly when the responsibility of data integrity and ownership is entrusted to a sole private supplier in a monopoly.

The disparity in definitions of a vaccinated horse also compromises the data upon which risk assessments are made and impacts on the integrity of the vaccination database register that determines vaccination status that many vets base their treatment plans on.

# Reporting of adverse reactions

The lack of timely and transparent reporting has not helped instill confidence.

# **Economic impact**

EQ does not have the resources to accurately quantify the economic impact of the Equivac HeV vaccine to the industry in Queensland, including breeding and export.

18 Email to 2016 CDI organising committee 19 February 2016

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<sup>&</sup>lt;sup>15</sup> Rural Industries Research and Development Corporation (RIRDC) HHalter Longitudinal cohort study of horse owners: Publication March 2016, p56 <a href="https://rirdc.infoservices.com.au/items/16-002">https://rirdc.infoservices.com.au/items/16-002</a> (accessed 20 April 2016)

<sup>&</sup>lt;sup>16</sup> Funded by the Commonwealth of Australia, State of NSW and the State of Queensland under the National Hendra Virus Research Program

<sup>&</sup>lt;sup>17</sup> EA Hendra Working Group- Recommendation to the EA Board December 2015 http://www.equestrian.org.au/news/hendra-working-group-recommendations-now-available

We can confirm though that as a direct result of the EA by-law to mandate Hendra vaccination, EQ experienced a 25 per cent membership contraction in 2014-2015, which then corrected after the by-law was revoked. A membership reduction of that proportion would compromise the viability of any peak sporting organisation, which through the invaluable volunteer workforce contributions are able to deliver important participation and development opportunities to communities within a framework that has controls to provide a safe environment for members.

The positive impact of participation in sport and active recreation on physical health is now well accepted (Australian Institute of Health and Welfare 2010). 19

In 2015, EQ was left with no alternative but to bear the cost of engaging the services of an FEI veterinarian from New Zealand when local FEI vets imposed mandatory HeV vaccination as a condition of their attendance at the Queensland International Three-Day Event.

#### **RECOMMENDATION 1:**

EQ recommends that the Queensland Parliament formally requests the APVMA withdraw its product approval of the Equivac HeV vaccine until such time as laboratory and clinical tests, supported by longitudinal research, produce sufficient evidence to:

- significantly reduce the risk of adverse reactions causing death and severe disability of horses
- extend the effective vaccination period to a minimum of 12 months.
- 2. Who bears the risks of HeV infection and who incurs the costs and receives the benefits from each risk mitigation option.

The Hendra virus has claimed the lives of 70 horses since 1994; seven horses have died from possible or probable reactions to the vaccine since 2012.

### **Risks of HeV infection**

It's basically a lottery. One out a million chances a bat dropping to your horse and your horse is susceptible (sic). In laboratory conditions we have done that experiment once and we fail (sic). So it's very difficult to understand that process.<sup>20</sup>

Dr Linfa Wang Senior Principal Research Scientist CSIRO Australian Animal Health Laboratory

http://www.abc.net.au/catalyst/stories/2500895.htm

<sup>&</sup>lt;sup>19</sup> Australian Bureau of Statistics: Sport & Social Capital- March 2012 p6

There were 70 reported Hendra cases in horses from 1994-2015<sup>21</sup> or an average of three per year in 740,000 horses Australia-wide, and 150,000 horses in Queensland. In comparison, an average of 2.8 horses per year died from possible or probable reactions to the vaccine during the trial reporting period from late 2012 to mid- 2015.

The probability of a human fatality as a result of Hendra virus is extremely rare with a total of four deaths occurring from seven confirmed cases since 1994. The most recent death was in August 2009.

There has never been an incident of Hendra virus at an equestrian event, nor in an EQ registered performance horse. The data show that the risks of travelling to and from competitions, transmission of horse-to-horse infections such as strangles and equine herpes, and falls during competitions are far greater than being infected with HeV. For example, on April 13 2016 an isolated case of strangles caused the Wangaratta Races in Victoria to be shut down. <sup>22</sup>

An average of 20 people die per year from horse-related injuries. Eight percent of the 410 horse-related deaths that occurred between 1979 and 1998 were caused by motor vehicle traffic accidents involving a collision with horse riders or horse-drawn vehicles or during animal drawn vehicle accidents.<sup>23</sup>

The annual rate of deaths from motor vehicle traffic accidents involving a collision with horse riders or horse drawn vehicles 1979-1998 (1.73) is more than five times higher than annual Hendra fatalities (0.31) during the period from the first incident 1994-2016.

The seven confirmed human Hendra Virus cases all became infected following high level exposures to respiratory secretions and/or blood of a horse infected with Hendra virus, such as assisting with post mortem examination of a dead horse without appropriate personal protective equipment (PPE), performing invasive veterinary procedures or having extensive exposure to respiratory secretions without appropriate PPE. Other people have reported similar contact with infected horses but have remained well and their blood tests have shown no evidence of infection... No one with a lower level exposure (eg grooming, feeding, patting) has ever developed Hendra virus infection or shown evidence of infection in blood tests.<sup>24</sup>

### Costs of HeV infection and benefits from risk mitigation

EQ is unable to quantify the cost of HeV infections, however our members believe the cost of vets not treating, or delaying treatment of non-vaccinated horses is inflated and disproportionate to the number of occurrences of the virus, both in humans and horses.

<sup>&</sup>lt;sup>21</sup> Queensland Department of Agriculture and Fisheries Hendra virus fact sheet, <a href="https://www.business.qld.gov.au/industry/agriculture/animal-management/horses/hendra-virus-owners">https://www.business.qld.gov.au/industry/agriculture/animal-management/horses/hendra-virus-owners</a> (accessed 1 April 2016), HHALTER fact sheet <a href="https://www.asid.net.au/documents/item/454">https://www.asid.net.au/documents/item/454</a> (accessed 1 April 2016)

<sup>&</sup>lt;sup>22</sup> Herald Sun 14 April 2016 <a href="http://www.heraldsun.com.au/sport/superracing/vic-racing/wangaratta-races-off-due-to-highly-contagious-strangles-disease/news-story/e189d8fa8a0965e1449d947af8d0f1ac">http://www.heraldsun.com.au/sport/superracing/vic-racing/wangaratta-races-off-due-to-highly-contagious-strangles-disease/news-story/e189d8fa8a0965e1449d947af8d0f1ac</a> (accessed 15 April 2016)

<sup>&</sup>lt;sup>23</sup> Australian Injury Prevention National Injury Survey 2000

http://aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129549468 (accessed 1 April 2016)

<sup>&</sup>lt;sup>24</sup> Queensland Health Hendra Virus Infection fact sheet http://conditions.health.qld.gov.au/HealthCondition/condition/14/217/363/Hendra-Virus-Infection (accessed 1 April 2016)

For example, EQ members have been charged up to \$500 by vets for PPE equipment and exclusion tests. The retail cost of a PPE suit is \$6. Combined with safety glasses, masks, gloves and other consumables a kit can be prepared for under \$30. The cost of an exclusion test is \$56, plus courier costs.

When attending any sick unvaccinated horse, there is a \$500 upfront payment required to cover the costs of laboratory sampling and review, courier fees, protective wear and veterinary professional fees for the above. Without undertaking this process we will be unable to attend and treat your horse. <sup>25</sup> Gold Coast Equine Hospital

3. Whether the guidelines/procedures required for veterinarians attending horses that are not vaccinated against HeV are proportionate to the consequences.

The reliance veterinarians place on the Hendra vaccine is inconsistent with APVMA advice and the manufacturer's (Zoetis) disclaimer that it is not 100 per cent effective.

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.<sup>26</sup>

APVMA

Despite this advice Queensland vets are averse to using PPE.

Others say all will be ok if we wear PPE. I can tell you that dressing up like a spaceman, and dressing owners up like spacepeople carries its own risk working with fractious horses in hot Queensland conditions. PPE greatly increases the chance of needle stick injury, heat exhaustion or injury. Dr Nathan Anthony President of the Equine Veterinarians Association

However when seeking government funding of PPE for private veterinarians, the AVA said:

It is crucial that veterinarians can continue to attend sick horses to investigate suspected and exclusion cases of Hendra virus infection.<sup>28</sup>

EQ considers the veterinary profession should follow the lead taken by the medical profession to improve work practices as a consequence of the emergence of infectious diseases such as HIV Aids by adopting the use of appropriate PPE.

<sup>26</sup> http://apvma.gov.au/node/12881 (accessed 31 March 2016)

<sup>&</sup>lt;sup>25</sup> Email to clients 8 April 2016

<sup>&</sup>lt;sup>27</sup> The Horse Magazine, June 2015 <a href="http://www.horsemagazine.com/thm/2015/05/hendra-qa-spacesuits-cash-cows-russian-roulette/">http://www.horsemagazine.com/thm/2015/05/hendra-qa-spacesuits-cash-cows-russian-roulette/</a> (accessed 30 March 2016)

<sup>&</sup>lt;sup>28</sup> Hendra virus response, AVA policy briefing 5 July 2011 published in Primary Industries Ministerial Council Record and Resolutions, 28 October 2011 p54

Many EQ members have shared their concerns about the practice of vets refusing to treat unvaccinated horses until the negative HeV test results were returned. This included serious concerns about the welfare of horses that were denied treatment, and potential safety risks to humans who were trying to nurse sick horses without professional vet guidance.

While there is no legal obligation to abide by the veterinarian's oath, EQ members who have experienced their horses being denied timely treatment believe vets have not acted in the best interests of horse welfare, based on inaccurate risk assessment and misinterpretation of workplace health and safety requirements.

#### **RECOMMENDATION 2:**

EQ recommends the Queensland Parliament introduce a legislative requirement for veterinarians to:

- take a veterinary oath as a requirement of registration
- wear appropriate PPE as a standard practice when treating sick and injured horses
- treat sick and injured horses regardless of their vaccination status.

#### **RECOMMENDATION 3:**

EQ recommends a review and restructure of the Veterinary Surgeons Board of Queensland, as the sole statutory body with legislative responsibility for the regulation of veterinary science in Queensland, to:

- empower the board to administer the recommendations outlined above
- expand the diversity of the Board to increase industry and consumer representation.
- 4. Impacts on the equine industry and the economy arising from veterinarians applying a policy not to treat unvaccinated horses.

The veterinarians' policy of not treating unvaccinated horses is discriminatory to Equestrian Queensland members.

# Impacts on equine industry - competitions

The future of Olympic level equestrian competitions in Queensland is at risk because some of the five FEI accredited veterinarians in Queensland have, despite there being no FEI directive to do so, made mandatory Hendra vaccination a condition of service to event organisers.

Under FEI rules, the event organisers require an FEI accredited veterinarian delegation team to meet the FEI sanction, which is needed for it to be an international qualifier that riders competing in dressage, show jumping and eventing require for Olympic pathways.

EQ considers that the placing of conditions on some elements of equestrian sports and not the whole industry, such as racing, pacing, polo, polocrosse, reining, campdrafting, pony club is discriminatory against its members.

The effect of these actions have caused undue stress on voluntary event organisers and disadvantaged many competitors.

79 per cent of event organisers who have conducted mandatory Hendra vaccinated events indicated a reduction in nominations, reinforcing that it is not encouraging participation in events.

There are Hendra Vaccination pre requisites for this CIC One Day Event. The committee did not make this decision lightly, in fact we literally did not have a choice.<sup>29</sup>

Fig Tree Pocket Equestrian Committee

The Royal National Association (RNA) Brisbane Show reported a 42 per cent decrease in entries in 2013 when it introduced mandatory vaccination, and a 25 per cent decrease in 2014.30

The EQ member survey responses highlighted that not only are the majority of individuals against mandatory Hendra vaccination, but the decision to vaccinate was influenced to gain access to competition and that mandatory events have restricted competitors' ability to continue pathways.

EQ members further consider mandatory Hendra vaccination discriminates against horses and competitors who live in Queensland and Northern NSW because the recurring costs and known adverse reaction risks present unique and unfair barriers to competition pathways that competitors from other states don't experience. Several EQ members have had their competition entries rejected by interstate event organising committees because their horses were not Hendra vaccinated.

The horse and rider combination, which where rejected, I am trying to prepare for the Olympic Games Tokyo 2020. Due to this decision I am unable to follow our goals, contrary to competitors from other regions in Australia.

Ulrich Klatte
Owner Belcam Stud

5. The impact of Workplace Health and Safety actions on the decision by veterinarians not to attend unvaccinated horses and results of previous Workplace Health and Safety HeV investigations where there have been human infections.

EQ is unable to comment on these matters with authority because none of our members have any known direct experience with a Hendra virus infection.

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<sup>&</sup>lt;sup>29</sup> FTPEC email to competitors, 3 July 2015

<sup>30</sup> Report from Phil Harpham on behalf of RNA council to Queensland Horse Industry Alliance 20 November 2014

We are, however, concerned that the veterinarians' key argument for mandatory vaccination has shifted from a concern for their personal safety to their perceived risks due to Workplace Health and Safety obligations and fear of prosecution. As such we consider there is a role for the Queensland Government in increasing awareness and understanding of WHS requirements as they relate to veterinarians and equestrian events.

### **Conclusion**

As a not-for-profit member based organisation, EQ has a responsibility to represent member interests, an overwhelming majority of whom are opposed to mandatory Hendra vaccination. Some of the reasons include:

- Disparity in definition of vaccination status causing confusion and inconsistency in treatment and management
- encroachment of civil liberties to remove choice on whether vaccinate for a product which:
  - o has adverse reactions known to APVMA
  - o has additional cases which were not reported to APVMA
- imposition of variable costs that are not subsidised, resting the burden solely on the horse owner/rider.
- Potential liability for event organisers.
- insufficient longitudinal data on breeding.

We remain concerned that our sport has been targeted due to misunderstanding of risks, and trust the committee finds our submission insightful and informative and our recommendations realistic and achievable.

Yours sincerely,

David Finch Chair Equestrian Queensland

Woolloongabba QLD 4102