RACING APPEALS TRIBUNAL NEW SOUTH WALES

TRIBUNAL MR DB ARMATI

RESERVED DECISION

31 AUGUST 2018

APPELLANT KYLIE HUGHES

AUSTRALIAN HARNESS RACING RULE 190,196A,196B

SEVERITY APPEAL

DECISION:

1. **Appeal Upheld**
2. **Disqualification of 2 years 2 months from 20 April 2017**
3. **Directions issued on appeal deposit orders**

BACKGROUND

1. Licensed trainer Kylie Hughes appeals against a decision of the stewards of 26 June 2017 to disqualify her from a period of 4 years, commencing on 20 April 2017, for 3 breaches of the rules. Breaches 1 and 3 were a disqualification of 4 years concurrent and breach 2 had no penalty imposed.

2. The 3 alleged breaches of the rules are as follows:

Breach 1

Rule 196A. (1) A person shall not administer or cause to be administered to a horse any prohibited substance

(i) for the purpose of affecting the performance or behaviour of a horse in a race or of preventing its starting in a race; or

(ii) which is detected in any sample taken from such horse prior to or following the running of any race.

(2) A person who fails to comply with sub-rule (1) is guilty of an offence.

Particulars

Pursuant to HRR 196A(1)(ii) and (2)-

Particulars being: you, Ms Kylie Hughes being the trainer of the registered horse Camelot Speedstar did on Friday, 17 March 2017 through the provision of a drip containing the product Vam did administer the prohibited substance cobalt to that horse which was detected by two approved laboratories in the urine sample taken from Camelot Speedstar following race 2 at Broken Hill on Friday, 17 March 2017.

Breach 2:

Rule 196B

(1) A person shall not without the permission of the Stewards within one (1) clear day of the commencement of a race administer, attempt to administer or cause to be administered an injection to a horse nominated for that race.

- (2) For the purposes of this Rule -
- (a) One clear day means the twenty four (24) hour period from 12.01 a.m. to 12 midnight;

(b) Administering an injection to a horse means the use of a hypodermic needle or other instrument to introduce or extract any substance from the horse;

(c) It is not necessary to establish whether any substance was injected or the nature of the substance injected.

(3) The Stewards shall order the withdrawal or disqualification of a horse that has been either administered or attempted to have been administered an injection in breach of sub-rule (1).

(4) A person who fails to comply with sub-rule (1) is guilty of an offence.

Particulars

Pursuant to HRR196B(1) and (4)

Particulars being: you, Ms Kylie Hughes being the trainer of the registered horse Camelot Speedstar on Friday, 17 March 2017 did, and without the permission of the stewards, administer an injection to that horse in contravention of rule 196B(1).

Breach 3:

Rule 190

(1) A horse shall be presented for a race free of prohibited substances.

(2) If a horse is presented for a race otherwise than in accordance with sub rule (1) the trainer of the horse is guilty of an offence.

Particulars

Pursuant to HRR190(1) and (2)

Particulars being: you, Ms Kylie Hughes being the licensed trainer of the registered horse Camelot Speedstar did present that horse to contest race 2 at Broken Hill on Friday, 17 March 2017 following which analysis of the urine sample taken post race has on the certification of two approved laboratories detected a prohibited substance, namely cobalt at a concentration greater than 100 micrograms per litre in urine.

3. The appellant had "pleaded guilty" before the stewards and, on their finding, at the earliest possible time. The appellant has maintained that admission of the breach of the rules on this appeal. Accordingly this is a severity appeal only.

4. The evidence has comprised the transcript and exhibits from the stewards inquiry, the stewards decision of 26 June 2017, the report of Dr Wainscott of 7 August 2017 together with its annexures the report of Dr Wainscott of 21 November 2017 together with its

annexures, the report of Dr Major of 3 October 2017 together with its annexures, the re-examination of Dr Paine in the Victorian RAD case of Zuereb 9 April 2018, an extract of a report by Burns and others-Journal of Veterinary Internal Medicine 2017 Effect of intravenous administration of cobalt chloride to horses on clinical and haemodynamic variables ("Burns"), the appellant's offence report. Doctors Wainscott and Major gave oral evidence.

5. The annexures to the reports of Dr Wainscott are:

> Journal of Dermatological Science volume 65 2012-Hypoxia regulates the expression of extra cellular matrix associated proteins in equine dermal fibroblasts via H1F1- Deschene and others (“Deschene”)
>
> Drug Testing and Analysis 17 August 2014 -Controlling the misuse of cobalt in horses-Ho and others (“Ho”)
>
> Drug Testing and Analysis-21 September 2014-Pharmocokinetics and selected pharmacodynamics of cobalt following a single intravenous administration to horses- Knych and others (“Knych”)
>
> BJSports med-17 October 2012-Cobalt chloride administration in athletes: a new perspective in blood doping?-Lippi and others (“Lippi”)
>
> Proceedings of the 20th international conference of racing analysts and veterinarians, Mauritius-2014-Detection of cobalt in equine plasma and urine samples-Brooks and others ("Brooks")
>
> Journal of Biological Chemists-2 May 2003-Cobalt inhibits the interaction between hypoxia-inducible factor-a and von Hippel-Lindau protein by direct binding to hypoxia-inducible factor-a- Yong and others (“Yong”)
>
> The American Physiological Society-23 June 2000-improved cardiac contractile functions in hypoxia -reoxygenation in rats treated with low concentrations CO2 Endoh and others (“Endoh”)
>
> The World Anti-doping Code International Standard Prohibited List January 2017

6. The annexures to the report of Dr Major are:

> IJBCB-9 August 2004-Hipoxia- inducible factor 1: regulation by hypoxic and non-hypoxic activators- Dery (“Dery")
>
> Journal of Saudi Chemical Society-6 December 2009-Cobalt chloride, a chemical inducer of hypoxia- inducible factor-1a in U251 human glioblastoma cell line- Okail (“Okail")

Neurochem Res-14 July 2014- CoCl2-Induced biochemical hypoxia down regulates activities and expression of super oxide dismutase and catalase in cerebral cortex of mice-Rani and another (“Rani”)

Preliminary report-undated-Evaluation of cobalt as a performance enhancing drug (PED) in racehorses- McKeever "and others (McKeever")

ACTA Physiologica-2010-Hypoxia preconditioning by cobalt chloride enhances endurance performance and protects skeletal muscles from exercise-induced oxidative damage in rats- Saxena and others (“Saxena”).

7. Cross examination of Dr Wainscott sought to elicit substantial criticisms of him personally on the basis that he was not up to date with current research. It is apparent from the cross examination that he had not read a number of reports and some only by way of extract, that he had not attended conferences except on one instance, that he did not subscribe to journals to keep himself informed and did not read material even when he was aware of its existence. The Tribunal does not have to determine that his evidence should be rejected on the basis of those criticisms. However it must be expressed that his evidence on these issues was surprising. At the end of the hearing the totality of the evidence is what is to be considered. If it is demonstrated that an opinion is now out of date then of course it may not be of any current use.

8. Dr Major was criticised because he sought to rely upon his own research, and on one on the basis that the research had not been published. The Tribunal prefers that it uses published, and if necessary peer-reviewed, research which out of fairness to the respondent is able to be read and analysed and critically reviewed. The respondent here could not do so and accordingly it would be against the principles of fairness that Dr Major’s own assessment of his research or unpublished others was to be given any weight.

9. The hearing of this appeal took two days and the respondent lodged, at the Tribunal’s request, a supplementary written submission upon which the appellant commented.

10. The appellant had not initially sought a stay of the stewards’ decision but the Tribunal of its own motion at the conclusion of the hearing on 20 June 2018 determined that a stay should be granted.

12. The grounds of appeal are that: cobalt was erroneously considered to be a class 1 substance under the Penalty Guidelines (“guidelines”); insufficient discounts for good disciplinary record; erroneously took into account purported aggravating factors; failed to adequately take into account's subjectives; penalties otherwise too severe.

13. The key issue for determination is the classification of cobalt in the Harness Racing NSW Penalty Guidelines which were last updated on 14 November 2016. Having regard to the arguments it is necessary to set out those guidelines in full and they state:

> “PENALTY GUIDELINES FOR THERAPEUTIC SUBSTANCES AND TCO2 POSITIVES:

CLASS 1

This category of drugs has the highest potential to affect performance and have no generally accepted medical use in the racing horse.

It includes, but is not limited to, central nervous systems stimulants and depressants, narcotic analgesics, synthetic EPO derivatives , including polyethylene glycolated – epoetin beta (PEG-EPO), ITPP, AICAR, snake venom, snail venom, other animal venom and all substances specifically referred to in AHRR 190A (2) Out of Competition Testing and any other substance not registered for use in equines and/or Humans.

The list below is some of those substances, but is not limited to:

- Anileridine
- Anabolic steroids (including HPC)
- Cobalt
- Etorphine
- Dipipanone
- Endorphins
- Human erythropoietin, darbepoetin alpha
- Human insulin, bovine insulin and porcine/canine insulin
- Diacetylmorphine (heroin), cocaine, cannabinoids and lysergic acid diethylamine (LSD)
- Amphetamines including amphetamine, methylamphetamine
- Methylenedioxyamphetamine and methylenedioxyamphetamine

First offence

- No less than five (5) years disqualification

Second offence

- No less than (10) years disqualification

CLASS 2

Drugs in this category have a high potential to affect performance but less of a potential than Class1.

They include but are not limited to psychotropic drugs, certain nervous system stimulants and depressants and neuromuscular blocking agents.

Local anaesthetics are included in this class because of their high potential for abuse as nerve blocking agents.

It also includes but is not limited to:

- TCO2
- SARMs
- SERMs (eg Tamoxifen)

First offence

- No less than two (2) years disqualification

Second offence
- No less than five (5) years disqualification

Third offence
- No less than ten (10) years disqualification

CLASS 3

This category includes those medications registered in Australia for veterinary use which have an accepted therapeutic use in the racing horse.

Australian registered human preparations with an accepted therapeutic use in the racing horse may also be included in this Class.

Includes all therapeutic substances.

First offence
- Twelve (12) months disqualification

Second offence
- Two (2) years disqualification

Third offence
- Five (5) years disqualification

Fourth offence
- Ten (10) years disqualification

Stewards may consider a reduction on compelling evidence that the person:

- Did not administer or caused to administer the prohibited substance
- Did not know or have reason to believe it was administered
- Taken all reasonable steps to ensure administered was not possible
- If a person makes an omission or pleads “guilty” to any offence”

14. The appellant submits that cobalt falls within class 3 and not class 1 and accordingly the starting point for a penalty for this appellant is a disqualification of one year and not five years. The stewards had adopted a starting point of a penalty of disqualification of five years on the basis that cobalt falls within class 1.

15. The appellant does not dispute that a period of disqualification must be imposed upon her and the necessity to further consider that possible outcome falls away.

16. As this is a de novo appeal the duty of the Tribunal is to determine the penalty for itself. The rules provide a range of penalties. However in 2012 penalty guidelines were introduced. In numerous decisions the Tribunal has specified how it would use those guidelines. In an ex-temporary decision of Joshua Carroll of 27 November 2015 the Tribunal said this:

> “13. The question then becomes (of) what penalty should be imposed for this breach. The first thing to consider is a starting point for the facts. It is important to recognise that each case must be dealt with on its own facts and circumstances. In numerous recent decisions – and there have been too many, it must be said – the Tribunal has indicated the approach it will adopt to the guidelines. In this case it will not give a lengthy dissertation on that approach. In summary, they are guidelines, not tramlines. They will be used by the Tribunal because to do otherwise would not leave the regulators or the industry with any form of understanding of what likely consequences might flow other than from reading Tribunal decisions.
>
> 14. The guidelines have been in operation since 2012. They exist in an environment which at the present time continues to throw up prohibited substance cases with a regrettable frequency. They were introduced at a time when the industry was subject to the green light scandal. They were introduced at a time when this Tribunal had reflected that the stewards had been unduly lenient in respect of prohibited substance matters, not only in this code but the other codes. They are embraced by a draconian prohibited substance regime that has been referred to in a number of cases, and the nature of it is not repeated. They are harsh. The regulator, in drafting them, intended them to be harsh. The reasons for that need not be examined. The Tribunal has accepted that that is the approach the regulator wishes to take and not only is a period of disqualification, which is not opposed in this case by the appellant, appropriate, but it is one of the few tools available to the regulator to try and provide a level playing field.
>
> 15. It is the fact that, despite the efforts of the regulator, trainers continue to present with prohibited substances. It is therefore that this Tribunal must take strong steps to provide support to the regulator in its endeavours to find a regime in which all associated with the industry can enjoy the appropriate level playing field that is desired.”

17. Consistent with a number of recent decisions the Tribunal will use the penalty guidelines to assist it in determining an appropriate civil disciplinary penalty but on the basis that it emphasises that they are guidelines and not tramlines. Importantly each individual case must be assessed on its facts and circumstances and where they lie in respect of the guidelines generally and in other cases with which the particular drug has been involved-the parity issue.

FACTS

THE CONDUCT

18. The conduct facts have played a very small part in this case. Essentially no facts on the conduct of the appellant were led. The Tribunal therefore determines the relevant facts from the determination of the stewards.

19. It is not in issue that the appellant was the trainer of the subject course and it participated in the particularised race. The appellant accepts the prohibited substance cobalt was detected from a post race sample at 168 and 164. The appellant accepts that cobalt is a prohibited substance. The appellant accepts that she administered a substance to the horse by injection on race day and she did not have the permission of the stewards

to do so. Those findings and admissions establish the facts necessary to find each of the three breaches established.

20. During a stable inspection after the detection the appellant volunteered that 48 hours prior to the race she injected 20 mils of Vam, Tripart and Cophus B.

21. During the inquiry, which was conducted with the appellant by telephone, the appellant admitted that at about 9 am on the morning of the race she had given the subject horse a drip of Langs solution to which she herself had added 10 mls of Vam and 10 mls of Cophus B. The appellant admitted that she knew she was in breach of the rules. The appellant denied that she knew the product Vam contained cobalt. The appellant stated she had received no professional advice regarding her treatment regime. The appellant admitted that she had been employed in a produce store for several years and had sold the product Vam on a regular basis.

SUBJECTIVES

22. The appellant is now aged about 48 years and is in a relationship. She received a modest weekly wage at a produce store and gave figures, which are kept confidential, about income from harness racing. She has usual expenses. At the time of the breach she had four horses in work. She had no employees but unpaid assistants. She said that she had been associated with the industry for over 30 years as a hobby trainer and driver and had no prior positive swabs. She actively supported the Mildura Harness racing Club as a committee person and the Broken Hill Harness Racing Club by nominating horses. She describes her love for horses

23. The appellant provided four references to the stewards' inquiry.

24. Mr Lucas was her employer at the at the produce store and she was a dedicated employee. He describes the appellant as a board member of the Mildura Harness Racing Club and she was an asset to that club being always willing to help out.

25. Ms Brown is the owner of the stock feed business and commends the appellant's character and that she was a conscientious and valuable employee, honest hard-working and loyal. She describes her as committed to horses and the industry and had said how devastated the appellant has been by the subject breaches.

26. Ms Allan-Gange has been an owner and participant in the industry for 30 years and is a personal supporter of the appellant who she has known for 20 years. She was surprised by the charges which she said were inconsistent with her previous professional and personal reputation. She says the appellant has always been professional and ethical and has expressed genuine regret for her actions.

27. Mr John Nicholson first met her some 18 years ago and was in a relationship with her. He describes her incredible work ethic and love for horses, that she is hard-working and

has a devotion to and love of horses. Whilst he is not aware of the particulars of the charges he is not aware of any other blemishes by her.

28. The appellant admitted the breaches to the stewards and has maintained those admissions on appeal. She has co-operated with the stewards and on this appeal. She is entitled to the full 25% discount for those facts.

29. The appellant has no prior matters and this is a strong subjective factor. This is particularly so as she has been associated with the industry for over 30 years, although in a limited form by reason of the small number of horses in training.

30. The appellant is entitled to have her assistance to the harness racing industry taken in to account in a further reduction of the appropriate starting point for the objective seriousness of her conduct.

31. The remaining subjective factors do not differentiate this appellant from the majority who are dealt with on appeal.

THE ISSUE

32. The issue for determination is penalty.

33. That determination requires a finding of whether cobalt is a class I or class 3 substance under the Penalty Guidelines and then a determination whether the Tribunal exercising its de novo function considers such an approach provides an appropriate penalty.The appellant says it is a class 3 and the respondent a class1.

34. The appellant says that rules of statutory construction should be applied. The appellant acknowledges guidelines and not statutes are being considered but that the principles are equally applicable when considering inconsistencies. That is it is necessary to find the underlying purposive nature of the classifications with consideration of the impact upon the individual such as the ability to work and earn income. Therefore it is said if there is a capacity to find either category applicable then there should be a finding that it is the lower category that applies. Otherwise it is said there would be a nonsense. As will be canvassed further this is particularly so, it is submitted, as Dr Wainscott conceded there is no distinction in relation to the red blood cell issue between class 1 and class 2 when considering the test "highest" against "high".

35. The respondent calls in aid Leeming JA in Day v Harness Racing NSW [2014] NSWCA 594 at 79 to 81. To paraphrase the finding it was that harness racing rules are not to be scrutinised in the same way as provisions in a regulation and provisions in a regulation are not to be scrutinised in the same way as an act. In particular this was so as the rules were not drafted by Parliamentary Counsel nor specialist drafting lawyers. Without repeating the cases he quoted the rules should be interpreted for the purpose and the readership to which they are addressed.

36. The appellant accepts these principles apply.

37. They will be applied here because what is being interpreted is a guideline and not a rule of the industry.

Vam

38. For emphasis the Tribunal repeats its finding on the facts that the appellant administered Vam at 9am on the morning of the race. The fact that the drip also contained Cophos B is ignored as there is no evidence that that substance has any relevance to the presence of the prohibited substance cobalt in the horse.

39. Vam is essentially vitamins (including B12) and minerals and within the vitamin B12 there is 1 mg of cobalt in the standard dose of 10 mL of Vam. If an average race horse is say 500kgs, being between 420 and 600 as appears in literature, then a 1mg dose would seem to be at 0.002 mg /kg. That compared to research report levels of administration is informative.

40. Dr Wainscott gave evidence that that standard dose of Vam at 9am on the morning of the race would produce the reading of 180 for cobalt in the post race sample. However the risk of exceeding the threshold of 100 would only exist for up to 12 hours.

41. Dr Wainscott gave evidence that Vam is a medication registered in Australia for veterinary use and that it has an accepted therapeutic use in the racing horse. He therefore correctly conceded that it falls within class 3. It is a medication.

42. Dr Wainscott agreed that the administration of Vam at 9am in the morning of a race is not going to be performance enhancing. For that reason he agreed that a reading over 100 or 200, depending on the source, is no indication of potential performance enhancement.

43. It is not in issue that the appellant's administration of Vam at 9am on the morning of the race produced cobalt in the urine of the horse and that cobalt, over the threshold (100), is a prohibited substance and therefore the Penalty Guidelines are engaged as are a number of rules and that at a minimum the conduct is to be assessed under class 3.

The Guidelines and the Rules

44. The key point in assessing where in the guidelines cobalt falls requires a purposive consideration of the guidelines and an understanding that the infelicities of drafting should not be considered too critically.

45. The guidelines deal with therapeutic substances. They refer to drugs in classes 1 and 2 and medications and preparations in class 3. However the guidelines are not to be read in isolation but are a byproduct of the rules.

46. Part 12 of the rules deals with prohibited substances.

47. HR 188 and188A provide power to determine what is a prohibited substance and specify a number and the general impact upon “mammalian body systems" (188A(1)(a)).

48. Critically 188A(10)(f) provides cobalt at a concentration of 100 mcg/L in urine as a prohibited substance.

49. HR190A(2) relevantly provides as prohibited substances:

> "(a) haematopoiesis- stimulating agents, including but not limited to erythropoietin (EPO)…
>
> "(l) hypoxia inducible factor (HIF)-1 stabilisers".

50. A penalty will only be required to be determined under the guidelines if a prohibited substance is found.

51. A medication or preparation which does not lead to the detection of a prohibited substance will not be considered under the guidelines.

52. As Vam is not detected in the urine of the subject horse its further consideration becomes irrelevant. As a medication it was the source of a prohibited substance. The focus is on the prohibited substance not the source. The focus is therefore upon cobalt.

Cobalt

53. Dr Major gave untested evidence that cobalt is an ingredient in many registered pharmaceuticals and is regularly administered with good intent and prescribed by veterinarians for the treatment of anaemia in racehorses. He says it is a core element in the synthesis of vitamin B12 and that vitamin B12 is necessary for life in horses. Accordingly he says cobalt falls within class 3. Cobalt is endogenous and accordingly a threshold was fixed above which its presence became prohibited in the racehorse (originally 200 now 100) .

54. The rules and guidelines are relevantly directed to prohibited substances and the determination in this case is a categorisation of cobalt as a prohibited substance and not just as an endogenous substance. Accordingly the fact that it falls within class 3 as an endogenous substance does not mean it cannot fall within class 1 as a prohibited substance.

55. Accordingly the drafting of the guidelines referring to therapeutic substances, drugs, medications and preparations is a mere reflection of drafting and not of purpose.

56. The words "category of drugs" in class 1 requires consideration of a prohibited substance as defined in the rules. Relevantly here that is cobalt above the threshold. Accordingly it is not Vam.

57. The discussion whether cobalt is an element, a substance or a drug does not need further analysis. For the purposes of this determination cobalt is a drug if found above the threshold.

58. The various reports in evidence describe cobalt and its relevance to the effects on the systems of horses, mammals and in tissue. There is a degree of repetition in the quotations but they are given in detail for completeness.

59. Cobalt can be given by inorganic cobalt salts, , as cobalt chloride CoCl2, and pharmacological products. There may be other sources. It can be given orally or intravenously.

60. Burns

"Cobalt is an essential micro nutrient that is present in mammalian systems in organic and inorganic (ionic) forms. Importantly, cobalt ion is a central cofactor of vitamin B12 (cobalamin) and is required for proper …hematopoiesis…regular intake of trace amounts of dietary cobalt is required for health.

Cobalt as inorganic cobalt salts is also an effective hypoxia mimetic.

Anecdotal reports of complications and sudden death after intravenous administration of CoCl2 are circulating…

..drug's known ability to act as a potent hypoxia mimetic stabilising hypoxia-inducible factor 1-alpha and enhancing hematopiesis in other species through increased erythropoietin production."

61. Ho

"Cobalt is a well-established chemical inducer of hypoxia like responses and had been used to treat anaemia in pregnant women, infants, and patients with chronic anaemia. Hypoxia causes gene modulation at the hypoxia inducible factor (HIF) pathway, leading to cell and tissue adaptation to the low oxygen conditions. The main mediator hypoxia inducible factor one alpha (HIFA) activates genetic sequences, including those of the erythropoietin (EPO) gene, which promotes efficient adaption to hypoxia…. The high RBC counts would return to normal 9 to 15 days after cobalt administration…. Supplementing with cobalamin does not benefit performance unless there is a nutritional deficit.

Cobalt is a central micronutrient in the form of vitamin B12 (cobalamin)…. Cobalt is acutely toxic in larger doses…. The cobalt induced activation of HIF, present in almost all animals cells, with transcription of a range of hypoxia responsive HIF -target genes, probably promotes tumour development and growth.

.. Cobalt salts… are attractive blood doping agents to enhance aerobic performances…. Gene therapy targeting the HIF pathway has been reported as an attractive alternative to traditional techniques of blood doping…

Due to the ability of cobalt to act as an erythropoietic agent in equine sports…

.. cobalt is naturally occurring in equine biological samples."

62. Knych

"Cobalt acts by stabilising a factor known as hypoxia inducible factor one alpha (HIF1A). HIF1A regulates cellular and systemic oxygen homoeostasis by binding to DNA coding for genes such as erythropoietin (EPO)….. Under hypoxic conditions, or following cobalt administration, degradation of HIF1A is inhibited, leading to activation of the EPO gene, increasing the number of reticulocytes, red blood cells and hemoglobin.

… chronic administration of cobalt.. associated with a number of toxic effects… gastrointestinal sickness, thyroid dysfunction, and myocardial toxicity…"

63. Yong

"It has previously been established that cobalt mimics hypoxia and causes accumulation of HIF1A…"

64. Brooks

"Cobalt is a naturally occurring element required in low amounts for various functions in the equine and other animals. Cobalt is a natural constituent of numerous feedstuffs and a constituent of cyanocobalamin (vitamin B12)…. Numerous cobalt containing supplements..

Excessive amounts of cyanocobalamin do not seem to offer any performance enhancing effect but inorganic cobalt salts have been recognised as having the potential to increase aerobic capacity through a boost in erythropoiesis caused by an increased amount of erythropoietin synthesis triggered by modulation at the hypoxia inducible factor pathway."

65. Saxena

"Cobalt is a widely used hypoxia mimetic. It induces the hypoxic environment by stabilising hypoxia-inducible factor one alpha… The precise mechanism of HIF stabilisation by cobalt is not fully understood….. Cobalt may allow activation of the cellular oxygen sensor.. Also, cobalt may directly enhance HIF1a stabilisation through reactive oxygen species formation."

Class 1

66. The respondent says that there are three categories in class 1 and those categories are to be found respectively in each of the three paragraphs under the heading "CLASS1".

67. The appellant says that there is only one category and that is to be found in the first paragraph and paragraphs 2 and 3 merely provide for substances, or drugs, that must be captured by paragraph 1.

68. The Tribunal is satisfied that a purposive interpretation of the guidelines, applying the test set out above, means that the intent of the drafters was clearly to provide by the use of the expression "it includes" in paragraph 2 that if any of those listed were found then they would fall within the meaning of all of the words in paragraph 1.

69. Further it is found that that a purposive interpretation means that "the list" in paragraph 3 is intended to provide that each of the named drugs in that list is firstly incorporated in to the matters captured by paragraph 2 and, secondly, in addition are to be included as one of the ”category of drugs" captured by paragraph 1.

70. Cobalt is specifically listed in paragraph 3. Whether it falls within AHRR190(2) in paragraph 2, which is the respondent's position, requires determination of the meaning of hypoxia inducible factor (HIF)-1. The appellant says it does not.

71. However, that becomes a somewhat irrelevant consideration because on the above finding cobalt falls within paragraph 1. Whether it is correctly so listed as falling within all of the words of paragraph 1 does not matter because the purposive interpretation found is that that is what is intended.

72. To be clear it is found that cobalt is a class 1 substance because the regulator says it is by specifically naming it.

73. Nevertheless it is appropriate to give some consideration to the two days of evidence and argument that have addressed the meaning of paragraph 1.

74. The argument for the respondent that class 1 has three categories is not accepted. The expressions "it includes" and "the list above" provide for supplementation not exclusivity.

75. The first paragraph of class 1 has four ingredients each of which must be established. They are "this category of drugs", "has the highest potential to affect performance”, "and have no generally accepted medical use" and "in the racing horse".

"This category of drugs"

76. This has been dealt with above and it has been found that cobalt above the threshold is a category of drug within the meaning of this paragraph.

"And have no generally accepted medical use"

77**.** This issue is dealt with as, narrowing the determination in respect of its meaning, will reduce the considerations on the performance affectation issue.

78. As found above the focus must be upon cobalt as a prohibited substance and not Vam.

79. It is found that Vam, properly administered, has a generally accepted medical use in the racing horse.

80. It is found that cobalt below the threshold has a generally accepted medical use in the racing horse if it is an ingredient in a registered pharmaceutical product. There is no direct evidence that cobalt is legally administered other than by its inclusion in a registered pharmaceutical product. There is no evidence that cobalt is a medication registered in Australia for veterinary use.There is no evidence in these proceedings that cobalt above the threshold has an accepted medical use in the racing horse. In past determinations, and on the evidence here, it is to the contrary.

81. Dr Major agreed that a straight cobalt deficiency in a horse has not been reported.

82. The Tribunal finds that cobalt above the threshold has no generally accepted medical use in the racing horse.

"In the racing horse"

83. The application of the guidelines must be to the racing horse.

84. The fact that the rules, in determining what is or is not a prohibited substance, analyse, in some cases, impact upon mammalian systems is not relevant to the test under the guidelines.

85. This becomes particularly important in the later analysis of the HIF1 stabiliser in mammals generally. Of course in determining whether there may be an impact of the type required on a racing horse research on other mammals is relevant.

“Has the highest potential to affect performance"

86. This issue has consumed a substantial period of time in the preparation of this case and its hearing. The main focus of the evidence was upon positive affectation. Two experienced veterinarians have provided reports and given evidence. Numerous scientific reports have been referred to. As a result of the evidence the issues narrowed. Because of concessions made the evidence trail will not be fully dissected but those conclusions and agreements adopted.

87. The Tribunal emphasises that it makes its determinations upon the agreements and concessions and the evidence before it. Its conclusions must be considered in the future in light of those remarks. This decision cannot be a determinative finding on all of the positives and negatives of cobalt in the racing horse. No doubt other witnesses will give evidence and other reports will come to light which will lead to further consideration, and possible changes in the regulatory approach, to the drug cobalt. There is no doubt that over recent years, since cobalt first came to prominence in the sporting world, the science and regulatory approaches have changed.

88. Accordingly many of the cases referred to in the hearing must be considered dated because of those changes. The fact that the Tribunal has previously ruled cobalt is a class 1 drug cannot be determinative now because of the evidence adduced in these proceedings. There is a need to revisit the issue.

89. Dr Wainscott in his first report did not address this issue of potential affectation. Dr Major in his report did and Dr Wainscott replied to each of the issues raised.

90. Dr Major first dealt with Haematopoietic agents then HIF stabilisers, rejected both as having potential to affect performance of the horse, then analysed the performance enhancing arguments and concluded cobalt had no potential to affect the performance of the horse.

Haematopoietic

91. Haematopoiesis is the process of producing cellular blood from bone marrow.

92. Dr Major in his report concluded there is no evidence that cobalt is a haematopoietic in the horse.

93. Dr Wainscott in his report in reply agreed that cobalt is not a haematopoietic in a horse but said studies show it is in other mammals. He said it is an HIF1 stabiliser and has the potential to increase EPO expression and thus able to exert a haematopoietic affect in the horse because it has in other mammals. The other mammals issue and the HIF1 stabilisers will be examined below.

94. It must be concluded, in the absence of direct evidence, that cobalt is not a haematopoietic in a horse.

95. As this was raised by the appellant and does not form part of the respondent's case it does not need closer examination.

HIF1 Stabilising Effect

96. The analysis of the issue of potential to affect performance raises consideration of the application of the second paragraph of class 1 which sets out an inclusive list which contains AHRR190A(2). Relevantly that is subparagraph "(2)(l)-hypoxia inducible factor (HIF)- 1 stabilisers".

97. Dr Wainscott gave evidence that an HIF factor is an hypoxia-inducible factor. That it is a master controller that directs responses to hypoxia. Hypoxia inducible factors are always in the body. He agreed to the following: they are responsive to hypoxia, that is the hypoxia induces the HIF; if the HIF does not degrade that can induce the expression of EPO and that will lead to the production of additional red blood cells to bring the body back into balance which is what the body is designed to do; the stopping of the degradation of HIF factors is because the way they degrade is effectively by oxidisation; when you retard the degradation of HIF factors you effectively stop the oxidisation process because of a lack of oxygen which is the hypoxic state-you fool the body to believe that. He gave evidence that HIF stabilisation has been shown to effect the expression of 50 or 60 different genes in the body and some of those are involved in increasing blood vessels going to muscles.

98. Dr Wainscott in his report said there is clear consensus in scientific literature that cobalt is an HIF-1 stabiliser . He relied on Deschene, Lippi, Ho and Knych. They describe the work done by an HIF.

99. The relevant quotes from Ho and Knych are set out in paragraphs 61 and 62.

100. Deschene

That part of Deschene to support his theory is:

"The ability of CoCl2 to act as a hypoxia mimetic in the subsequent experiments was validated by measuring its effect on the expression of HIF1A . CoCl2 consistently and rapidly induced the expression of HIF1A protein (fourfold increase) at 3 hours and 6 hours; at 12 hours HIF1A concentrations remained elevated (twofold) but then declined to finally reach control levels by 24 hours."

101. Lippi

"Hypoxia activates a large number of genes that have essential roles in cell and tissue adaptation to conditions of low oxygen. Such a complex response is mainly mediated through endogenous gene modulation at the HIF pathway. Under normoxic conditions, the main mediator HIF1a is rapidly degraded by the proteasome. However, under conditions of lower oxygen, HIF1a undergoes a stabilisation process and ultimately induces activation of genetic sequences, including those of the erythropoietin gene, that promote efficient adaptation to hypoxia."

Lippi helpfully provided a chart to show the effect of a cobalt chloride administration:
Generation of oxygen reactive species (ROS)= Stabilisation of hypoxia inducible factor 1α (HIF1α)= Erythropoietin (Epo) gene transcription= Epo increase in plasma= Enhanced erythropoiesis= Improvement of anaerobic athletic performances
Cobalt overload= Oxidative damage= Tissue damage and dysfunction

"Cobalt is a relatively rare transition metal with properties similar to those of iron, chromium, and nickel. Cobalt chloride, a water soluble compound traditionally used to treat anaemia in pregnant women, infants, and patients with chronic anaemia undergoing long term haemodialysis, is a well established chemical inducer of hypoxia-like responses, such as erythropoiesis and angiogenesis in vivo. The precise mechanism of this induction is not fully understood. However, the hypoxialike response probably involves increased DNA binding activity of HIF1a, as cobalt stabilizes HIF1a t(h)rough generation of reactive oxygen species by a non-enzymatic, nonmitochondrial mechanism. The final result of this induction is enhanced erythropoietin production and more efficient stimulation of the erythropoietic response, achievable at the moderate oral dose of 30 mg/kg."

102. Dr Wainscott in his reply report relied upon some of Dr Major's reports as follows:

103. Yong

"The hypoxia inducible factor (HIF) activates the expression of genes that contain a hypoxic response element. The A- subunits of the HIF transcription factors are … stabilised under hypoxic conditions… It has previously been established that cobalt mimics hypoxia and causes accumulation of HIF1A and HIF2A.

Hypoxia is a critical stimulus in many physiological and disease states. Cells respond to hypoxia by regulating the expression of a number of genes, including

erythropoietin… This regulation is mediated in part by transcription factors of the hypoxia-inducible factor (HIF) family. HIF1A and HIF2A basic… proteins.

It has been well documented that cobalt, a transition metal, mimics hypoxia by causing the stabilisation of HIFA. However the biochemical mechanism by which cobalt stabilises HIFA remains unknown."

104. Rani

"The biochemical sensor of the conditions of hypoxia is presence of stable factor called hypoxia inducible factor (HIF-1).

HIF-1, a transcription factor that senses the cellular oxygen deficiency…

Cobalt chloride (CoCl2) has been used… generate hypoxia like condition by stabilising HIF-1 by inhibition of HIF_1."

105. The appellant put in evidence the report by Saxena. It also provided helpful explanations relating to the issue.

106. Saxena

See paragraph 65 above, and:

"HIF1A is the regulatory subunit of HIF1 which is the master regulator of several hypoxia inducible genes including HO1.. The HIF1A expression increased after cobalt supplementation, training as well as in cobalt training group indicating an active involvement of the HIF system after cobalt supplementation. Also, an increase in the expression level of HIF induced during expression… confirms the activation of the oxygen sensing system in the skeletal muscle that leads to hypoxia adaptation.

107. Dr Major in his report concluded that that there is no evidence that even in very high levels of administration, cobalt has an HIF–1 stabilising effect in the horse.

108. To support that conclusion he analysed a number of research papers. He stated that hypoxia inducible factor is not peculiar to horses or mammals. He analysed various dosages and magnitude for cobalt and various levels in body tissue and fluids.

109. He criticised reliance upon Ho because the conclusions were founded upon unreasonable extrapolation. That arose because Ho relied upon Very that that report focused on cancer and vascular disease and did not deal with red blood cells. Therefore Dr Major says there is no support for the inference that cobalt induces haematopoiesis.

110. He continued that the research foundation for HIF comes from laboratory cell culture but that was based upon human malignant brain tumour cells cultured in a dish and the use of cobalt per litre in the testing by Al Okail was between 2946 and 11,786 mcg/L whereas the equine blood plasma threshold is 25.

111. Therefore he concluded that it cannot be inferred that cobalt will have a demonstrable HIF stabilising activity in the horse at concentrations derived by administration of non-toxic doses or at all.

112. He criticised the use of Rani which studied cobalt chloride in mice because an equivalent dose for a horse, as given to the mice, would be 20,000 mg whereas the recommended dose is 1 mg.

113. He criticised the use of Deschene because that was a study of a single cultured layer of equine fibroblasts from deceased horses in a glass dish and did not address stimulation of red blood cells or performance affectation.

114. He conceded that the research demonstrated HIF effects in laboratory tissue culture but not in the horse.

115. He analysed the doses given in various research reports by Dr Wainscott (1 mg), Ho (1 mg), Knych (49 mg), McKeever (50 mg), Burns (2000 mg), Saxena (5000 mg) and Rani (20,000 mg) as well as his own research (50 mg). He said the average intake for a horse was 2.6 mg per day.

116. He said that despite those doses there was no change in red blood cell parameters, erythropoietin, haematocrit, oxidative metabolism - importantly EPO. He did say in the Rani report there was a upregulation of HIF1A in the mice.

117. Dr Major was critical of many of the reports because of the adoption of: unsupported, unreferenced statements (Lippi); use of outdated reference works (Lippi); use of assertions levered off other papers (Ho); that reports have become dated (Davis); there was unreasonable extrapolation (Ho).

118. Dr Major was critical of the reliance upon research on other than horses (Dery, Al Okail, Rani, Deschene, Davis).

119. Dr Wainscott in his reply report did not agree. He says there is evidence for its existence in the horse and in mammals. He relied upon analysis of reports by Deschene and Brooks for horses and Al Okail, Rani and the World Anti Doping International Standards Prohibited List. He conceded that most of Lippi's thousands of reports were based upon extraction form others' research and not his own research.

120. Dr Wainscott placed particular emphasis upon Deschene as giving unequivocal evidence that cobalt acts as a HIF1 stabiliser because it was demonstrated in equine derived fibroblast cells.

121. In answer to the challenges on concentrations he noted Brooks used an equivalent of 908 mg of cobalt and this produced plasma levels of 33,000 ug/L. This was higher than used by Deschene and Al Okail in achieving HIF stabilisation and even after 5 days levels were still within the range of concentrations used by Al Okail.

122. Dr Wainscott also referred to the World Anti-doping Code International Standards Prohibited List which classifies cobalt as an HIF stabiliser. The Tribunal finds little weight should be given to this fact as reasons for the classification are not given.

123. After all the challenges to his theory Dr Wainscott in re examination maintained that cobalt is a performance enhancer because “it’s an HIF stabiliser”. He was not asked to reanalyse the arguments put against his theory. It was a mere simplistic repetition of his belief.

124. Interestingly the appellant put in evidence a cross examination of Professor Paine (“Paine”). He is the author of “Pharmocokinetics of inorganic cobalt and vitamin B12 supplement in the thoroughbred horse:differentiating cobalt abuse from supplementation” Equine Veterinary Journal 2017 1-7. The report is not in evidence.

125. Professor Paine was cross examined before RAD Vic in Xuereb, 9 April 2018. Having described what an HIFA stabiliser is he gave the following evidence in re-examination:

> “Q. So is cobalt an HIF1A stabiliser?
>
> A. it has been shown in in vitro experiments with laboratory test tubes that it is a hypoxia inducible factor stabiliser.
>
> Q. Thus, as a consequence of that, does it have the potential to increase EPO in horses?
>
> A. It has the potential to increase EPO within any mammal, including horses.
>
> Q. And thus effect a haemopoietic effect on the horse?
>
> A. Potentially it can exert the effect you've just described, so an increase in EPO, ultimately an increase in red blood cell production by the interaction with bone marrow to do that, yes.”

126. Dr Wainscott agreed that a horse’s immediate response to an hypoxic event is to release red blood cells from the spleen. That is cobalt does not trigger the additional red blood cells, that is the EPO is not triggered. And that is because the horse’s spleen releases red blood cells.

127. Dr Wainscott also agreed that no research has been undertaken to look at an HIF stabilising effect because EPO was the thing looked at.

128. Dr Wainscott also agreed that an administration of cobalt to a horse will not produce red blood cells and EPO other than by use of the spleen.

129. Dr Major agreed that cobalt stabilises the hypoxia inducible factor and that there are many chemicals that have that affect. This was a general statement and not restricted to the horse.

130. The appellant submitted that the evidence is that cobalt has the theoretical possibility of being an HIF1 stabiliser, in sufficient but unknown quantities, and the Drs Wainscott and Major agreed on that. It was submitted that it was not in fact such a stabiliser.

Potential for Cobalt to Affect Performance

131. There are three issues: potential, affect performance and positive or negative affectation.

132. The appellant says there is no potential to positively affect performance.

133. The respondent says all three of these are established that is, the potentiality, affectation on performance and both positively and negatively.

134. The appellant submits that there is no evidence to support a finding of negative affectation.

135. Affect performance should be analysed first.

136. Towards the end of Dr Wainscott's evidence and in response to questions from the Tribunal, Mr Sheales, for the appellant, summarised relevant operations of a horse's system and Dr Wainscot agreed with that summary. To paraphrase it, it was as follows.

137. The theory of cobalt is that you fool the kidney into believing that you need more oxygen circulating and the kidney then artificially stimulates what would normally occur because of the presence of cobalt. The kidney stimulates the production of EPO which then stimulates the production of new red blood cells. An example was given on the assumption that the horse has 100 red blood cells (this is not the fact and the figures are for demonstration purposes only) of which 70 are circulating generally around the body and 30 in the splenetic reserve. When the horse gallops the horse will expel the 30 into the general bloodstream and you will have 100 circulating. After that event the horse will take back the 30 the red blood cells and leave 70 circulating. With the addition of cobalt you produce 30 more cells through the bone marrow and they circulate and so a total of 130 is circulating. Therefore when the horse receives cobalt it does have an hypoxic stimulation. It was then demonstrated from the Burns' report the horse uses the red blood cells it already has in the spleen and doesn't make any new ones, that is the red blood cells are just sitting there and may come out to resolve an hypoxic event and the body brings itself back into balance, that is the red blood cells are just taken back into the spleen. This differentiates other mammals from horses where the other mammals do not have a splenetic reserve. Because of the use of the splenetic reserve red blood cells, the hypoxic event is resolved and there is no trigger of stimulation of EPO. That is there is no hypoxia event, it is a mimetic effect. That is the body is fooled. Therefore if there is no EPO stimulation you do not have the production of new red blood cells.

138. The parties are in agreement with a number of conclusions: There is no stimulation of EPO after a single dose of cobalt; The adverse effect of the cobalt administration is for one hour only; That adverse affectation would require dosages of 4, 2 or 1 mg per kilo intravenously and very close to the race-that would produce stratospheric readings probably in the thousands; A recommended administration of Vam would not produce readings above 200.

139. Dr Wainscott agreed that the administration of cobalt to a racehorse does not stimulate the production of EPO and therefore there is no affect on the horse by way of enhancement of performance.

140. This concession removes the need to consider, on positive affectation, the effect of chronic administration of cobalt, large dose verse small dose administration and any time related issues after administration.

141. The Tribunal notes the reports that confirm that agreement, namely, Paine, Burns, Knych. The unpublished report of McKeever is noted but not relied upon. The report of Le Compte, not in evidence, titled “Influence of dietary cobalt on nutrient digestibility and serum cobalt concentrations in horses” Journal of Equine Veterinary Science 2017 52 at p84 was relied upon by Dr Major.

142. Dr Wainscott’s evidence is that he has never contended to the contrary but only advanced the possibility, that is the potential.

143. There is a considerable body of evidence before the Tribunal on the positive affectation issue. It does not need to be analysed, as it was in such detail in these proceedings, any further. There is agreement that this administration of Vam, which produced the prohibited substance cobalt, could not have affected the performance of the horse by way of enhancement of performance. However what is being assessed is not Vam but cobalt.

144. The actual positive affectation case falls away, subject to the potential positive affectation issue.

145. The evidence to support the potential for positive affectation is that of Dr Wainscott relying upon the reports of Saxena, Endoh, Brooks and Paine.

146. Saxena analysed endurance performance in rats. He found hypoxia preconditioning by cobalt chloride enhances endurance performance and protects skeletal muscles from exercise-induced oxidative damage. Dr Wainscott opined that if it happens in rats it should happen in other mammals.

147. Endoh also analysed rats and found improved cardiac contractile functions in hypoxia re-oxygenation in rats treated with cobalt. Dr Wainscott opined that if it happens in rats it should happen in horses.

148. Brooks found inorganic cobalt salts have been recognised as having the potential to increase aerobic capacity… triggered by modulation of the hypoxia inducible factor pathway.

149. Paine on potentiality is set out in paragraph 125 above. That re-examination has to be in the context of the concessions he made in cross examination. Relevantly that that EPO increase would take hours, days a week or so because it is effected through the bone marrow. Later he said the resultant increase in red blood cells would be over a significant period of time. He also said a high dose would be necessary. That is a low dose of 1 to 5 mgs will not give an increase in red blood cell production. A single dose of 15mgs will not give an increase in red blood cell count- confirming Knych. Also he stated that

there is no evidence that cobalt chloride increases red blood cell by the production of EPO.

150. It is apparent that reconciling the evidence of Dr Paine in cross examination as against re- examination is not without its difficulties.

151. Of further interest he agreed with Knych that extrapolation from species to species, especially from human to horse, should be treated with extreme caution.

152. Dr Wainscott analysed statistics for cobalt detection in harness racing horses and opined that the practice of cobalt doping had dropped markedly after the threshold was introduced and therefore there must have been some belief of performance benefit associated with its use. This has merit but does not provide evidence to confirm the theory.

153. The Tribunal understands the difficulties of carrying out scientific research on horses with potentially harmful or toxic substances because of ethical and practical constraints. However it is troubled by reliance placed upon research in mammals other than horses. The guidelines require performance enhancement of a horse. There are many difference between species of mammals for example the presence of a splenetic reserve in horses. The research reports on rats and other mammals is such that it is difficult to accept that it necessarily is applicable to horses.

154. As the Tribunal understands the case for the respondent it is that positive affectation is a potential purely through the process involving HIF stabilisation.

155. The next determination is on negative affectation.

156. Dr Major did not assess that in his report. The appellant adduced no evidence on the issue.

157. The respondent relies upon the report of Burns and quotes the following in submissions:

> “While little evidence of enhanced hematopoiesis was observed in this study, in endocrine and cardiovascular effects that would be associated with risk of harm and adverse effects to the horse and indirectly to human riders and handlers were observed. All mares had increased serum concentrations of cortisol and ACTH shortly after drug administration, suggesting that treatment was associated with robust activation of the hypothalamic-pituary-adrenal axis and represents a potent psychologic stressor. The mild increase in L-lactate concentrations observed shortly after cobalt administration could have been a response to severe hypertension, tissue hypoxia, or a combination of the two. The increases in cTnl noted within 4-6 hours of drug infusion were in excess of those noted in horses undergoing strenuous physical exercise.. and might be associated with risk of adverse cardiac events. The arrhythmias that were observed…. would also appear to support the presence of this risk."

158. The Tribunal notes that a number of reports comment upon negative affectation.

159. In reporting upon human affectation Lippi stated:

"In addition, it has been reported that liver, kidney, heart (sic) accumulate cobalt to a greater extent, causing hepatotoxicity, nephrotoxicity, organ damage and dysfunction even at a dose of 33.3 mg/kg (quoting Ayala-Fierro).

Owing to the severe and often unpredictable side-effects, cobalt chloride administration may turn out to be a serious concern for the sporting community and athletes' health.'

160. Ho stated for horses:

"Cobalt is acutely toxic in larger doses… There is evidence suggesting that cobalt salt may cause severe gastrointestinal, endocrine, cardiovascular, haematological, reproductive, neurological and immunological responses."

161. Endoh stated for rats:

"in hypoxia and re-oxygenation, CO2 pretreated hearts exhibited a significantly higher rate pressure product.. and coronary flow… and lower end diastolic pressure.. compared with the control hearts.

162. Knych stated for humans:

"..chronic administration of cobalt, presumably due to deposition of cobalt in tissues and organs, has been associated with a number of toxic effects, which has limited its use as a therapeutic agent. Adverse effects including gastrointestinal sickness, thyroidal dysfunction, and myocardial toxicity have been reported and as a result much safer agents have replaced the use of cobalt.'

163. Al Okail stated for humans;

"however, excess exposure of cobalt can lead to tissue and cellular toxicity.'

164. Burns stated for horses;

"chronic cobalt exposure has been associated with neurotoxicosis, cardiotoxicosis, and endocrine abnormalities in humans primarily in association with occupational exposure and cobalt containing orthopaedic implants.

All mares were anxious after receiving the infusion, showing nostril flaring, muscular tremors and fasciculation, pawing, and straining to urinate by five minutes after the CoCl2 infusion; this persisted for 60 minutes in mares receiving higher doses… Mild-to-moderate signs or abdominal pain in the 15 to 20 minutes after drug infusion evidenced by treading, kicking at abdomen, posturing repeatedly to urinate.

Mares receiving the higher CoCl2 doses..developed tachycardia within one minute. Cardiac dysrhythmias …occurred in the first 10 minutes.. Profound hypertension was observed… Cardiac output increased after administration of all doses but more than doubled in mares receiving the highest doses, returning to baseline values between 45 and 60 minutes.. Developed prominent oral mucous membrane

congestion that persisted for 20 minutes. At all doses, cardiovascular variables returned to baseline by 1 to 2 hours after administration.

Urine from horses receiving the highest doses became discoloured (red to red-brown), tested positive for blood on a urine dipstick, and contained visible tissue debris as early as 15 minutes after infusion; these gross changes persisted for up to 240 minutes.

..endocrine and cardiovascular effects that would be associated with risk of harm and adverse effects to the horse and indirectly to human riders and handlers were observed.

..intravenous administration of CoCl2 to adult horses is associated with hemodynamic instability and distress… could result in important consequences for animals provided multiple doses long-term. These manifestations argue that the effects of CoCl2 are harmful and likely associated with multiple body systems.

..an animal welfare issue and threatens the well-being of racing animals; administration of CoCl2 at these doses is harmful to horses… Cobalt salts should not be administered to horses intravenously at these doses."

165. Dr Wainscott in cross-examination said that the administration of cobalt within the preceding seven days of racing has a potential to be detrimental. That evidence was based upon Burn's references to detrimental affectation. He acknowledged that those detrimental affectations all resolved within an hour. However on large intravenous doses he noted there had been no research, likewise with chronic oral administration.

166. The respondent relies upon the fact that it is not necessary to prove that the substance in fact had a negative affect only its potential.

167. A discussion on time and dosage is necessary.

168. The appellant has sought to approach this matter on the basis that race day testing is of no benefit. That is said to arise because the administration of Vam at the recommended dose rates has no performance enhancing benefit. It was submitted that the cobalt reading of 180 did not to provide any proof of performance affectation.

169. This is said to be the case because of the elimination time of cobalt from the horse. The Tribunal earlier set out the finding that to affect performance a very large dose would have to be given immediately before the presentation to race.

170. Some of the reports referred to the elimination times.

171. Extracts from Burns were set out earlier to the effect that nostril flaring, muscular tremors et cetera persisted for 60 minutes. The increase in cardiac output returned to baseline values between 45 and 60 minutes. The prominent oral mucous membrane congestion persisted for 20 minutes. Cardiovascular variables returned to baseline by 1 to 2 hours. Transient increase in hematocrit and red cell count returned to baseline levels within 1 hour. The discolouration of urine etc persisted for up to 240 minutes. Burns also reported as follows:

"the geometric mean (range) of plasma half-life of cobalt for all horses in this study was 12 days."

172. Ho

"The high RBC counts would return to normal 9 to 15 days after cobalt administration.

Peak urinary and plasma total cobalt levels for these three products were all observed within two hours of the last administration (noted by the Tribunal to include Vam)…Vam showed the longest detection time in urine of about 12 hours.

The initial elimination of half -life for plasma total cobalt was observed to be about 2-6.4 hours and the terminal elimination half- life was found to be about 42-68 hours. Similar to plasma, urinary total cobalt levels decreased rapidly and dropped below the proposed threshold of 75 in G/ML within 12 hours of last administration."

table 4 shows for administration with cobalt containing supplement, Vam, a peak total cobalt level of 374-424 and a maximum detection time of 11.6 hours.

"Cobalt containing supplements, especially injectables, could cause urinary and plasma total cobalt levels to exceed the respective threshold within the first 24 hours.'

173. Deschene further agreed, as set out above;

"after administration of CoCl2… HIF1A concentrations declined to finally reach control levels by 24 hours."

174. Brooks

"The peak concentration (290..) occurred in the 4-8 hours post administration sample. There was a rapid phase elimination in the first 14 hours following the administration where the concentration of cobalt fell to levels around 40… Cobalt was detected out to the last sample collected (120 hours).

175. Knych

table 2 shows the whole blood concentration was at 106 at 12 hours dropping to 46 at 48 hours.

176. Lippi

"in fact, after a single oral dose, the blood cobalt concentration -time curve appears triphasic. It peaks at 3.2 hours and displays an absorptive half life of 0.9 hours, and elimination phase half life of 3.9 hours, and a terminal elimination half life of 22.9 hours. Therefore, the plasma kinetics of cobalt chloride mean that, at present, reliable in- competition anti-doping testing is not possible."

177. In opening submissions the appellant stated that Burns demonstrated that regardless of dosage, the reaction in the horse's body stabilised within an hour. Therefore it was submitted that it is not possible to affect performance, good or bad, that even if cobalt retards the degradation of HIF factors it does not progress beyond that because they stabilise.

178. In cross-examination Dr Wainscott agreed that administrations of cobalt will be out of the system within two days unless very large doses are given. He further agreed that it would be extremely unlikely that there was any prospect of giving a horse enough cobalt that it would still be detectable 22 days later in a race day sample. He said it would be up to 120 hours.

179. Dr Wainscott further agreed that the report of Scollay (not in evidence) 2015 head of equine medicine for the Kentucky Horse Racing Association, who conducted administration trials of cobalt upon three horses with a dose of 3 mg per kilo, demonstrated that the horses were "fine" after an hour. This was after the administration over days of over 7500 doses of Vam. Scollay also reported there was no EPO stimulation. Dr Wainscott was not aware that Scollay had reported "we can rule out cobalt as a performance-enhancer as a result of my testing."

180. Dr Wainscott also agreed in cross examination there would be a risk of exceeding the cobalt threshold for only about 12 hours after an administration of Vam.

181. Dr Wainscott when further questioned on Burns agreed that the only variation in red blood cell count was between 1 and 2 hours after large administrations.

"The Highest"

182. Class 1 requires the highest potential and class 2 a high potential.

183. It is apparent from the evidence that these words are meaningless and add nothing to the test. Their purpose may have been to differentiate between levels of seriousness and accordingly different penalties.

DETERMINATION

184. The evidence set out above demonstrates the complexity of the issues requiring determination. The experts and the parties have, fortunately, reached some common ground but remain at arms length in respect of a number of critical issues.

185. Having regard to the agreements reached the following are the determinations required: is cobalt an HIF stabiliser; does cobalt have the potential (and only the potential) to positively affect performance in the racing horse; does cobalt have the potential to negatively affect performance in the racing horse.

HIF Stabiliser

186. Until recently this was an accepted fact amongst researchers, veterinarians , experts and regulators. It is apparent that the science about the effects of cobalt has changed. It is also apparent that further research is required in relation to its effect upon the horse.

187. These findings are apparent because the recent demonstrations by researchers have shown that building blocks for the theory it is an HIF stabiliser have been shaken.

188. Dr Wainscott's position essentially has not changed. Despite having recent research put to him he remains of the opinion that cobalt is an HIF stabiliser. For horses he relied upon the findings of Deschene. For mammals he relied upon findings from research on humans and mice. His reasoning is as set out above.

189. Dr Major's criticisms of older research papers and use of research in mammals other than horses is set out above. He was particularly critical of extrapolating research on mammals other than horses and the Tribunal notes the caution in using that research is accepted by others, for example, Professor Paine and Knych.

190. Dr Major says that reliance should not be placed upon Deschene as establishing affectation in the racing horse because that research dealt with cells of deceased horses in a glass dish.

191. The Tribunal is not satisfied on the evidence it has that Deschene's research findings can be extrapolated to a living racehorse. That is concluded because there is no analysis of the lack of a splenetic effect in a cell. That removes a substantial foundation of Dr Wainscott's theory.

192. It is noted Professor Paine was of the opinion that cobalt is an HIF1A stabiliser. Whether he only relied upon "in vitro experiments with the laboratory test tubes" is not known. If he did that would seem to be reliance upon Deschene and that foundation is not accepted. If he did not his theory is unexplained. He expressed the opinion that cobalt had the potential to increase EPO in a horse and also effect an haemopoitec effect. It is noted that a haemopoitic effect is not relied upon by the respondent.

193. The recent research removes any level of comfort in extrapolating research findings from mammals other than the horse. That is because of the operation of the splenetic reserve in the spleen in the horse and that splenetic effect does not exist in other mammals- certainly those the subject of the reports in evidence. The basis for extrapolating such an approach is not established by the respondent.

194. The difficulty in making a determination on this issue is the accepted fact that the administration of cobalt to a racehorse does not stimulate the production of EPO.

195. There is no research on whether that fact has any impact upon HIF stabilisation. The expert witnesses in this case were not asked the question. The processes relating to the production of red blood cells in a horse, when it's splenetic reserve of red blood cells is activated, remains for the Tribunal an unanswered question on whether that process eliminates the need for the use of an HIF stabiliser.

196. It is noted that Saxena reported that "the precise mechanism of HIF stabilisation by cobalt is not fully understood."

197. It is open to conclude that the use of the HIF stabiliser, as the master controller, is not needed to produce red blood cells as the EPO process is not activated because the spleen has done it's job.

198. The Tribunal considers that the burden is upon the respondent to establish to a reasonable level of satisfaction that the HIF stabiliser is activated by, or operative because of, the administration of cobalt.

199. It seems to the Tribunal that the recent research of Burns has thrown up a need for scientists and experts to revisit the issue of the role of the HIF stabiliser as a result of the administration of cobalt.

200. There is no doubt that previously the fact that cobalt is an HIF stabiliser was clearly demonstrated in mammals, other than the horse, and accepted to be of such an effect in the horse. The foundation for those conclusions in the horse seem to have been removed.

201. It may well be that regardless of the fact that the horse's use of the splenetic reserve will produce an EPO effect and therefore more run red blood cells from the bone marrow after actions in the kidney, it will only be able to take place because of, or in conjunction with, the operation of the HIF pathway. Or that the HIF pathway will still operate independently of those events.

202. The theoretical possibility that it is, and remains so, is not demonstrated to a level of reasonable satisfaction on the evidence in this case.

203. The potential that it might so operate is not established on the evidence.

204. The respondent fails to establish that cobalt is an hypoxia inducible factor (HIF)-1 stabiliser within the meaning of HR190A(2)(l).

Potential to Positively Affect Performance

205. As already found it is an agreed fact that cobalt does not positively affect performance in a racing horse. The case for the respondent is based upon potential only.

206. It is important to again recognise that for many years the rules have been interpreted, and written, on the basis that the regulator does not have to prove how the drug came to be present, when it was administered or the amount of drug administered. This has been the case because no test can positively answer those questions. There are too many variables. The testing can only show what was present at the time the sample was taken. As expressed earlier the focus is upon the prohibited drug cobalt not the administered substance Vam.

207. Many of the foundations of the respondent's case fall away because they are based upon research in mammals other than horses. The Tribunal has found that that research should not be extrapolated to the horse on the HIF stabilising test. Essentially nothing further is advanced on the potential affectation test.

208. The Brooks research on horses on this point dealt with inorganic cobalt salts and their impact upon the HIF pathway. For the reasons earlier expressed on the use of the HIF pathway in a horse the respondent does not satisfy the reasonable comfort test that potentiality can be found on that evidence.

209. The Paine evidence that there is potential was based upon the HIF factor established through the in vitro test summarised earlier. These rationale have been rejected.

210. The agreed fact is that any positive affectation from cobalt in small doses is non-existent and in large doses dissipates before it would have any impact on race day.

211. The evidence establishes however that very large doses very close to a race would produce stratospheric readings. But the evidence does not provide anything that will establish that such activity in such a reading necessarily has any positive affectation on performance or any potential to do so.

212. The respondent fails to establish to a reasonable level of satisfaction that cobalt has a potential to positively affect the performance of the horse.

Potential to Negatively Affect Performance

213. The numerous negative effects of cobalt have also been summarised earlier.

214. To recapitulate it is acutely toxic in larger doses. It accumulates in various parts of the body. It can have severe and often unpredictable side effects. It can lead to muscle flaring, muscular tremors and fasciculation, pawing and straining to urinate, abdominal pain, treading, kicking at the abdomen, tachycardia, cardiac dysrhythmia, profound hypertension increase, cardiac output, prominent oral mucous membrane congestion, discolouration of urine etc.

215. These various adverse side-effects do not persist for any lengthy period of time, perhaps the worst of them for up to 240 minutes but mostly disappear within 1 or 2 hours of administration.

216. Dr Wainscott said that potential detrimental affectation from cobalt would be up to 7 days but the actual affectation diminished within hours. It is noted he said that for large intravenous doses and chronic oral administration, no research had been conducted on detrimental affectation on performance.

217. There is no evidence that after the various adverse side effects have ceased that a horse would have any residual or remaining detrimental affectation because of those side-effects. The Tribunal can only express surprise that after any of the above side effects that there would not be detrimental affectation. However there is no evidence of this.

218. It is to be noted that detrimental affectation is to performance not just to the horse. There is no evidence that those side-effects lead to affectation of a horse presented to race. If it was presented to race within the time frames by which a side-effect had not disappeared there would be presentation with a negative affectation. Again there is no evidence that any of the listed side effects, or any combination of them, would necessarily be negative on performance. The Tribunal is asked to assume and declines to do so.

219. The fact that a horse may have used its splenetic reserve prior to performing is not a factual matter advanced by the respondent as equating to negative affectation or its potential.

220. There is however evidence that larger doses are acutely toxic. As the regulator does not have to prove what dose was administered, or when, there remains the possibility that a horse which has received large doses has toxic side-effects.

221. Common sense dictates, in the absence of evidence, that a horse suffering from toxic side-effects potentially will not be able to run on its merits and may be suffering from substantial welfare issues. The various reports on accumulation provide support for this conclusion. Again however there is no research or support other than un tested theories.

222. That is, potential for adverse affectation is untested and theoretical only. The fact there may be a welfare concern needs to be established by evidence, not conjecture.

223. The Tribunal cannot be comfortably satisfied that cobalt has the potential to negatively affect performance in the racing horse.

Highest

224. For completeness the Tribunal is satisfied that cobalt under class 1 has a higher potential to affect performance, negatively, than those drugs that fall in class 2. It is not necessary to come to a conclusion on positive affectation differences between higher and high in class 1 compared to class 2.

Other Class 1 issues

225. The appellant advance arguments that the other substances listed in paragraph 3 of Class 1 should be considered on the basis they are endogenous and the majority are enhancers.

226. This issue does not have to be analysed further as the regulator has specifically put cobalt in the list and it does not matter why.

Summary of the Findings on Class 1

227. The Tribunal finds that cobalt above the threshold falls within class 1 because it is listed as such.

228. The Tribunal does not find, to the level of comfortable satisfaction, that cobalt above the threshold has the potential to positively or negatively affect performance but does find that it has no generally accepted medical use in the racing horse.

PENALTY DETERMINATION

Objective Seriousness

229. Issues of integrity, message to industry and trainer, level playing field, privilege of a licence, husbandry practices and welfare of the horse have been repeatedly set out in past determinations by this Tribunal, the equivalent entities in the states and territories and applied by the stewards throughout the country under the uniform rules. This decision does not require repetition.

230. The most important factor in assessing a starting point on an objective seriousness test is, of course, to focus upon the actual conduct of the appellant and the facts and circumstances surrounding that conduct. The message to be given to the industry on these facts is a substantial one.

Breach 1

231. Here the appellant, contrary to the rules, administered a legal substance on race day. In assessing the seriousness of the fact of administration the race day conduct must be viewed most seriously as against other trainers who have presented a horse with a positive on race day but whose conduct did not take place on race day.

232. The substance administered was a regularly used and prescribed medication which, when administered in accordance with prescription, is beneficial to the horse. The appellant administered the substance in accordance with the manufacturer's recommendations and in accordance with a proper method of administration-intravenous injection.

233. The appellant did not administer a prohibited substance per se. For example, she did not administer a drench which was loaded with cobalt and which was popular amongst some trainers in this code and the thoroughbred code some time ago. She did not administer cobalt (acknowledging that Vam contains cobalt). She did not directly administer cobalt by some other means.

234. The submissions for the respondent picked up the concerns of the stewards at their inquiry on the precise time that the appellant administered. It was either prior to departing for the races or at the races. As expressed during submissions the evidence does not enable a finding to be made on this point. If established this issue may have effected the subjectives reductions.

235. The evidence establishes that at a reading of 180 there was no performance enhancing benefit for the horse at the subject race and no evidence of any performance negative affectation. The horse apparently ran on its merits. The level playing field was not breached. There was no direct welfare issue.

236. There is a telling failure of husbandry. The appellant did not know Vam contained cobalt. It would have been apparent from a sensible reading of the label. The respondent advanced the fact the appellant was involved in the sale of the product but did not expand that issue to demonstrate more serious failures by reason of it. The focus is upon the fact a trainer did not know precisely that which was being administered and likely consequences of administration. That is a telling failure of a husbandry type and must make the objective conduct more serious.

237. The subjective findings have addressed the discount for the self reporting. This is of course also relevant on objective seriousness. Recent decisions have adopted three categories for assessing prohibited substance matters, that is, proof of administration, no explanation of the administration and proof it occurred without fault because of some external means. On those principles this would be a category one and liable to a higher penalty than the other two. However this Tribunal has reflected in previous decisions on the necessity to distinguish those who admit administration against those who are found out as having done so by other means.

238. On that three category assessment, while the matter would fall within category one, and attract a substantial penalty, that must be diminished by the fact it was self reporting that brought the actual administration to notice. Of course the fact that it is an administration matter under breach 1 is the gravamen of the breach but that gravamen must be assessed on the basis that it was associated with administration on race day.

239. Issues of integrity of the industry are enlivened because a positive presentation for cobalt has a negative impact upon the image of the industry. Race day conduct is always more serious.

240. By her actions the appellant has demonstrated a lack of appreciation of the privilege of a licence.

241. In assessing a starting point for a breach of class I the guidelines provide for 5 years.

242. The Tribunal has previously expressed a finding that the guidelines do not mean that every case must have a starting point expressed in that guideline. The facts and circumstances of the individual case must be considered.

243. The objective seriousness of the appellant's conduct does not justify a starting point of 5 years.

244. This is a class 1 breach and accordingly the starting point for class 3 of 1 year does not provide an appropriate starting point for this conduct. Likewise if a starting point of 2 years is considered appropriate for class 2 then there must be some room given for a differentiation between class 1 and class 2.

245. Because of the change in the assessment of cobalt and its affectation upon a horse previous determinations of starting point by considering parity cases have less importance.

246. The cases referred to here are: Kelly, RATNSW 16 October 2014-disqualification 2 years 10 months; Tyndall, RATNSW 18 February 2015-disqualification 3 years; Chapple, RATNSW 18 March 2015 -disqualification 2 years 6 months. Each of these cases started at 5 years but the penalty was reduced for subjectives.

247. Regardless of those difficulties under the guidelines the objective seriousness here, considering all of the above factors, warrants a starting point of 4 years.

Breach 2

248. This was treated by the stewards as an alternative to breach 1. No submissions were made that a different approach should be adopted.

249. While the Tribunal is of the opinion that this is not an alternative matter it will, on the facts of this case, treat it as such.

250. Therefore no penalty will be imposed in respect of the admission breach 2.

Breach 3

251. The conduct here is the same as that which is embraced by breach 1. The difference being that breach 1 contains the wrong conduct of administration on race day but to be caught on race day there must be a presentation on race day. Breach 3 embraces the actual presentation on race day.

252. In assessing objective seriousness this is less serious than the administration conduct captured by breach 1. It is a class 1 under the guidelines and has a starting point of 5 years.

253. It is determined that there be a starting point of 2 years.

Cumulative/Concurrent

254. The rules provide that penalty should be cumulative unless another order is made.

255. The conduct captured by breaches 1 and 3 has a high degree of commonality. It all occurred on the same day, involved one horse only and there is a link between an administration on race day and a presentation on race day.

256. The stewards determined that the two penalties be served concurrently. It has not been suggested that the Tribunal deal with the matter in any other way.

257. The Tribunal determines that the penalties for breaches 1 and 3 be served concurrently.

Subjectives

258. As set out in paragraph 28 a discount of 25% is allowed for admissions.

259. As set out in paragraphs 29 and 30 there is a further discount for good past record, association with the industry for 30 years and for assistance to the industry. A further discount of 20% is allowed for those matters.

260. The subjective matters apply to each of the breaches. A lesser message is required to be given to this trainer as there is strong comfort that the conduct will not be repeated.

261. From the starting point penalties there will be a discount for subjective matters of 45%. For ease of calculation the discounts are rounded in months.

Penalty

Breach 1

262. From a starting point of a disqualification of 4 years there will be a discount for subjective factors of 22 months.

263. A period of disqualification of 2 years and 2 months is imposed.

264. That period of disqualification will commence on 20 April 2017 being the date on which the appellant was suspended under rule 183.

Breach 3

265. From a starting point of a disqualification of 2 years there will be a discount for subjective factors of 11 months.

266. A period of disqualification of 1 year 1 month is imposed.

267. That period of disqualification of 1 year 1 month is to be served concurrently with the period of disqualification of 2 years 2 months imposed for breach 1.

268. That period of disqualification will commence on 20 April 2017 being the date on which the appellant was disqualified for breach 1.

EFFECT OF ORDERS

269. The appellant is disqualified for a period 2 years and 2 months to commence on 20 April 2017.

270. The stay order of 20 June 2018 ceases to have effect. If any period of that stay has been enjoyed then the calculation of the termination date of that disqualification will need to take any such period in to account.

271. The effect of those findings is that grounds of appeal 2, in part,(insufficient discounts) and 4 (penalty too severe) are established.

271. The severity appeal is upheld.

APPEAL DEPOSIT

272. The parties were not asked to make submissions on the appeal deposit. The Tribunal's function at the determination of the appeal is to order it refunded, forfeited or repaid in part.

273. In view of the fact that the severity appeal has been successful it is open to the Tribunal to order the appeal deposit refunded.

274. However as submissions have not been received on that order , or any other appropriate order, no such order will be made for a period of 7 days from the date of this decision to enable the respondent to make an application for forfeiture of the whole or part of that deposit. If no such written application is made within that period of 7 days then, without further order, the appeal deposit will be refunded. If such an application is made the appellant will be asked to respond.