

ARTRYA™

Coronary Artery Disease. We see you.

2 November 2023

Australian Securities Exchange
Level 40, Central Park
152-158 St George's Terrace
PERTH WA 6000

Attention: Ms Laura Gomme (by email – ListingsCompliancePerth@asx.com.au)

Dear Ms Gomme

We refer to your letter to Artrya Limited (Artrya or the Company) dated 30 October 2023. We respond to each of your questions as follows:

1. Does AYA consider the Information to be information that a reasonable person would expect to have a material effect on the price or value of its securities?

The Company does not consider the Information to be information that a reasonable person would expect to have material effect on the price or value of its securities other than the fact that it had re-engaged in a process with the FDA following its previous unsuccessful application.

Please see the explanation for this view in the response to question 2 below.

2. If the answer to question 1 is “no”, please advise the basis for that view.

The announcement on 3 May 2023 confirmed that a Q-Submission (Q-Sub) had been lodged with the FDA, and that this step and the Q-Sub meeting with the FDA were enabling steps and an important part of the FDA process respectively, but in the view of the Company they are only that, steps in a process for a decision by the FDA.

The final 510(k) application, which is a further step in the process, was expected to be submitted to the FDA by the end of October 2023. This is clearly stated in the announcement that this was an expected date only.

Accordingly, the Company was keeping the market informed of the steps in the process by way of updates, but importantly these steps are not the final decision in the FDA process. The Company considers that the event which a reasonable person would expect to have a material effect on the price or value of its securities is the “failure to receive” or “approval of” FDA 510(k) clearance for commercial use of the Salix product.

By way of example, this was evidenced in the Company's announcement on 16 June 2022 when Artrya informed the market that it had been unsuccessful in achieving FDA 510(k) approval for its initial application. In the period 16 to 17 June 2022 the market price of AYA's securities fell 36% from a closing price on 15 June 2022 of 71.5 cents to a closing price of 46 cents on 17 June 2022.

Artrya Limited
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3. When did AYA first become aware of the Information? Please comment specifically on when AYA became aware that its 510(k) application would not be submitted by the end of October 2023.

In an announcement to the market on 9 June 2023 the Company advised the outcome of a successful Q-Sub meeting with FDA thereby providing a clear direction for the final FDA 510(k) submission process. During the Q-Sub meeting AYA and the FDA agreed on a pathway to a 510(k) regulatory clearance for the Salix product.

At a Board meeting held on 17 October 2023 the Board was advised that the Company would not be in position to lodge a final FDA 510(k) submission around the end of October as all Q-Sub targets as guided by the FDA Q-Sub meeting would not be fully achieved. To lodge a final FDA 510(k) submission without all FDA feedback being fully addressed would place at risk the quality of the submission and future timing of an FDA approval.

It was decided by the Board at that meeting to not lodge the final FDA 510(k) submission based on the expected end of October 2023 timeframe but to defer the lodging of the final FDA 510(k) submission to allow a more complete quality submission addressing all feedback from the FDA from the Q-Sub meeting.

The Company prepared the necessary disclosure promptly without delay and released the information to the market in its Quarterly Report lodged before market open on 19 October 2023.

4. If AYA first became aware of the Information before the relevant date, did AYA make any announcement prior to the relevant date which disclosed the information? If so, please provide details. If not, please explain why the Information was not released to the market at an earlier time, commenting specifically on when you believe AYA was obliged to release the Information under Listing Rules 3.1 and 3.1A and what steps AYA took to ensure that the Information was released promptly and without delay.

Refer to response in question 3.

5. Please confirm that AYA is complying with the Listing Rules and, in particular, Listing Rule 3.1.

We confirm that the Company is and remains in compliance with the Listing Rules and in particular Listing Rule 3.1.

6. Please confirm that AYA's responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of AYA with delegated authority from the board to respond to ASX on disclosure matters.

The Company's responses to the questions above have been authorised and approved by the Chairman and the Chief Executive Officer of the Company who both have delegated authority from the Board to respond to ASX disclosure matters.

Yours faithfully

Kevin Hart
Company Secretary



30 October 2023

Reference: 83297

Mr Kevin Hart
1257 Hay Street
West Perth WA 6005

By email: kevinh@endeavourcorp.com.au

Dear Mr Hart

Artrya Limited ('AYA'): General – Aware Query

ASX refers to the following:

- A. AYA's announcement titled 'Artrya lodges key submission in FDA process' released on the ASX Market Announcements Platform ('MAP') on 3 May 2023 as 'price sensitive' which disclosed, among other things:

'As foreshadowed in the recent quarterly update, the company can confirm that a Q-Submission (Q-Sub) has now been lodged with the FDA, a key enabling step in the US regulatory process. Artrya expects a Q-Sub meeting with the FDA within 9 to 12 weeks.

The Q-Sub meeting is an important part of the FDA process at which Artrya will present its approach to software development and clinical reader study design to get FDA agreement on how the product is being developed.

...

It is expected that the final 510(k) application will be submitted to the FDA by the end of October 2023. This remains in line with previous advice to the market'

- B. AYA's announcement titled 'Quarterly Activity Report and Appendix 4C' released on MAP on 19 October 2023, which disclosed, among other things:

'During the quarter we focused on three core areas advancing our path to commercialisation. The first is our FDA 510(K) submission where we have made important progress on the roadmap set out during our successful Q-Sub meeting with the FDA in June, which gave us detailed feedback and clarify on how to reduce the time between lodging the submission and obtaining approval.

We have methodically worked through the priority checklist set out in the roadmap and are on track to deliver a quality application in coming months. The additional time taken in this phase means our submission will not be made at the end of October, as previously estimated. The deferral of the submission ensures it will be of the highest standard and compliant with all FDA requirements, important to secure a timely approval process, which we anticipate to be late June 2024.'

(the 'Information')

- C. Listing Rule 3.1, which requires a listed entity to immediately give ASX any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity's securities.
- D. The definition of "aware" in Chapter 19 of the Listing Rules, which states that:

"an entity becomes aware of information if, and as soon as, an officer of the entity (or, in the case of a trust, an officer of the responsible entity) has, or ought reasonably to have, come into possession of the information in the course of the performance of their duties as an officer of that entity" and section 4.4

in Guidance Note 8 Continuous Disclosure: Listing Rules 3.1 – 3.1B “When does an entity become aware of information.”

- E. Listing Rule 3.1A, which sets out exceptions from the requirement to make immediate disclosure, provided that each of the following are satisfied.

“3.1A Listing rule 3.1 does not apply to particular information while each of the following is satisfied in relation to the information:

3.1A.1 One or more of the following applies:

- It would be a breach of a law to disclose the information;*
- The information concerns an incomplete proposal or negotiation;*
- The information comprises matters of supposition or is insufficiently definite to warrant disclosure;*
- The information is generated for the internal management purposes of the entity; or*
- The information is a trade secret; and*

3.1A.2 The information is confidential and ASX has not formed the view that the information has ceased to be confidential; and

3.1A.3 A reasonable person would not expect the information to be disclosed.”

- F. ASX’s policy position on the concept of “confidentiality”, which is detailed in section 5.8 of Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B*. In particular, the Guidance Note states that:

“Whether information has the quality of being confidential is a question of fact, not one of the intention or desire of the listed entity. Accordingly, even though an entity may consider information to be confidential and its disclosure to be a breach of confidence, if it is in fact disclosed by those who know it, then it ceases to be confidential information for the purposes of this rule.”

Request for information

Having regard to the above, ASX asks AYA to respond separately to each of the following questions and requests for information:

1. Does AYA consider the Information to be information that a reasonable person would expect to have a material effect on the price or value of its securities?
2. If the answer to question 1 is “no”, please advise the basis for that view.
3. When did AYA first become aware of the Information? Please comment specifically on when AYA became aware that its 510(k) application would not be submitted by the end of October 2023.
4. If AYA first became aware of the Information before the relevant date, did AYA make any announcement prior to the relevant date which disclosed the information? If so, please provide details. If not, please explain why the Information was not released to the market at an earlier time, commenting specifically on when you believe AYA was obliged to release the Information under Listing Rules 3.1 and 3.1A and what steps AYA took to ensure that the Information was released promptly and without delay.
5. Please confirm that AYA is complying with the Listing Rules and, in particular, Listing Rule 3.1.

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6. Please confirm that AYA's responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of AYA with delegated authority from the board to respond to ASX on disclosure matters.

When and where to send your response

This request is made under Listing Rule 18.7. Your response is required as soon as reasonably possible and, in any event, by no later than **12 PM AWST Friday, 3 November 2023**. You should note that if the information requested by this letter is information required to be given to ASX under Listing Rule 3.1 and it does not fall within the exceptions mentioned in Listing Rule 3.1A, AYA's obligation is to disclose the information 'immediately'. This may require the information to be disclosed before the deadline set out in the previous paragraph and may require AYA to request a trading halt immediately.

Your response should be sent to me by e-mail at **ListingsCompliancePerth@asx.com.au**. It should not be sent directly to the ASX Market Announcements Office. This is to allow me to review your response to confirm that it is in a form appropriate for release to the market, before it is published on the ASX Market Announcements Platform.

Trading halt

If you are unable to respond to this letter by the time specified above, you should discuss with us whether it is appropriate to request a trading halt in AYA's securities under Listing Rule 17.1. If you wish a trading halt, you must tell us:

- the reasons for the trading halt;
- how long you want the trading halt to last;
- the event you expect to happen that will end the trading halt;
- that you are not aware of any reason why the trading halt should not be granted; and
- any other information necessary to inform the market about the trading halt, or that we ask for.

We require the request for a trading halt to be in writing. The trading halt cannot extend past the commencement of normal trading on the second day after the day on which it is granted. You can find further information about trading halts in Guidance Note 16 *Trading Halts & Voluntary Suspensions*.

Suspension

If you are unable to respond to this letter by the time specified above, ASX will likely suspend trading in AYA's securities under Listing Rule 17.3.

Listing Rules 3.1 and 3.1A

In responding to this letter, you should have regard to AYA's obligations under Listing Rules 3.1 and 3.1A and also to Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B*. It should be noted that AYA's obligation to disclose information under Listing Rule 3.1 is not confined to, nor is it necessarily satisfied by, answering the questions set out in this letter.

Release of correspondence between ASX and entity

ASX reserves the right to release all or any part of this letter, your reply and any other related correspondence between us to the market under Listing Rule 18.7A.

Questions

If you have any questions in relation to the above, please do not hesitate to contact me.

Yours sincerely

Laura Gomme

Senior Adviser, Listings Compliance