

30 January 2025
Reference: 104951

Stuart Roberts
Listings Compliance
20 Bridge St
Sydney NSW 2000

By email: ListingsComplianceSydney@asx.com.au

We refer to your letter dated 20 January 2025 regarding the Company's (ASX:EIQ) announcements "Pre-Submission Meeting with US FDA for Heart Failure" released on 24 December 2024. We respond to your questions using the same numbering as in your letter.

1. The Company considers the information disclosed in the Announcement to be material.
2. The Announcement provides critical updates about the Company's progress in obtaining FDA clearance for its heart failure clinical decision support solution, EchoSolv HF. The request for a pre-submission meeting is a vital regulatory step, as it signifies that the Company has reached an advanced stage in its development. To be in a position to request this meeting, a company must have gathered sufficient preliminary data, compiled key documentation and formulated a regulatory strategy that enables meaningful engagement with the FDA. FDA clearance is a prerequisite for commercialising EchoSolv HF in the US and gaining subsequent access to a significant revenue opportunity, which is central to the Company's commercialisation strategy.

Given the significant market implications and the milestone's proximity, a reasonable person would expect this information to have a material effect on the price or value of EIQ's securities.

3. Not applicable.
4. The Announcement provides key updates on the Company's progress toward FDA clearance for EchoSolv HF. The request for pre-submission meeting with the FDA, with the meeting expected to be scheduled for Q1 CY2025, marks a critical step in finalising the validation study protocol and confirms that the Company is on track to meet regulatory requirements.

The Company also stated in the Announcement that FDA clearance is anticipated in H2 CY2025, providing a clear roadmap for regulatory approval and market entry. The next step in this process is the validation study, which is scheduled to commence in the following quarter.

Finally, the Announcement highlights the significant market opportunity, emphasising the potential of EchoSolv HF.

Together, these details provide investors with a comprehensive understanding of the importance of the request for pre-submission meeting and its impact on EIQ's commercial strategy.

5. The Company confirms that it is in compliance with the Listing Rules and, in particular, Listing Rule 3.1.
6. The Company confirms that the Board has approved the responses listed above to the questions raised in the ASX query letter dated 20 January 2025 in accordance with the Company's published continuous disclosure policy.

Yours sincerely,

Jessamyn Lyons
Company Secretary
Echo IQ Limited



20 January 2025

Reference: 104951

Ms Jessamyn Lyons
Company Secretary
EchoIQ Limited
Level 3, 88 William Street, Perth WA 6000

By email: jess.lyons@nexiaperth.com.au

Dear Ms Lyons

EchoIQ Limited ('EIQ'): ASX Query

ASX refers to the following:

- A. EIQ's announcement titled "Pre-Submission Meeting with US FDA for Heart Failure" marked as "market sensitive" and released on the ASX Market Announcements Platform ('MAP') on 24 December 2024 (the 'Announcement'), which disclosed that:
- *AI and Medical Technology company Echo IQ ("the Company" or "Echo IQ") (ASX:EIQ) is pleased to advise it has submitted a formal request to the US Food & Drug Administration ("FDA") for a pre-submission meeting to approve the design for a proposed validation trial which will test its heart failure screening tool ("EchoSolv HF") in detecting various forms of heart failure.*
 - *During the pre-submission meeting, the Company will liaise with the FDA on its curated dossier on EchoSolv HF and confirm design of its validation study.*
- B. 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.
- C. Section 4.15 of Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B* ('GN 8'), which states that:
- "Wherever possible, an announcement under Listing Rule 3.1 should contain sufficient detail for investors or their professional advisers to understand its ramifications and to assess its impact on the price or value of the entity's securities...*
- Entities should not use an announcement under Listing Rule 3.1 as a guise to publish material that is really promotional, political or tendentious in nature rather than being information that a reasonable person would expect to have a material effect on the price or value of its securities."*
- D. Section 7.10 of GN 8, which states that:
- "ASX is alive to listed entities making market announcements with a view to "ramping up" the price of their securities...*
- Whenever ASX detects what it suspects to be a ramping announcement, it will give careful consideration to suspending the entity's securities from trading and issuing a query letter to the entity asking the entity:*
- *if it marked the announcement as market sensitive when it was lodged on MAP, to identify what information in the announcement the entity considered was market sensitive and why;...*

In an appropriate case, ASX may also require the entity to publish a corrective announcement confirming that the information in the ramping announcement was not material, or was incomplete or misleading, and that investors should not make investment decisions based on the announcement."

E. Footnote 293 of section 7.10 of GN 8, which states that (relevantly):

"ASX has observed instances of ramping announcements being made: (a) just before a capital raising, with the apparent intent of boosting the price for the capital raising; (b) just after a capital raising, with the apparent intent of facilitating a profitable exit for some of the investors who acquired securities in the capital raising; and (c) following the appointment of a new adviser who is remunerated in whole or in part by the issue of securities in the entity."

Request for information

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

1. Does EIQ consider the information disclosed in the Announcement, or any part thereof, to be information that a reasonable person would expect to have a material effect on the price or value of EIQ's securities?
2. If the answer to question 1 is "yes", please explain the basis for that view.
3. If the answer to question 1 is "no":
 - 3.1 Please explain why the Announcement was marked as market sensitive.
 - 3.2 Please explain the Listing Rule or Corporations Act basis necessitating the disclosure of the Announcement and the basis for that view.
4. Please identify the details in the Announcement that would enable EIQ's investors or their professional advisers to understand the materiality of a pre-submission meeting with FDA and to assess the impact on the price or value of EIQ's securities.
5. Please confirm that EIQ is complying with the Listing Rules and, in particular, Listing Rule 3.1.
6. Please confirm that EIQ'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 EIQ 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 **9:30 AM AEDT Friday, 24 January 2025**.

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, EIQ'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 EIQ to request a trading halt immediately.

Your response should be sent by e-mail to ListingsComplianceSydney@asx.com.au. It should not be sent directly to the ASX Market Announcements Office. This is to allow us 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.

Suspension

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

Listing Rules 3.1 and 3.1A

In responding to this letter, you should have regard to EIQ'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 EIQ'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

We reserve the right to release a copy of this letter, your reply and any other related correspondence between us to the market under listing rule 18.7A.

Yours sincerely

ASX Compliance