



G Medical Innovations Holdings Ltd  
ARBN 617 204 743

21 October 2019

Anjuli Sinniah  
Senior Adviser, Listings Compliance (Perth)

By email: ListingsCompliancePerth@asx.com.au

Dear Ms Sinniah

G Medical Innovations Holdings Limited (**G Medical** or the **Company**) refers to ASX's letter dated 16 October 2019 (**Letter**) and its responses dated 8 October 2019 to ASX's previous queries (**Previous ASX Response**).

Detailed below are the Company's responses to the questions in the Letter. Unless otherwise defined, capitalised terms in this letter have the same meaning given to those terms in the Letter and the Previous ASX Response.

**1. In the GMV Response, GMV discloses that it has not yet received the NMPA approval for its medical devices. In the announcement dated 4 June 2019, GMV disclosed the NMPA approval was anticipated in the first half of the 2019 financial year. In the announcement dated 30 July 2019, GMV revised the timeframe to during the second half of 2019. In the GMV Response, GMV revised that deadline to around mid-2020.**

**1.1 Please explain the reasons for the delay in obtaining the NMPA approval.**

The reasons for the delay in obtaining the NMPA approval are as follows:

- (i) the Chief Principal Investigator (**PI**) for the leading hospital sadly and unexpectedly passed away in June 2019, resulting in delays to the clinical trial. Having regard to this, additional time was required for the NMPA committee to nominate and approve a new PI to the Company, to allow the new PI to review and adopt on-going clinical trials (processes, paperwork, logistics, protocols) and to re-orientate the supporting clinical staff to the trial to the new PI's specific expectations, requirements and protocols. The process recommenced in August 2019;
- (ii) new clinical trial protocols had to be submitted to the NMPA, as well as to two additional hospitals, being:
  - a. the Guangzhou Women and Children's Medical Center - which occurred on 25 September 2019; and
  - b. the Zhujiang Hospital of Southern Medical University - which occurred on 16 October 2019;
- (iii) in consideration of the summer period, it was substantially more challenging than expected to identify and recruit qualified patients presenting obligatory symptoms for the relative clinical trial, particularly patients registering outlier range requirements for temperature data; and
- (iv) the ethical committee at the Shenzhen hospital (being the nominated clinical site for volunteer SPO2 trial) had indicated to the Company that they would have convened to consider and approve the protocols to the "controlled SPO2 reduction" clinical trial at a

committee meeting in July 2019, however subsequently cancelled this meeting and postponed it until the end of September 2019. Final approval to approve the protocols to the "controlled SPO2 reduction" clinical trial has now been received and was provided to the Company on 15th October 2019.

The Company wishes to highlight that much of the reasons detailed above in respect to the delays to the NMPA approval were disclosed to shareholders in the Company Update announcement dated 30 July 2019.

To provide further clarity, not dissimilar to any other biotechnology company seeking a regulatory approval for a medical device, and in providing a general overview, the process is dependent on (but not limited to) the:

- (i) submission, review and approval processes of a regulatory body and the associated time frames;
- (ii) clinical trial requirements as stipulated by a regulatory body;
- (iii) appointment of the supervising chief principal investigator;
- (iv) establishment of sponsoring hospitals and institutions;
- (v) patient recruitment and suitability;
- (vi) total number of required patients to the specific trial;
- (vii) number of separate trials in consideration to the medical device's feature set and diagnostic indications subject to clinical scrutiny;
- (viii) type, size, complexity of the clinical data reviews and analysis; and
- (ix) number, nature, requirements and time frames of audits for both the clinical trial and the hospital, as conducted by the regulator,

of which many are subject to time frames reliant on, and at the sole discretion of the governing or regulatory body and/or third-party provider.

**1.2 Is GMV aware of any reason why the NMPA approval may be denied? If so, please detail the reasons. If not, please detail the reasons.**

No, on the basis that:

- (i) the ongoing clinical trials have passed all tests completed to date;
- (ii) the Company has received formal notification that it has passed all requirements of the NMPA during the regulator's mid-term auditing process, being a key milestone in the NMPA approval process (as announced in the Company Update announcement dated 30 July 2019);
- (iii) the Company successfully passed the technical lab test by the NMPA;
- (iv) the Company has not previously been denied any regulatory approvals for its medical devices (in respect to those approvals sought by the Company); and
- (v) Dr Geva has specific expertise in the regulatory approval processes for medical devices, having previously successfully obtained 47 regulatory approvals across FDA, CE and NMPA, (of which 5 of them were for the Company) at 100% success rate, throughout his career.

**1.3 Noting that the Boletong Agreement and the SilverLake Agreement are contingent on receiving the NMPA approval and the delay to date, has GMV considered what course of action it will take in respect of the Boletong Agreement and the SilverLake Agreement if the NMPA approval is not obtained? Please explain what the course of action is.**

No, as the Company continues to successfully complete all requirements to the NMPA for the Prizma device, and, as at the date of this Letter, is not aware of any reason why NMPA approval will not be obtained. If (for whatever reason) NMPA approval is not obtained, the Company will not proceed with the Boletong Agreement and the SilverLake Agreement, given that they are known (as previously announced) conditions precedent to the Agreements.

**2. The Boletong Revenue Projection was released on 27 July 2017. Since then, GMV has not received the NMPA approvals for its Prizma devices which is required for Boletong to purchase a minimum quantity of units being no less than US\$67,500,000. ASX notes that GMV have set out the basis on which the Board of GMV are satisfied that Boletong are able to perform its obligations:**

**2.1 Please explain whether the basis upon which the Board have satisfied itself is considered a “reasonable basis” pursuant to ASIC’s Regulatory Guide 170 noting specifically RG 170.17, RG170.41, RG 170.42 and RG170.50 and that over 2 years have elapsed since the Boletong Revenue Projection was released;**

The Board has satisfied itself on the basis of:

- (i) the matters detailed in its response to question 8 of the Previous ASX Response; and
- (ii) the significant and specific experience of the Company's executive management team plus certain of the Board members, including their historical success in:
  - a. the development and commercialisation of proprietary intellectual property and medical devices; and
  - b. operating and promoting companies with operations and business models analogous to that of the Company,

and the executive management team's recommendations in respect to the Boletong Agreement and the Boletong Revenue Projection.

Having regard to the matters detailed above, the Board considers that no independent verification was, or is, required.

**2.2 Has GMV conducted due diligence into Boletong and the Boletong Agreement since the delay of the NMPA approval, noting that over 2 years have elapsed since the date of execution? If so, please provide details of the due diligence undertaken.**

The Company has not conducted any additional due diligence investigations since the delay of the NMPA approval. The Company reiterates that Dr Geva has had recent communications with the CEO of Boletong, who has personally confirmed that the Boletong Agreement remains unchanged and that Boletong awaits notification from the Company in respect to the grant of NMPA approval for the Prizma device.

**2.3 In light of the time that has elapsed, does GMV intend to formally maintain, retract or revise the Boletong Revenue Projection? Please explain the reasons for maintaining, retraction or revision (as applicable).**

The Company maintains the Boletong Revenue Projection on the basis of the matters detailed in the response in question 2.1 above and its response to question 8 in the Previous ASX Response.

3. The FCL Revenue Projection was released on 10 November 2017. Since then, FCL have not yet established the requisite 'Letter of Credit'. Noting that on 5 September 2018, GMV disclosed that "whilst GMV remains confident of distributing the full quantum of units under the agreement, as previously disclosed the Tier 1 partners of FCL have not yet formalised a definitive arrangement with FCL and thus FCL have not yet established their 'Letter of Credit' and on this basis, GMV cannot categorically state that the full anticipated revenues under the previously disclosed Agreement with FCL can be achieved until such time as the above have been formalised" and noting ASIC's Regulatory Guide 170::

3.1. Does GMV intend to formally retract or revise the FCL Revenue Projection? Please explain the reasons for retraction or revision (as applicable).

No.

3.2 Has GMV conducted due diligence into FCL and the FCL Agreement since the FCL delay noting that almost 2 years have elapsed since the date of execution and that GMV has previously disclosed that GMV cannot state that the full anticipated revenues can be achieved until the significantly delayed Letter of Credit is formalised? If so, please provide details of the due diligence undertaken.

The Company has not conducted additional formal due diligence investigations since the delay, however, the Company's has continuing and ongoing activities and engagement with FCL (refer to the Company's response to question 15 of the Previous ASX Response for further details).

4. The GMV Response discloses that the Zingmobile Agreement expired on 1 May 2019 which was not disclosed at the time it expired. Noting the Zingmobile Revenue Projection and ASIC's Regulatory Guide 170:

4.1 Does GMV consider the expiration of the Zingmobile Agreement to be information that a reasonable person would expect to have a material effect on the price or value of its securities?

No, the Company does not consider the expiration of the Zingmobile Agreement to be information that a reasonable person would expect to have a material effect on the price or value of its securities.

4.2 If the answer to question 4.1 is "no", please advise the basis for that view.

On the basis that:

- (i) the expiration date of the Zingmobile Agreement was disclosed on 3 May 2018 (refer to the ASX announcement on 3 May 2018 titled G Medical Receives Conditional Purchase Order From Zingmobile For Prizma Medical Smartphone Case) (the **Announcement**);
- (ii) the value attributed to the conditional purchase order was of substantially lesser value to that of the other arrangements that the Company had in respect to the Prizma device (as at 1 May 2019);
- (iii) the value attributed to the conditional purchase order, being a single and non-recurring purchase, was deemed immaterial in consideration of the Company's ongoing quarterly revenue and operations (as at 1 May 2019); and
- (iv) the value attributed to the conditional purchase order was deemed immaterial to the Company's enterprise value (as at 1 May 2019).

**4.3 When did GMV first become aware that Zingmobile would not be able to perform its obligations under the Zingmobile Agreement?**

For clarity, rather than the Company becoming aware that Zingmobile would not be able to perform its obligations under the Zingmobile Agreement, the Company became aware that Zingmobile was not able to satisfy the conditions under the Zingmobile Agreement (refer to the Announcement for further details) in or around May 2019.

As detailed in the Company's response to question 17 of the Previous ASX Response, "*Whilst the Zingmobile Agreement has expired on the basis that the relevant regulatory certification condition to the Zingmobile Agreement (being in-country 'Singapore' regulatory approval for the Prizma) was not met within the requisite expiry deadline, the Company continues to engage with Zingmobile (and its partner) who is continuing to seek the requisite mandatory regulatory clearances*".

**4.4 If the answer to question 4.1 is "yes" and GMV first became aware of Zingmobile would not be able to perform under the Zingmobile Agreement prior to the expiration date of 1 May 2109, please explain why this information was not released to the market at an earlier time, noting the value of the Zingmobile Agreement and commenting specifically on when you believe GMV was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps GMV took to ensure that the information was released promptly and without delay.**

Not applicable.

**5. The GMV Response discloses that it has not received any monthly payments from Hygea prior to the Hygea restructure and will not receive any payments pending resolution of Hygea's restructure. ASX notes that GMV have set out the basis on which the Board of GMV are satisfied that Hygea are able to perform its obligations the GMV Response:**

**5.1 Please explain whether the basis upon which the Board has satisfied itself is considered a "reasonable basis" pursuant to ASIC's Regulatory Guide 170 noting specifically RG 170.17, RG170.41, RG 170.42 and RG170.50 and noting that the Hygea Revenue Projection was released on 30 January 2019;**

The Board has satisfied itself on the basis of:

- (i) the matters detailed in its response to question 30 of the Previous ASX Response; and
- (ii) the significant and specific experience of the Company's executive management team plus certain Board members, including their current and historical success in:
  - a. the development and commercialisation of proprietary intellectual property and medical devices; and
  - b. operating and promoting companies with operations and business models analogous to that of the Company,

and the executive management team's recommendations in respect to the Hygea Agreement and the Hygea Revenue Projection.

**5.2 If the due diligence detailed in the GMV Response into Hygea was conducted prior to or post the Hygea restructure? If conducted post-restructure, has GMV conducted any due diligence into Hygea and the Hygea Agreement noting that the Agreement will not proceed pending resolution of the Hygea restructure? If so, please provide details of the due diligence undertaken.**

Not applicable. The Company reiterates (as detailed in its response to question 30 of the Previous ASX Response) that, in respect to Hygea's restructuring, the process remains "*current and ongoing*".

For further clarity and as detailed in its response to question 30 of the Previous ASX Response (and in paragraphs 5.1 and 5.2 above) the Company had completed substantial due diligence both prior (as detailed in the Company's response in paragraphs (a) and (b) to question 30 of the Previous ASX Response), and subsequent to (as detailed in paragraph (c) and (d) to question 30 of the Previous ASX Response), the execution of the Hygea Agreement.

**5.3 In light of the time that has elapsed, does GMV intend to formally maintain, retract or revise the Hygea Revenue Projection? Please explain the reasons for maintaining, retraction or revision (as applicable).**

Having regard to the Company's responses to questions 5.1 and 5.2 above and its response to question 30 of the Previous ASX Response, the Company maintains the Hygea Revenue Projection.

**6. Please confirm that GMV is complying with the Listing Rules and, in particular, Listing Rule 3.1.**

Confirmed.

**7. Please confirm that GMV'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 GMV with delegated authority from the board to respond to ASX on disclosure matters.**

Confirmed.

Yours sincerely

Steven Wood  
**Company Secretary**  
**G Medical Innovations Holdings Ltd**



16 October 2019

Mr Steven Wood  
Company Secretary  
G Medical Innovations Limited

By email: [sw@grangeconsulting.com.au](mailto:sw@grangeconsulting.com.au)

Dear Mr Wood

**G MEDICAL INNOVATIONS LIMITED – ASX QUERY**

The capitalised terms used in this query letter have the same meaning as in the ASX query letter dated 2 September 2019 (“Query Letter”).

ASX Limited (“ASX”) refers to the following:

1. GMV’s response to ASX’s Query Letter lodged on MAP and released at 09:49am AEST on 9 October 2019 (“GMV Response”) disclosing that the Boletong Agreement remains in effect while GMV awaits NMPA approvals for its Prizma device. The GMV Response also discloses that the Board have satisfied themselves that Boletong will perform its purchase obligations under the Boletong Agreement on the following basis:
  - 1.1. for a period of 7 months prior to the execution of the Boletong Agreement, executive and key management personnel of the Company including (and not limited to) Dr Geva and Mr George Hu (general manager of Guangzhou Yimei Innovative Medical Science and Technology Co., Ltd, a wholly owned subsidiary of the Company) conducted due diligence investigations, had face to face meetings and various other communications with the key management team and CEO of Boletong, including:
    - 1.1.1. conducting site visits to Boletong’s operations which comprised of over 100 employees across sales, marketing and clinical services (refer above in respect to the business of Boletong); and
    - 1.1.2. meeting with Boletong’s existing contracted channel partners, including (but not limited to) Shandong China Telecom and a number of public health care companies;
  - 1.2. GMV understands that Boletong holds a government contract for the provision of monitoring services to patients within a regional population of circa 9 million individuals, under which it receives reimbursement for each patient monitored;
  - 1.3. GMV understands that Boletong has significant investment backing from a Tier 1 Chinese pharmaceutical company as well as having sufficient revenues in its own capacity to satisfy the financial requirements under the Boletong Agreement;
  - 1.4. GMV and Boletong intend to establish a joint venture partnership pursuant to which Boletong has agreed to establish a 50 to 60 (persons) doctors and nurses centre for the provision of health care services; and
  - 1.5. recent communications between Dr Geva with the CEO of Boletong, who has personally confirmed that the Boletong Agreement remains unchanged and that Boletong awaits notification from HMV in respect to the grant of NMPA approval in respect of the Prizma device.
2. In the GMV Response, GMV discloses that FCL has advised GMV that it has not yet received the requisite in-country (Taiwan and India equivalent to ‘FDA’) regulatory approval to allow for the marketing and sale and distribution of the Prizma device in Taiwan and India. Further FCL have advised that FCL has not formalised

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its arrangements with its Tier 1 Partners are the regulatory approvals for the Prizma device have not been received by FCL. The Board of GMV are satisfied that FCL will perform its obligations under the FCL Agreement on the basis of the following:

- 2.1. the FCL Agreement is subject to further definitive agreements between FCL and its Tier 1 channel partners; whereby if executed, the Company has previously satisfied itself with the proposed Tier 1 partners' capacity and ability to perform under the FCL Agreement (refer to the ASX announcement dated 10 November 2017 – Additional Definitive Agreements to Complete), and this assessment remains unchanged;
- 2.2. FCL arranged face to face meetings (amongst other various communications and arrangements) between executive and key management personnel of the Company, including (but not limited to), Dr Geva and with the key management team of their proposed Tier 1 channel partners (including Reliance Communications, Jio, BSNL Mobile, Vodaphone India, Airtel) and also provided the Company with financial modelling representing a reasonable basis for their forecasts having regard to their channel partners;
- 2.3. various ongoing engagements between executive and key management personnel of the Company, including and not limited to, Dr Yacov Geva (CEO) and with executive and key management personnel of UBHL and FCL and their potential channel partners, including (but not limited to):
  - 2.3.1. Mr Ho, Managing Director of UBHL, as well as other executives of UBHL;
  - 2.3.2. Mr Mehul Parekh (Chairman of Unimark Remedies);
  - 2.3.3. Mr Siddhartha Srivastava (Chairman of IOL Netcom);
  - 2.3.4. Mr Virendra Nath (Managing Director of Skyway Finance Ltd); and
  - 2.3.5. Ms. Winsome (Chairman Bamboos Healthcare HK);since the execution of the FCL Agreement;
- 2.3.6. FCL to date, continues to pursue its regulatory approval processes in Taiwan and India;
- 2.3.7. FCL to date, continues to engage in marketing and product education of G Medical's medical devices, including (but not limited to):
  - 2.3.7.1. arranging meetings with in-country physicians, being the potential prescribers and support services to, and endorsers of, the Company's medical devices;
  - 2.3.7.2. conducting numerous tradeshows showcasing G Medical's medical products;
  - 2.3.7.3. continuing (via UBHL) to showcase G Medical's medical products to its clients and via their website;
  - 2.3.7.4. prior to the execution of the FCL Agreement:
  - 2.3.7.5. the executive and key management personnel of the Company, including (but not limited to), Dr Geva, conducted due diligence and/or detailed reviews on both FCL and its Tier 1 Partners, and were satisfied with the presented business plans outlining



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- FCL's ability to successfully sell and distribute G Medical's medical devices both directly and in collaboration with their Tier 1 Partners, including the provision of the necessary ancillary support services to the Prizma device;
- 2.3.7.6. the Company worked closely with FCL on its sales and distribution model and had verified the working background and track record of the individual team members;
  - 2.3.7.7. the Company examined and was satisfied with the financial positions of the major shareholders to UBHL, FCL's parent company;
  - 2.3.7.8. the Company was satisfied to the merit of the business relationships between FCL and its Tier 1 partners;
  - 2.3.7.9. the Company was satisfied as to the ability of FCL's Tier 1 partners' capacity and ability to perform under the FCL Agreement; and
  - 2.3.7.10. the executive and key management personnel of the Company, including (but not limited to), Dr Geva were involved in face-to-face meetings with FCL's Tier 1 Partners and was satisfied that these parties had the intention to enter into definitive arrangements with FCL.
3. In the GMV Response, GMV discloses that the Zingmobile Agreement expired on 1 May 2019 which was not specifically disclosed at the time the agreement expired.
  4. In the GMV Response, GMV discloses that it has not received any monthly payments from Hygea pursuant to the Hygea Agreement prior to the restructure. Further, the Board of GMV have satisfied themselves that Hygea will be able to complete its obligations on the following basis:
    - 4.1. the Company has undertaken extensive due diligence investigations in respect to Hygea, its two subsidiaries and the underlying business including (but not limited to);
      - 4.1.1. a review of the Hygea Group's unaudited financial data and management accounts, which were provided to the Company prior to the execution of the Hygea Agreement;
      - 4.1.2. a review of a due diligence report prepared by Clifton Lawson Allen dated 14 May 2018, and provided to the Company in respect to amongst other matters, the business of Hygea, the quality of its earnings, income statements analysis, working capital analysis, quality of assets analysis, balance sheet analysis, financial statements, executives and management and corporate organizational analysis;
      - 4.1.3. a review of an Information Memorandum dated 28 November 2018, provided to the Company by Hygea in respect to Hygea's business, its financials, operations, existing infrastructure, distribution networks, growth and acquisition strategies, management team;
    - 4.2. the Company's executive and key management personnel, including (but not limited to), Dr Geva, Mr Kobi Ben-Efraim (CFO), Mr Heumann engaged in extensive face to face meetings, site visits, discussions, telephone calls, emails, with executive and key management of Hygea, including (but not limited to), the two Vice Chairmen of Hygea, CEO of Hygea, Board Members of Hygea, the executives of Hygea's major financial partners (Bridging Finance Inc), the key management of Hygea's major operation partners and service providers, prior (and subsequent) to the execution of the Hygea Agreement in respect to:

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- 4.2.1. the Hygea group's (including its subsidiaries) business structure and network of integrated group practices (IGP);
  - 4.2.2. its size and reach across its IGP networks, clinics and practices and its patient profile;
  - 4.2.3. Hygea's business and growth strategy, synergies with the Company and roll-out strategy for the Company's medical devices; and
  - 4.2.4. Hygea's groups balance sheets and financials including in their respect to their ability to meet their contractual commitments under the Hygea Agreement and purchase of the medical devices;
  - 4.2.5. subsequent to the execution of the Hygea Agreement the Company has continued its extensive engagement with, and due diligence processes on, Hygea, particularly in respect to other potential opportunities with Hygea and its group, including and not limited to:
    - 4.2.5.1. commissioning an additional independent legal and due diligence report from Proskauer Rose LLP (New York) on 14 March 2019; and
    - 4.2.5.2. continuing the Company's services integration and provision of cardiac monitoring services to Hygea's group through the Company's wholly owned US IDTF centres; and
    - 4.2.5.3. the Company's executive and key management personnel, including (but not limited to), Dr Geva, Mr Ben-Efraim and Mr Heumann have continued their engagement with the executive and key management of Hygea, as well as with the executives of Hygea's major financial partners (Bridging Finance Inc), in respect to Hygea's current and ongoing restructuring processes via various face to face meetings in the United States and Israel, telephone calls, emails and other forms of electronic communication.

5. ASIC's Regulatory Guide 170: *Prospective financial information*, in particular:

- a. RG 170.11 - *We believe the general test of whether prospective financial information must be disclosed is whether it is:*
  - (a) *relevant to its audience; and*
  - (b) *reliable (i.e. there must be a reasonable basis for it: see GIO Australia Holdings Ltd v. AMP Insurance Investment Holdings Pty Ltd (1998) 29 ACSR 584).*
- b. RG 170.17 - *The making of a statement that contains prospective financial information (i.e. a forward-looking statement) **must have reasonable grounds or it will be taken to be misleading under s728(2) or 769C of the Corporations Act. What are 'reasonable grounds' should be determined objectively in light of all of the circumstances at the time of the statement, so that a reasonable person would view as reasonable the grounds for the statement** [emphasis added].*
- c. RG 170.18 - *We consider that prospective financial information based on hypothetical assumptions (rather than reasonable grounds) is likely to be misleading and provide little information value to investors. In our view, prospective financial information without reasonable grounds is not material to investors, nor would an investor reasonably require it or reasonably expect to find it in a disclosure document or PDS.*

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d. RG 170.41 - *We generally consider that **prospective financial information for a period of more than two years may require independent or objectively verifiable sources of information to establish that there are reasonable grounds to provide it. However, for an existing business preparing a statement on estimates for up to two years, we will generally not regard as necessary independent verification if there otherwise appear to be reasonable grounds to make the statement. Directors should state why they believe the information is objectively reasonable. We may still take action on a statement on estimates for up to two years if we believe there are no reasonable grounds to provide it** [emphasis added].*

e. RG 170.42- *The reasonable grounds requirement means that there should be a relevant factual foundation for the prospective financial information and that the information is not contrived: see *George v. Rockett* (1990) 170 CLR 104 and *Re Aldred & Dept of the Treasury* (1994) 35 ALD 685.*

f. RG 170.50 - **The general principles in this regulatory guide also apply to advertising because of the interaction of s769C and 1041H.** [emphasis added]

Section 769C states:

*For the purposes of this Chapter, or of a proceeding under this Chapter, if:*

- (a) *a person makes a representation with respect to any future matter (including the doing of, or refusing to do, any act); and*
- (b) *the person does not have reasonable grounds for making the representation; the representation is taken to be misleading.*

Section 1041H states:

*A person must not, in this jurisdiction, engage in conduct, in relation to a financial product or a financial service, that is misleading or deceptive or is likely to mislead or deceive.*

g. RG 170.59 - *Investors should be given enough information to enable them to:*

- (a) *assess whether the prospective financial information is relevant and reliable (i.e. to form their own view about how reasonable the grounds are for making the statement); and*
- (b) *identify with certainty the facts and circumstances that support prospective financial information, as well as being able to demonstrate that the information is reasonable.*

h. RG 170.61 - *A disclosure document or PDS must specifically disclose any assumptions used in compiling prospective financial information that materially affect the forecast outcome. The assumptions should be detailed and specific enough to enable the investor to work through all of the prospective financial information. This may require details about how returns are calculated during each year that the information covers. Among other things, assumptions about expenditures, revenues, inflation rates and other such variables should be clearly disclosed and highlighted if different assumptions have been used for different parts of the term that the prospective financial information covers.*

i. RG 170.62 *Investors must be able to assess:*

- (a) *the validity of the assumptions on which the prospective financial information is based;*
- (b) *the likelihood of the assumptions actually occurring; and*
- (c) *the effect on the prospective financial information if the assumptions vary.*

j. RG 170.63 - *We expect a disclosure document or PDS to disclose material assumptions about:*

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- (a) *specific future economic conditions; and*
- (b) *particular circumstances affecting a company or financial product and the industries relevant to that company or financial product.*
- k. RG 170.64 - *Disclosure of the material assumptions allows an investor or adviser to make an informed assessment of an issuer's prospects, or a person as a retail client to make an informed decision whether to acquire the product.*
- l. RG 170.65 - *An assessment of the impact of these assumptions on prospective financial information should also be included. However, a disclosure document or PDS does not have to:*
- (a) *state general assumptions, such as the absence of war or natural disasters, unless the forecast takes these events into account; or*
- (b) *disclose assumptions that would not materially affect the prospective financial information.*
- m. RG 170.66 - *It is not sufficient to state the general nature of an assumption. Specific quantities or amounts should be set out. For example, it may not be sufficient to state that prospective financial information is based on an anticipated recovery in equity markets, without setting out the amount of the required recovery: see GIO Australia Holdings Ltd v. AMP Insurance Investment Holdings Pty Ltd (1998) 29 ACSR 584.*
- n. RG 170.67 - *We consider that because the presence or absence of reasonable assumptions is a factor in any determination of whether an issuer has satisfied the relevant disclosure obligation, the basis for the assumptions underlying the prospective financial information should be stated in the disclosure document or PDS in order that an investor has some means of assessing that information: see Miba Pty Ltd v. Nescor Industries (1996) 141 ALR 525 and Wesfi Ltd v. Blend Investments Pty Ltd (1999) 31 ACSR 69.*
- o. RG 170.68 - *Disclosure of the basis for prospective financial information may reduce the capacity of the information to mislead because such disclosure assists the assessment/decision of an investor or retail client.*
- p. RG 170.78 - *Investors must be able to assess the reliability of prospective financial information. To do this, they should be able to assess whether the key assumptions are likely to occur. Therefore, a disclosure document or PDS must disclose material details about the enquiries and research undertaken and the process followed in preparing the information.*

A complete copy of the Regulatory Guide is available at:

<http://download.asic.gov.au/media/1240943/rg170-010411.pdf>

6. Section 4.15 of ASX's Guidance Note 8 Continuous Disclosure: Listing Rules 3.1 – 3.1B "Guidelines on the contents of announcements under Listing Rule 3.1" which states, amongst other things that:

*"Similarly, depending on the circumstances, ASX would generally expect an announcement about the signing of a market sensitive contract with a customer to include information about:*

- *the name of the customer;*
- *the term of the contract;*
- *the nature of the products or services to be supplied to the customer;*

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- *the significance of the contract to the entity;*
  - *any material conditions that need to be satisfied before the customer becomes legally bound to proceed with the contract; and*
  - *any other material information relevant to assessing the impact of the contract on the price or value of the entity's securities.*

*In disclosing the significance of the contract to the entity, regard should be had to the guidance below about forward looking statements. For example, a statement about the projected revenue to be derived from a customer contract or any other projection that is a proxy for revenue will be a forward looking statement and therefore must have a reasonable basis in fact or else it will be deemed to be misleading."*

*"See notes 114 and 115 and accompanying text. Note also that if an entity does make a statement about the projected revenue to be derived from a customer contract or any other projection that is a proxy for revenue and the entity becomes aware that the projection is materially overstated, that may trigger an obligation under Listing Rule 3.1 to make a corrective announcement."*

7. Listing Rule 3.1, which requires a listed entity to give ASX immediately 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.

Having regard to the above, ASX asks GMV to respond separately to each of the following questions and requests for information in a format suitable for release to the market in accordance with Listing Rule 18.7A:

1. In the GMV Response, GMV discloses that it has not yet received the NMPA approval for its medical devices. In the announcement dated 4 June 2019, GMV disclosed the NMPA approval was anticipated in the first half of the 2019 financial year. In the announcement dated 30 July 2019, GMV revised the timeframe to during the second half of 2019. In the GMV Response, GMV revised that deadline to around mid-2020.
  - 1.1. Please explain the reasons for the delay in obtaining the NMPA approval.
  - 1.2. Is GMV aware of any reason why the NMPA approval may be denied? If so, please detail the reasons. If not, please detail the reasons.
  - 1.3. Noting that the Bolelong Agreement and the SilverLake Agreement are contingent on receiving the NMPA approval and the delay to date, has GMV considered what course of action it will take in respect of the Bolelong Agreement and the SilverLake Agreement if the NMPA approval is not obtained? Please explain what the course of action is.
2. The Bolelong Revenue Projection was released on 27 July 2017. Since then, GMV has not received the NMPA approvals for its Prizma devices which is required for Bolelong to purchase a minimum quantity of units being no less than US\$67,500,000. ASX notes that GMV have set out the basis on which the Board of GMV are satisfied that Bolelong are able to perform its obligations:
  - 2.1. Please explain whether the basis upon which the Board have satisfied itself is considered a "reasonable basis" pursuant to ASIC's Regulatory Guide 170 noting specifically RG 170.17, RG170.41, RG 170.42 and RG170.50 and that over 2 years have elapsed since the Bolelong Revenue Projection was released;
  - 2.2. Has GMV conducted due diligence into Bolelong and the Bolelong Agreement since the delay of the NMPA approval, noting that over 2 years have elapsed since the date of execution? If so, please provide details of the due diligence undertaken.

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- 2.3. In light of the time that has elapsed, does GMV intend to formally maintain, retract or revise the Boletong Revenue Projection? Please explain the reasons for maintaining, retraction or revision (as applicable).
3. The FCL Revenue Projection was released on 10 November 2017. Since then, FCL have not yet established the requisite 'Letter of Credit'. Noting that on 5 September 2018, GMV disclosed that "whilst GMV remains confident of distributing the full quantum of units under the agreement, as previously disclosed the Tier 1 partners of FCL have not yet formalised a definitive arrangement with FCL and thus FCL have not yet established their 'Letter of Credit' and on this basis, GMV cannot categorically state that the full anticipated revenues under the previously disclosed Agreement with FCL can be achieved until such time as the above have been formalised" and noting ASIC's Regulatory Guide 170:
- 3.1. Does GMV intend to formally retract or revise the FCL Revenue Projection? Please explain the reasons for retraction or revision (as applicable).
- 3.2. Has GMV conducted due diligence into FCL and the FCL Agreement since the FCL delay noting that almost 2 years have elapsed since the date of execution and that GMV has previously disclosed that GMV cannot state that the full anticipated revenues can be achieved until the significantly delayed Letter of Credit is formalised? If so, please provide details of the due diligence undertaken.
4. The GMV Response discloses that the Zingmobile Agreement expired on 1 May 2019 which was not disclosed at the time it expired. Noting the Zingmobile Revenue Projection and ASIC's Regulatory Guide 170:
- 4.1. Does GMV consider the expiration of the Zingmobile Agreement to be information that a reasonable person would expect to have a material effect on the price or value of its securities?
- 4.2. If the answer to question 4.1 is "no", please advise the basis for that view.
- 4.3. When did GMV first become aware that Zingmobile would not be able to perform its obligations under the Zingmobile Agreement?
- 4.4. If the answer to question 4.1 is "yes" and GMV first became aware of Zingmobile would not be able to perform under the Zingmobile Agreement prior to the expiration date of 1 May 2109, please explain why this information was not released to the market at an earlier time, noting the value of the Zingmobile Agreement and commenting specifically on when you believe GMV was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps GMV took to ensure that the information was released promptly and without delay.
5. The GMV Response discloses that it has not received any monthly payments from Hygea prior to the Hygea restructure and will not receive any payments pending resolution of Hygea's restructure. ASX notes that GMV have set out the basis on which the Board of GMV are satisfied that Hygea are able to perform its obligations the GMV Response:
- 5.1. Please explain whether the basis upon which the Board has satisfied itself is considered a "reasonable basis" pursuant to ASIC's Regulatory Guide 170 noting specifically RG 170.17, RG170.41, RG 170.42 and RG170.50 and noting that the Hygea Revenue Projection was released on 30 January 2019;
- 5.2. If the due diligence detailed in the GMV Response into Hygea was conducted prior to or post the Hygea restructure? If conducted post-restructure, has GMV conducted any due diligence into Hygea and the

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Hygea Agreement noting that the Agreement will not proceed pending resolution of the Hygea restructure? If so, please provide details of the due diligence undertaken.

- 5.3. In light of the time that has elapsed, does GMV intend to formally maintain, retract or revise the Hygea Revenue Projection? Please explain the reasons for maintaining, retraction or revision (as applicable).
6. Please confirm that GMV is complying with the Listing Rules and, in particular, Listing Rule 3.1.
7. Please confirm that GMV'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 GMV 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 **3:00pm WST on 23 October 2019**.

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, GMV'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 GMV to request a trading halt immediately.

If you wish to request 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*.

ASX reserves the right to release a copy of this letter and your response on the ASX Market Announcements Platform under Listing Rule 18.7A. Accordingly, your response should be in a form suitable for release to the market.

Your response should be sent to me by e-mail at [ListingsCompliancePerth@asx.com.au](mailto: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.

### **Listing Rules 3.1 and 3.1A**

In responding to this letter, you should have regard to GMV'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 GMV's obligation

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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.

**Suspension**

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

**Enquiries**

If you have any queries or concerns about any of the above, please contact me immediately.

Regards

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**Anjuli Sinniah**  
Senior Adviser, Listings Compliance (Perth)