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14 April 2020

Mr Corey Lian  
Adviser, ASX Listings Compliance (Sydney)  
ASX Compliance Pty Ltd

Dear Mr Lian

**Re: TBG Diagnostics Limited ('Company' or 'TDL'): Response to ASX Query Letter**

We refer to your letter dated 24 March 2020 regarding the above matter (**24 March Letter**) and respond to your queries as follows:

- 1. Please provide a detailed explanation as to why the TDL directors 'reasonably believed' that the CE Mark certification remained confidential between the period of 14 March 2020 and the morning of 17 March 2020, especially in light of TDL's share price movements on 16 and 17 March 2020.**

The TDL directors genuinely and reasonably believed at the time that the information relating to the receipt by TBG Biotechnology Xiamen Inc ('**TBG Xiamen**') of the CE Mark certification in respect of COVID-19 Virus Diagnostic Kits ('**COVID Diagnostic Kits**') had remained confidential between 14 March 2020 and the morning of 17 March 2020 for the following reasons:

- As indicated in TDL's response to ASX Aware Query on 19 March 2020, Dr Chang first became aware of the CE Mark certification in respect of the COVID Diagnostic kits on Saturday, 14 March 2020 at 4.15pm (GMT) (i.e. 7:15pm AEDT) when he was informally notified of the CE Mark certification by Mr Bill Ou, a director of TBG Xiamen who is based in Taiwan, via WeChat private message (see attachment referred to in paragraph 2(b)(i) below).
- Dr Chang then immediately relayed this message to his fellow Australian based directors, Ms Emily Lee and Mr Jitto Arulampalam ('**Australian Directors**'), via private text messages (see attachment referred to in paragraph 2(b)(ii)) for internal communications and for the purpose of arranging for the preparation of an ASX announcement of the CE Mark certification for release to the market (where required).
- While, as detailed in paragraphs 2(b)(i) and (ii) below, these private messages contained a hyperlink to a WeChat page in China providing information regarding TBG Xiamen's COVID Diagnostic Kits obtaining EU Mark Certification ('**Hyperlink**'), it was not made known to any of the TDL directors at the time that the Hyperlink or the content thereof was made available to TBG Xiamen's WeChat followers, and was accessible by persons who had a WeChat account and access to the Hyperlink.

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- (d) As discussed in paragraph 2(d) below, the TDL directors are not, and were not at the time, involved in the day to day management of TBG Xiamen and its business operations. The TDL directors had no involvement whatsoever in the social media release via the Hyperlink.
  - (e) Nevertheless, the information relating to the CE Mark certification of the COVID Diagnostic Kits was considered by the TDL directors to be material information.
  - (f) TDL directors therefore expected TBG Xiamen to inform all TBG Xiamen directors (including TDL's nominated directors, as detailed in paragraph 2(d) below) of the information relating to the CE Mark certification of the COVID Diagnostic Kits and any proposed public announcement prior to its release.
  - (g) While Dr Stanley is, and was at the time, the only TDL director appointed to the board of TBG Xiamen, no approval had ever been requested by TBG Xiamen from Dr Stanley, nor any other directors nominated to the TBG Xiamen Board by TDL (as detailed in paragraph 2(d) below), in respect of the Hyperlink and its content.
  - (h) Owing to the above and the fact that Dr Chang and the Australian Directors had generally used private text messages for the purposes of private/ internal communications only and the Hyperlink was provided to the TDL directors via private message channel, the TDL directors reasonably believed at the time that it was provided by Mr Bill Ou for internal communications only, and was not publicly accessible.
  - (i) It is also noted that TDL shares had historically been thinly traded. This was the case after the announcement made on 27 February 2020 of TBG Xiamen's subsidiary, Changsha ChangYe Medical Laboratory Corp (which the TDL board decided to adopt as the formal English translation of TBG Xiamen's subsidiary on and from 28 February 2020 in place of the previously used English translation "Zhangsha ZhangYe Medical Laboratory Corp"), being approved as a designated testing lab for coronavirus. Accordingly, TDL directors had not expected any material share price movements during the relevant period. Hence, the TDL directors were not actively monitoring the trading of TDL shares on 16 and 17 March 2020 and therefore, were not aware of the share price movements on 16 and 17 March 2020 until the Company secretary was contacted by ASX in the morning of 17 March 2020.
  - (j) At no time prior to the discussion with ASX on 17 March 2020, were the TDL directors aware of any leakage of information concerning the CE mark certification of the COVID Diagnostic Kits.
  - (k) The TDL directors first suspected that the information relating to the CE Mark certification might have been leaked shortly after being informed by the Company secretary of his discussion with ASX on 17 March 2020.
  - (l) Given the urgency of this matter and the time difference between Australia and Taiwan to coordinate a phone call of directors, shortly after being informed by the Company secretary of the suspected leakage of information and ahead of the phone call, Mr Jitto Arulampalam requested a trading halt in order to facilitate the finalisation of the ASX announcement (which were in process of being prepared internally at the time). The trading halt was subsequently ratified by the TDL directors.

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- (m) Furthermore, at no time prior to the announcement of the CE Mark certification on 18 March 2020, did the TDL directors disclose the CE Mark certification of the COVID Diagnostic Kits to any other persons except to those who were subject to confidentiality obligations to TDL at the time.
  - (n) Nor were the TDL directors aware of, or informed by TBG Xiamen or any other persons of, any disclosure of the CE Mark certification of the COVID Diagnostic Kits to any other persons at the time except to those who were subject to confidentiality obligations to TDL at the time.
  - (o) It is noted that Mr CK Wang, the remaining director of TDL, was only informed of the CE Mark certification of the COVID Diagnostic Kits by phone from Dr Chang on 17 March 2020 at 4:11pm (GMT) (or 7:11pm (AEDT)).
  - (p) On the above basis, the TDL directors genuinely and reasonably believed that the information relating to the COVID Diagnostic Kits remained confidential at all times between 14 March 2020 and the morning of 17 March 2020.
  - (q) It is noted that Dr Chang's email communication to his fellow Australian Directors on 16 March 2020 at 9:45pm (GMT) (i.e. 12:45am AEDT on 17 March 2020), is supportive of the reasoning given in paragraph (p) above.

In that email, Dr Chang emphasised the importance of keeping the information confidential. One would reasonably expect that such emphasis would not have been given had Dr Chang known at the time that there was a leakage of information (whether via the Hyperlink, its content or otherwise).

- (r) It is noted that both Ms Emily Lee and Mr Jitto Arulampalam have managed a number of ASX listed companies and are fully aware of the importance to make immediate and fulsome disclosure of market / price sensitive information. Ms Emily Lee and Mr Jitto Arulampalam would have instructed the company secretary to immediately place a trading halt on 16 March 2020 had they known at the time that there was a leakage of information (whether via the Hyperlink, its content or otherwise).
- (s) The TDL directors' awareness of the importance to make immediate and fulsome disclosure of market / price sensitive information as detailed in paragraphs 1(b) and 1(q) above is further supported by:
  - (i) TDL's announcement on 6 April 2020 about the recent change to the Chinese government export policy that had prevented TBG Xiamen from exporting the COVID Diagnostic Kits; and
  - (ii) Ms Emily Lee's private test message on 14 March 2020 (as detailed in paragraph 2(b)(ii) below), which indicates that the TDL directors were aware of the requirement to make, and had commenced the process of collating information required for, a fulsome disclosure the COVID Diagnostic Kits and its CE Mark certification to the market immediately.

The TDL directors first became aware of the Hyperlink and its contents being publicly accessible by anyone who has the Hyperlink and a WeChat account, **only** after further investigations and enquiries with TBG Xiamen following receipt of the 24 March Letter from ASX.

The TDL directors have since made enquiries and have realised now that TBG Xiamen had released an update to its employees and subscribers via the WeChat social media

page on 14 March 2020, and that Mr Bill Ou had become aware of the CE Mark certification via this WeChat page.

The TDL directors recognise now that there has been a breakdown in communication protocols between it and TBG Xiamen's management personnel in relation to this matter, and are now taking steps to implement stronger communication protocols to ensure that relevant information from TBG Xiamen is communicated to them swiftly and prior to any public announcement being made by TBG Xiamen.

The TDL directors have also reviewed the trading reports for 16 and 17 March 2020 and confirm that they had no contact with any of the share buyers / sellers on those trading days in the period between 14 March and 17 March 2020.

**2. Please provide copies of the requested documents to ASX.**

**(a) TBG Xiamen's application for the CE Mark certification, its correspondence with the relevant authority concerning the CE Mark certification, and the final CE Mark certification**

Copies of TBG Xiamen's CE Mark certification for the COVID Diagnostic Kits and the required technical information, are attached to this letter as Appendix A<sup>1</sup>.

It is noted that to obtain the CE Mark certification, TBG Xiamen had determined that European Directive IVD Directive 98/79/EC on in vitro diagnostic medical devices ('**EU IVD Direct 98/79/EC**') applies to the Coronavirus Diagnostic Kits.

Pursuant to Article 9 of that EU IVD Directive 98/79/EC, a manufacturer seeking to affix the CE marking on its devices, needs to follow the conformity assessment procedures referred to in Annex III of that Directive and draw up the EC declaration of conformity and the technical documentation required by that Annexure III.

TBG Xiamen had therefore followed the conformity assessment procedures set out in EU IVD Directive 98/79/EC by:

- (i) conducting a series of tests to verify and assess the conformity of the COVID Diagnostic Kits with the requirements of the EU IVD Directive 98/79/EC;
- (ii) following satisfaction of the testing results:
  - (A) preparing the required technical information; and
  - (B) issuing an "EC Declaration of Conformity", so called CE Mark certification.

TBG Xiamen's EU authorised representative, SUNGO Europe B.V. had also confirmed on 11 March 2020 that TBG Xiamen's issuance is in agreement to EU standards by issuing a declaration of notification.

According to EU IVD Directive 98/79/EC, no application to the relevant authority is required in order to affix COVID Diagnostic Kits with CE marking. Therefore, there is no application or correspondence with the relevant authority in relation to the CE Mark certification of the COVID Diagnostic Kits.

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<sup>1</sup> Appendixes provided with this letter are not for public release.

**(b) Correspondence between Dr Stanley Chang and TBG Xiamen personnel in relation to the CE Mark certification, including (but not limited to) correspondence on 14 and 16 March 2020**

Extracts of the communications between Dr Stanley Chang and TBG Xiamen personnel and between Dr Chang and the other directors of TDL and a certified translation are attached to this letter as Appendix B.

- (i) Page 1 of Appendix B is an extract of the WeChat communication between Dr Stanley Chang and Mr Bill Ou on Saturday 14 March 2020, when Dr Chang first became aware of the CE Mark Certification (around 4.15pm GMT).
- (ii) Pages 2, 3, 4, 5 and 6 of Appendix B are extracts of communications between Dr Chang on one hand and Ms Emily Lee and Mr Jitto Arulampalam, on the other hand, on Saturday 14 March 2020 notifying them that the COVID Diagnostic Kits had received CE Mark certification.

We note the following:

- As indicated above, the Hyperlink was forwarded by Mr Ou to Dr Chang, who then on-forwarded to the Australian Directors, via private text messages.

Given the Hyperlink was provided via private communications and for the reasons set out above, both Dr Chang and the Australian Directors honestly believed the Hyperlink was not publicly available and the information relating to the COVID Diagnostic Kit remained confidential at the time.

- Ms Emily Lee did draw to the attention of Dr Chang to the necessity for TDL to make ASX announcement at the time.
- While the Hyperlink to the WeChat page was provided in the private communication between Dr Chang and Mr Arulampalam on 14 March 2020, the contents of the Hyperlink were in Chinese, except an image of CE mark certification was in English. Mr Arulampalam is unable to read and understand Chinese and therefore was unable to decipher its contents.
- The information provided to Dr Chang and the Australian Directors on 14 March 2020 was therefore considered to be incomplete. Given the sensitivity of the matter, particularly the global demand for COVID-19 diagnostic kits, TDL directors considered it reasonably necessary to take precautionary measures and seek formal confirmation of this matter, including documentary evidence such as copies of the certificates confirming the CE Mark certification and associated technical information, in order to make fulsome and accurate disclosure to the market of the said CE Mark certification and TBG Xiamen's intended use of the COVID Diagnostic Kits.
- Promptly after receipt of the English translation of the information relating to the CE Mark certification of the COVID Diagnostic Kits on

the 17<sup>th</sup> March morning, Mr Arulampalam arranged a phone call with directors to discuss the step(s) that needed to be followed to ensure TLD's continuous compliance with the ASX Listing Rules (specifically, ASX Listing Rule 3.1), including, whether TDL could make an announcement or place the company on trading halt.

(iii) Pages 7, 8, 9 and 10, of Appendix B are extracts of correspondences between Dr Chang and Mr Jian Yang, the chairman of TBG Xiamen's board on 16 March 2020 around 9:11pm (GMT) (i.e. 12:11am AEDT on 17 March 2020), where Dr Chang received formal confirmation on the CE Mark certification and associated documents in respect of COVID Diagnostic Kits.

- Pages 11 to 18 of Appendix B comprise of:
  - a copy of the email sent by Dr Chang to Mr Arulampalam on 16 March 2020 at 9:45pm (GMT) / 17 March 2020 at 12.45am (AEDT), providing a copy of the formal CE Mark Certificate and users manual of COVID Diagnostic Kit and companion PCR device and advising them that Mr Willy Hsu is in the process of preparing an announcement. Dr Chang also emphasised to the directors to keep the information confidential; and
  - Copies of the attachments sent with the email.

(c) **Correspondence between Dr Stanley Chang and the other directors of TDL in relation to the CE Mark certification, including (but not limited to) correspondences between 14 and 17 March 2020**

Please refer to our comments in Paragraph 2(b) above

(d) **the agreement(s) governing the management, governance and operations of TBG Xiamen (following completion of the transactions detailed in paragraph A above), including details of TDL's involvement (if any) in the management, governance and operations of TBG Xiamen**

A copy of the joint venture agreement entered into between TBG Inc, (a wholly owned subsidiary of TDL), TBG Xiamen, the founding shareholders of Changsha ChangYe Medical Laboratory Corp (previously referred by the name "Zhangsha ZhangYe Medical Laboratory Corp") ('**ChangYe Founding Shareholders**') and others on or around December 2018 in relation to their investment in, and the management, governance and operation of, of TBG Xiamen ('**JV Agreement**') and a certified translation are attached to this letter as Appendix C.

As announced on Monday 17 December 2018, TBG Inc entered into the JV Agreement with the ChangYe Founding Shareholders and Dongyuan Huaxin (Beijing) Capital Management Co Ltd ('**Dongyuan**') under which:

- (i) the ChangYe Founding Shareholders acquired a total of 42.1% of the issued shares in TBG Xiamen in consideration for it transferring all of the issued shares in Changsha ChangYe Medical Laboratory Corp ('**ChangYe**'); and
- (ii) Dongyuan acquired 11.25% of the issued shares for cash consideration,

reducing TDL's indirect shareholding (through its wholly subsidiary TBG Inc) in TBG Xiamen to below 50% (namely, 46.65%) ('**ChangYe Acquisition**').

It is noted that the JV Agreement was fully executed and exchanged on late Friday 14 December 2018.

Upon completion of ChangYe Acquisition, TBG Xiamen ceased to be a subsidiary of, and became an investee of, TDL.

As a holder of 46.65% of the issued voting shares in TBG Xiamen only, TDL/TBG Inc does not have control over any decisions required to be determined by the shareholders of TBG Xiamen. Nor does TDL/TBG Inc have control of TBG Xiamen's board and/or the management and operations of TBG Xiamen.

### **Responsibility of shareholders of TBG Xiamen**

Following completion of ChangYe Acquisition, the governance and overall management of TBG Xiamen and its business operations are vested in Dongyuan and the ChangYe Founding Shareholders, as provided in clause 16 of the JV Agreement, while TBG Inc retains the responsibility for overseeing and managing TBG Xiamen's research and development and product manufacture (Chapter 9 of the JV Agreement).

### **Composition of the TBG Xiamen Board**

Pursuant to Chapter 7 of the JV Agreement, the board of TBG Xiamen comprises of 7 directors, of which:

- (a) TBG Inc has a right to appoint 3 directors; and
- (b) the ChangYe Founding Shareholders and Dongyuan collectively have a right to appoint 4 directors (including the Chairman and the Vic Chairman).

As at the date of the letter, the board of TBG Xiamen comprises of the following personnel

Name	Role	Location	Appointed by
Stanley Chang	Director	Taiwan	TBG Inc
Eugene Cheng	Director	Taiwan	TBG Inc
Bill Ou	Director	Taiwan	TBG Inc
Xiao-Jun Zhao	Director	China	ChangYe Founding Shareholders and Dongyuan
Feng Pan	Director	China	ChangYe Founding Shareholders and Dongyuan
Jian Yang	Chairman and director	China	ChangYe Founding Shareholders and Dongyuan

Jing Liu	Director	China	ChangYe Founding Shareholders and Dongyuan
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The TBG Xiamen's board is responsible for determining the material decisions in relation to the company, including amendments to constitution, capital raising, merger and divestment, only.

### **Day-to-day management of TBG Xiamen**

It is noted that the directors appointed by TDL to the board of TBG Xiamen are non-executive directors and are involved nor participate in the day-to-day management and governance of TBG Xiamen.

The day-to-day management and governance of TBG Xiamen and its business operations (including formulation of policies, business plan and budgets to be applied in the conduct of the business) are in fact vested in the General Manager and Deputy General Manager(s) of TBG Xiamen, appointed by the Dongyuan and the ChangYe Founding Shareholders,

In addition to the General Manager and the Deputy General Managers, TBG Xiamen has 3 supervisors who are responsible for the audit of the company's financial information, the TBG Xiamen board's compliance with the law and the company's policies and the enforcement of any breach or non-compliance by a director of TBG Xiamen.

### **CE mark certification of TBG Xiamen**

In this instance, it is noted that the Chinese based directors of TBG Xiamen (being those directors appointed to the TBG Xiamen board by Donguan and ChangYe Founding Shareholders) were responsible for overseeing the compliance with the conformity assessment procedures required for the CE mark certification of COVID Diagnostic Kits. Dr Chang had no involvement in this matter and relied on information provided or disclosed by the Chinese based directors of TBG Xiamen.

- (e) **The arrangements that TDL implemented with TBG Xiamen following completion of the transactions detailed in paragraph A of the 24 March Letter to facilitate TDL's receipt of information regarding TBG Xiamen such that it can comply with its obligations under the listing rules, including listing rule 3.1**

It is noted that TBG Xiamen has not formally adopted any disclosure or communication policy to facilitate TDL's receipt of information regarding TBG Xiamen.

Whilst TDL, via TBG Inc, has nominated three directors to the board of TBG Xiamen, as indicated above, all of them are based in Taiwan. Since completion of the ChangYe Acquisition, neither TDL nor any of its nominated directors to the board of TBG Xiamen has been involved in the day to day management of TBG Xiamen (including the compliance with the conformity assessment procedures required for the CE mark certification of COVID Diagnostic Kits).

TDL therefore relies heavily on the Chinese based directors (being those directors appointed to the TBG Xiamen board by Donguan and ChangYe Founding Shareholders) to provide information regarding TBG Xiamen on a

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timely basis. Usually, such information is communicated to TDL nominated Taiwanese based directors via TBG Xiamen board meetings.

Through the recent CE mark certification incident, the TDL directors recognise now that this informal communication protocol between TBG Xiamen and TDL may not provide secure, effective and efficient information flow that is necessary to enable TDL to comply with its disclosure obligations under ASX Listing Rule 3.1.

TDL directors are now taking steps to implement stronger communication protocols to ensure that relevant information from TBG Xiamen is communicated to them swiftly and prior to any public announcement being made by TBG Xiamen.

**(f) Any agreement(s) or purchase order(s) received to date for the sale of TBG Xiamen's COVID-19 Virus Diagnostic Kits in Europe**

It is noted that there is currently no agreement or purchase order received for the sale of TBG Xiamen's COVID-19 Virus Diagnostic Kits in Europe.

However, several potential customers have requested for sample of the COVID Diagnostic Kits. Please see Appendix D, an email from a potential customer in Italy requesting samples. Other potential customers requested for samples by phone calls.

**(g) The licensing agreement between TBG Taiwan and TBG Xiamen referred to on page 6 of the Preliminary Final Report**

A copy of the licensing agreement between TBG Biotechnology Corp. ('**TBG Taiwan**') and TBG Xiamen on or about 1 December 2017 (while both companies were still wholly subsidiaries of TDL) ('**Licensing Agreement**') and a certified translation are attached to this letter as Appendix E.

**(h) The approval by the Health Competent Authority of the Province of Hunan of ChangYe as a designated testing lab for 2019-nCov**

A copy of the approval notice issued by the Health Commission of the Province of Hunan of ChangYe as a designated testing lab for 2019-nCov on 13 February 2020 (as announced on 27 February 2020) ('**Testing Lab Approval**') and a certified translation are attached to this letter as Appendix F.

It is noted that the TDL directors reasonably considered this information did not constitute price/market sensitive information having regard to all circumstances at the time. Out of abundance of caution, the TDL directors decided to make disclosure of the Testing Lab Approval. The fact that there was no price movement after the disclosure seems to support the TDL directors' assessment at the time that the Testing Lab Approval was not a price sensitive information.

**(i) The office lease agreement(s) between TBG Taiwan and Medigen Biotechnology Corporation**

A copy of the office lease agreement between TBG Taiwan and Medigen Biotechnology Corporation dated 1 January 2018 and a certified translation are attached to this letter as Appendix G.

TDL has formed a view that the office lease agreement reflects the arm's length commercial rent payable for office of the same or similar size in the surrounding area.

TDL also considered that having regard to the rent payable and the revenue generated from its business operations at the time, the office lease did not warrant disclosure at the time.

**(j) The agreements and/or purchase orders and the invoices pertaining to the sales of goods to Medigen Biotechnology Corporation in FY2017, FY2018 and FY2019**

Copies of the invoices pertaining to the sales of goods to Medigen Biotechnology Corporations in FY2017, FY2018 and FY2019 and a certified translation are attached to this letter as Appendix H.

**3. Who manufactures or will manufacture TBG Xiamen's COVID Diagnostic Kits?**

It is noted that TBG Xiamen manufactures, and it is anticipated that it will continue to manufacture, its own COVID Diagnostic Kits.

**4. How many COVID Diagnostic Kits has TBG Xiamen manufactured to date, how many has it sold and how much revenue has it derived from the sale of these kits to date?**

It is noted that 4,200 COVID Diagnostic Kits had been manufactured by TBG Xiamen as at 25 March 2020. Several potential customers have inquired and requested for samples of the kits, however, there is no purchase order as at the date of this letter.

**5. How many Coronavirus test samples from Hunan Province have been analysed by ChangYe to date, and how much revenue has been derived by ChangYe/TBG Xiamen for the provision of these services to date?**

It is noted that 18,215 samples from Hunan Province had been analysed by ChangYe as at 24 March 2020, and a revenue of RMB2,914,400 had been derived by ChangYe for the provision of these services between 13 February 2020 and 24 March 2020.

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

The Company is currently in compliance with the Listing Rules, and in particular, Listing Rule 3.1.

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

Confirmed. This response has been authorized accordingly.



Jitto Arulampalam  
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Executive Chairman

On behalf of the Board of Directors  
TBG Diagnostics Limited

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24 March 2020

Reference: 15933

Mr Justyn Stedwell  
Company Secretary  
TBG Diagnostics Limited  
Level 27  
101 Collins Street  
Melbourne VIC 3000

By email

Dear Mr Stedwell

**TBG Diagnostics Limited ('TDL'): Query Letter**

ASX refers to the following:

- A. TDL's announcement titled 'Acquisition of Zhangsha ZhangYe Medical Laboratory Corp', which was released on the ASX Market Announcements Platform ('MAP') on 17 December 2018 and included the following statements:

*'[TDL] has entered into an agreement (through its wholly owned subsidiary TBG Biotechnology Xiamen ("TBG Xiamen")) to acquire Zhangsha ZhangYe Medical Laboratory Corp. ("ZhangYe"), a company incorporated in China which conducts a business of providing medical laboratory testing services to hospitals and the community ...*

*In consideration for the acquisition of 100% issued capital in ZhangYe the Company will transfer shares constituting 42.1% of TBG Xiamen to the founding shareholders of Zhangsha ZhangYe Medical Laboratory Corp.*

*Dongyuan Huaxin (Beijing) Capital Management Co Ltd ("Dongyuan"), one of the parties in the agreement, is a private equity firm incorporated in China and will provide capital investment into TBG Xiamen ...*

*Under the agreement with Dongyuan, shares equaling 11.25% of TBG Xiamen's share capital will be issued to Dongyuan for cash consideration of RMB 10,679,283, which will be reinvested in TBG Xiamen ("Dongyuan Investment") ...*

*After completion of the transactions, the Company will hold 46.65% of the equity in TBG Xiamen and TBG Xiamen will hold 100% of the equity in ZhangYe, such that the Company will indirectly hold an interest of 46.65% in ZhangYe ...'*

- B. TDL's annual report for the financial year ended 31 December 2018, which was released on MAP on 26 March 2019 and included the following disclosures:

- a) *'Out of total revenues, \$954,586 (2017: \$1,815,907) was derived from a related party in Taiwan. This revenue is attributable to the In Vitro Diagnostics segment.'*
- b) In Note 27(b) to the financial statements: Related party transactions with TDL's ultimate parent company, Medigen Biotechnology Corporation, a company incorporated in Taiwan, namely:
- 'Revenues - Sale of goods' of \$954,586 in FY2018 and \$1,815,907 in FY2017.
  - 'Expenses - Office lease' of \$181,377 in FY2018 and \$175,190 in FY2017.

- 'Receivables from related party - Trade receivables' of \$319,450 at 31 December 2018 and \$587,854 at 31 December 2017.
- C. TDL's half year report for the six months ended 30 June 2019, which was released on MAP on 30 August 2019, and included the following disclosure:
- 'Related party sales to the parent, Medigen Biotechnology Corp. amounted to \$425,619 (2018: \$391,788) representing 27% (2018: 30%) of total revenues.'*
- D. TDL's preliminary final report for the financial year ended 31 December 2019 ('Preliminary Final Report'), which was released on MAP on 28 February 2020, and included the following disclosures:
- a) *'Out of total revenues, \$1,315,053 (2018: \$954,586) was derived from related parties in Taiwan and in China.'*
  - b) The carrying value of TDL's investment in TBG Biotechnology Corp. (Xiamen) Group (treated as an investment in associates accounted for under the equity method) was \$3,143,236 at 31 December 2019.
- E. TDL's announcement titled 'ZhangYe approved as designated testing lab for Coronavirus', which was released on MAP on 27 February 2020 and included the following statements:
- 'Zhangsha ZhangYe Medical Laboratory Corp. (ZhangYe), a subsidiary of TBG Biotechnology Xiamen ("TBG Xiamen") which TDL have invested in, has been approved by the Health Competent Authority of the Province of Hunan (China) as a designated testing lab for 2019-nCov among other labs. As a designated lab, currently considerable samples from all over Hunan Province have been sent to ZhangYe Medical Laboratories for analysis service, mainly from hospitals and corporate clients whose employees have to be screened.'*
- F. TDL's request for its securities to be placed in trading halt on 17 March 2020, which was granted by ASX, pending an announcement relating to the certification of TBG Xiamen's COVID-19 Nucleic Acid Diagnostics Kit.
- G. TDL's announcement titled 'CE Mark approval of COVID-19 Virus Diagnostic Kit' released on MAP on 18 March 2020, which disclosed that TBG Xiamen had received CE mark approval for its COVID-19 Nucleic Acid Diagnostics Kit ('Announcement') and noted that *'TBG Xiamen's kit will be available for immediate validation and purchase.'*
- H. ASX's price query letter dated 17 March 2020 and TDL's response, which were released together on MAP on 18 March 2020 (the 'Price Query').
- I. ASX's aware query letter dated 18 March 2020 and TDL's response, which were released together on MAP on 19 March 2020 (the 'Aware Query'), and included the following statements:
- a) *'TDL first became aware of the CE Mark certification on Saturday, 14 March 2020 when one of its' directors Dr Stanley Chang was informally notified of the CE Mark certification by TBG Xiamen's operations personnel in China.'*
  - b) *'... the TDL directors sought from TBG Xiamen's operations team the formal confirmation of this matter, including documentary evidence such as copies of the certificates confirming the CE Mark certification.'*
- The formal confirmation of the CE Mark certification and associated documentation was supplied to Dr Chang on the evening of Monday, 16 March 2020 and then on-sent by him to the Australian-based TDL directors on Tuesday, 17 March 2020 at 12.45am.'*

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- c) *'The TDL directors understood and reasonably believed that the relevant information remained confidential between the period of 14 March 2020 (receipt of informal notification of the CE Mark certification) and the morning of 17 March 2020 (receipt of formal documentary information to confirm CE Mark certification).'*

### Questions and Request for Information

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

1. Please provide a detailed explanation as to why the TDL directors 'reasonably believed' that the CE Mark certification remained confidential between the period of 14 March 2020 and the morning of 17 March 2020, especially in light of TDL's share price movements on 16 and 17 March 2020.
2. Please provide copies of the following documents to ASX and, if any of these documents are not in English, a certified translation of the document into English (not for release to the market<sup>1</sup>):
  - a) TBG Xiamen's application for the CE Mark certification, its correspondence with the relevant authority concerning the CE Mark certification, and the final CE Mark certification;
  - b) correspondence between Dr Stanley Chang and TBG Xiamen personnel in relation to the CE Mark certification, including (but not limited to) correspondence on 14 and 16 March 2020;
  - c) correspondence between Dr Stanley Chang and the other directors of TDL in relation to the CE Mark certification, including (but not limited to) correspondence between 14 and 17 March 2020;
  - d) the agreement(s) governing the management, governance and operations of TBG Xiamen (following completion of the transactions detailed in paragraph A above), including details of TDL's involvement (if any) in the management, governance and operations of TBG Xiamen;
  - e) the arrangements that TDL implemented with TBG Xiamen following completion of the transactions detailed in paragraph A above to facilitate TDL's receipt of information regarding TBG Xiamen such that it can comply with its obligations under the listing rules, including listing rule 3.1;
  - f) any agreement(s) or purchase order(s) received to date for the sale of TBG Xiamen's COVID-19 Virus Diagnostic Kits in Europe;
  - g) the licensing agreement between TBG Taiwan and TBG Xiamen referred to on page 6 of the Preliminary Final Report;
  - h) the approval by the Health Competent Authority of the Province of Hunan of ZhangYe as a designated testing lab for 2019-nCov;
  - i) the office lease agreement(s) with Medigen Biotechnology Corporation; and
  - j) the agreements and/or purchase orders and the invoices pertaining to the sales of goods to Medigen Biotechnology Corporation in FY2017, FY2018 and FY2019.
3. Who manufactures or will manufacture TBG Xiamen's COVID-19 Virus Diagnostic Kits?
4. How many COVID-19 Virus Diagnostic Kits has TBG Xiamen manufactured to date, how many has it sold and how much revenue has it derived from the sale of these kits to date?

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<sup>1</sup> The fact that ASX tells an entity that a document is not for release to the market does not prevent ASX from releasing any of the information contained in the document (as opposed to the document itself) to the market if ASX considers it necessary to inform the market.

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5. How many Coronavirus test samples from Hunan Province have been analysed by ZhangYe to date (see paragraph E above), and how much revenue has been derived by ZhangYe/TBG Xiamen for the provision of these services to date.
  6. Please confirm that TDL is complying with the Listing Rules and, in particular, Listing Rule 3.1.
  7. Please confirm that TDL's responses to the above questions and requests have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of TDL 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 **9:30am AEDT on Friday, 3 April 2020**.

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. 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 TDL'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 TDL'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.

#### **Enquiries**

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

Yours sincerely

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**Corey Lian**  
Adviser, Listings Compliance (Sydney)