ENFORCEABLE UNDERTAKING

Therapeutic Goods Act 1989

Section 42YL

The commitments of this undertaking are offered to the Secretary of the Australian Department of Health and Aged Care given for the purposes of section 42YL of the *Therapeutic Goods Act 1989* (**the Act**) by

2San Pty Ltd ACN 641 633 141

Definitions

The following definitions are used in this undertaking:

- the **Department** means the Commonwealth Department of Health and Aged Care
- the **Act** means the *Therapeutic Goods Act 1989* (Cth)
- **Products** means a 2San Bacterial Vaginosis Test and a 2San Pregnancy Kit Midstream
- **2San** means the person given the undertaking
- **Register** means the Australian Register of Therapeutic Goods
- the **Regulations** means *the Therapeutic Goods Regulations 1990*, and or the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth).
- the **Secretary** means the Secretary of the Australian Department of Health and Aged Care
- **TGA** means the Therapeutic Goods Administration, part of the Department

Persons giving this undertaking

(1) This undertaking is given to the Secretary by 2San Pty Ltd (ACN 641 633 141) (**2San**) of [redacted], NSW, 2000, Australia for the purposes of section 42YL of the Act.

Background

(2) 2San is a wholly owned subsidiary of 2San Global Holdings Ltd based in the UK. 2San imports and supplies in Australia therapeutic goods within the meaning of the Act.

(3) 2San imported into Australia and supplied medical devices being the Products that were not included in the Register. The same products in different packaging (and with different numbers of devices in the package) were registered being ARTG 368511 and ARTG 387374.

(4) On 15 December 2023, the TGA issued a Notice to 2San under section 45AB(1) of the Act requiring 2San to provide information to the TGA. 2San provided the information requested. On 4 March 2024, the TGA issued a notice to 2San giving it an opportunity to provide submissions as to why regulatory action should not be taken in relation to the alleged unlawful importation and supply of a medical device of a kind not included in the Register. On 28 March 2024, 2San notified the TGA that it admitted a contravention of section 41MIB(1)(a)(i) and (ii) of the Act. 2San did not seek to rely on the exemption in section 41MIB(2) of the Act.

(5) 2San ceased import of the Products in May 2023, when it became aware of a possible regulatory breach. It ceased supply of the Products in August 2023.

The Relevant Law

(6) Section 41MIB(1)(a) of the Act provides that a person contravenes that section if the person imports into Australia or supplies in Australia a medical device to which none of the exclusions in section 41MIB(1)(b) apply. None of the exclusions in section 41MIB(1)(b) applied to 2San. Section 41MIB(2) provides that subsection (1) did not apply if the person importing and/or supplying as the case may be was not the sponsor of the device at the time of the said importation or supply. 2San accepts that in the circumstances it was the sponsor of the Products when they were imported into Australia and supplied in Australia.

(7) A breach of section 41MIB is a civil penalty provision.

The Secretary's conclusion as to breach/contravention of the Act

(8) The Secretary has formed a reasonable belief that 2San has contravened section 41MIB(1)(a)(i) of the Act by importing into Australia the Products, based on documents supplied by 2San, at a time when the Products were not included in the Register.

(9) The Secretary has formed a reasonable belief that 2San has contravened section 41MIB(1)(a)(iii) of the Act by supplying in Australia the Products, based on documents supplied by 2San, at a time when the Products were not included in the Register.

Acknowledgement of breach

(10) 2San admits that the conduct described at paragraph (3) above contravened the Act.

(11) 2San has taken action to address the non-compliance with the Act including by:

(a) ceasing importation and supply of the Products for so long as they remain not included in the Register;

(b) employing a new member to join its global Quality and Regulatory department to be based in Australia (commencing 1 May 2024);

(c) entering into a Quality Agreement with 2San Global Holdings Ltd which includes the requirement of an annual audit conducted in person by the Global Director of Quality and Regulatory (**Quality Agreement**);

(d) implementing a Quality Management System (**Compliance Program**)

(e) making applications to the TGA for sponsorship of its own-branded products to create a more direct link with the TGA;

(f) enrolling in the TGA's Medical Device Vigilance Program.

Period of undertaking

(12) This undertaking comes into effect when both the following are satisfied:

(a) the undertaking is executed by 2San; and

(b) the Secretary accepts the undertaking so executed.

(13) Upon the commencement of this undertaking 2San undertakes to assume the obligations set out in paragraphs (15)-(23) below.

(14) This undertaking terminates two (2) years following its commencement.

Undertakings

(15) Under section 42YL of the Act 2San has offered, and the Secretary has agreed to accept the following undertakings:

(a) that it will not, for the period that this undertaking is in effect, in trade or commerce:

(i) import into Australia;

(ii) supply in Australia;

therapeutic goods in any way which is in breach of the requirements of the Act or Regulations;

(b) that for the period that this undertaking is in effect it will:

(i) remain a party to and comply with its obligations under the Quality Agreement;

(ii) participate in an annual audit by 2San Global Holdings Limited and deliver the audit report to the TGA;

(iii) participate in work by 2San Global Holdings Limited to seek to obtain certification under ISO 13485:2016 Medical devices: Quality management systems, Requirements for regulatory

purposes, making such systems and process changes as are required for 2San Global Holdings Limited to obtain and maintain such certification;

(iv) engage an externally qualified compliance professional and implement their recommendations as set out below;

(c) for the period that this undertaking is in effect, it will monitor and report on the implementation of this undertaking by:

(i) producing a written report to the TGA at the expiration of each six (6) month period while this undertaking remains in effect of the matters stated by subparagraph (b)(i)-(b)(iii) above. Such report will be signed off by the local Managing Director of 2San and the Global Director of Quality and Regulatory;

(d) that it will pay the costs of its compliance with this enforceable undertaking;

(e) that it will provide all documents and information requested by the Secretary from time to time for the purposes of assessing its compliance with the terms of this enforceable undertaking;

(f) that where 2San identifies any instances where it reasonably suspects that 2San has failed to comply with the Act or the Regulations, it will notify the TGA within 48 hours of these matters being identified.

Engagement of an external qualified compliance professional

(16) 2San undertakes, within one (1) month of the date of execution of this undertaking, at its own expense, to engage an external qualified compliance professional to advise and assist with the implementation of any suggested regulatory procedures to ensure that it does not contravene the Act.

(17) For the purposes of this undertaking, an external qualified compliance professional is a person with experience in advising on compliance matters concerning the regulation of therapeutic goods in Australia, who has no financial or other interest in the business activities of 2San.

Annual written report and interim reports

(18) For the period of this undertaking, 2San undertakes to require the external qualified compliance professional to provide an annual written report to the TGA regarding:

(a) its compliance with the Act;

(b) a review of its Compliance Program, and

(c) the relevant qualifications and experience of the external qualified compliance professional.

(19) The annual written report will, at a minimum, address and include the matters specified below:

(a) the external qualified compliance professional's assessment as to whether 2San has in place an effective Compliance Program that complies with the requirements of this undertaking; and

(b) the external qualified compliance professional's assessment as to whether the Compliance Program of 2San complies with medical device industry best practice; and

(c) details of the information gathered and examined during the review; and

(d) the name and relevant experience of the persons appointed by 2San as members of the global Quality and Regulatory department; and

(e) actions recommended by the external qualified compliance professional to ensure the effectiveness of the Compliance Program; and

(f) details of any identified non-compliance with the Act or the Regulations, as well as the details of corrective actions implemented by 2San to prevent a re-occurrence of these non-compliances; and

(g) a signed statement by the external qualified compliance professional that they have seen this undertaking, that they have prepared the annual written report and that, notwithstanding they were engaged by 2San, the report contains their impartial and professional assessments and opinions.

(20) 2San undertakes to ensure that:

(a) the first annual review is completed by the external qualified compliance professional and the written report relating to that review is provided by that person to the TGA prior to 31 December 2024;

(b) the second annual review is completed by the external qualified compliance professional and the written report relating to the review is provided by that person to the TGA prior to 31 December 2025;

(c) it implements all reasonable recommendations made by the external qualified compliance professional to ensure the effectiveness of the Compliance Program.

(21) If the TGA reasonably suspects that the Compliance Program is not being implemented effectively by 2San, the TGA may request that it prepare an interim report, in addition to the reports above. On receipt of such a request, 2San must:

(a) cause an interim report (to which paragraphs (19) and (20) apply) to be prepared by the external qualified compliance professional and provided to 2San within thirty (30) days of the request; and

(b) give a copy of the report to the TGA within fourteen (14) days after it is received by 2San.

Provision of assistance by 2San to the external qualified compliance professional

(22) 2San will ensure that the external qualified compliance professional has access to any information the external qualified compliance professional requires for the purposes of their review of the 2San Compliance Program, and the preparation of the annual written report.

Recall of products

(23) 2San will undertake reasonable efforts to recall the Products imported and supplied in Australia as part of the offending conduct as set out below.

(24) 2San will:

(a) instigate a recall which shall be a Class III recall to the retail level;

(b) deliver a recall letter to the single retail customer of the Products in Australia;

(c) advise the Australian Competition and Consumer Commission of the recall;

(d) confirm to the TGA that steps (b) and (c) above have been carried out within three (3) months of the date of execution of this Undertaking.

(25) 2San and the TGA acknowledge that in light of the Class and level of recall, the fact of the last supply being in August 2023, the nature of the Products themselves being immediate tests, and the similarity in packaging to legitimate products with a different sponsor, that a return of products is highly unlikely.

Industry awareness

(26) 2San has obtained membership of ARCS Australia, and in respect of that registration will:

(a) attend a conference in Sydney June 2024, by its Director of Global Quality & Regulatory; and

(b) seek to deliver at the conference a 20 minute presentation; and

(c) submit to the ARCS journal Cognitio a copy of the said presentation; and

(d) become engaged in a meaningful way with other ARCS functions at least during the period of the Enforceable Undertaking, including by attending conferences; and

(e) at the expiration of eighteen (18) months from the commencement of the Enforceable Undertaking, will deliver a written report to the TGA detailing its activities in respect of its ARCS membership over the preceding period.

Acknowledgements

(27) 2San acknowledges that:

(a) this undertaking was given voluntarily by 2San Pty Ltd (ACN 641 633 141);

(b) the Secretary may make this undertaking and information about this undertaking publicly available including by publishing it on the TGA's website for so long as the undertaking shall remain in effect;

(c) the Secretary may, from time to time, make public reference to this undertaking including in news media statements and in publications by the TGA or the Department including on various forms of social media;

(d) this undertaking in no way derogates from the rights and remedies available to the Secretary, the Commonwealth or to any other person arising from the conduct referred to in paragraph (3);

(e) the Secretary's acceptance of this enforceable undertaking does not affect the power of the Secretary to investigate or pursue a criminal prosecution, to seek a pecuniary civil penalty or use any other power available to the Secretary under the Act in relation to any contravention or breach, or possible contravention or possible breach of the Act (not referred to in the Background section of this enforceable undertaking) arising from future conduct;

(f) this undertaking has no operative force until accepted by the Secretary.

(28) 2San and the Secretary acknowledge that the date of this undertaking is the date on which it is accepted by the Secretary.

Executed by

The common seal of 2San Pty Ltd (ACN 641 633 141) was affixed in the presence of:

Secretary/Director

.....
Director

This 24th day of June 2024

ACCEPTED BY THE ACTING ASSISTANT SECRETARY OF THE REGULATORY COMPLIANCE BRANCH, HEALTH PRODUCTS REGULATION GROUP (INCORPORATING THE TGA AND THE OFFICE OF DRUG CONTROL) AS DELEGATE OF THE SECRETARY UNDER SECTION 42YL OF THE ACT

Tracey Lutton
Acting Assistant Secretary
Regulatory Compliance Branch

Delegate of the Secretary

This 28th day of June 2024