FOI 3581 – Infants' Friend – ARTG 367810

Documents sent to and received from Brookbar Pharma Pty Ltd (ACN 649149360) and/or its agents/representatives ("Sponsor") in relation to the change in sponsorship of Infants Friend and/or its reformulation and relaunch which meet the following descriptions:

Background information:

Infants' Friend Oral Liquid, ARTG 367810, Sponsor Brookbar Pharma Pty Ltd, was listed on the ARTG on 1/6/2021 as a **listed medicine**. This ARTG entry has never had a change in sponsorship or reformulation and does not contain chloroform. Brookbar Pharma Pty Ltd also has another therapeutic good included in the ARTG, which is a medical device.

There is a cancelled **Registered Complementary Medicine**, ARTG entry:

ARTG no	ARTG name	Sponsor	Cancelled from the ARTG
26678	Infants' Friend Oral Liquid bottle	Infant's Friend Pty Ltd	15/02/2021

Which does contain chloroform and two of the company contacts:

- [redacted]
- [redacted]

Are contacts for both:

- Infant's Friend Pty Ltd
- Brookbar Pharma Pty Ltd

A - safety data provided by the Sponsor (including with respect to active and excipient ingredients contained in the reformulation, and any dolente regarding the presence of chloroform in the previous formulation)

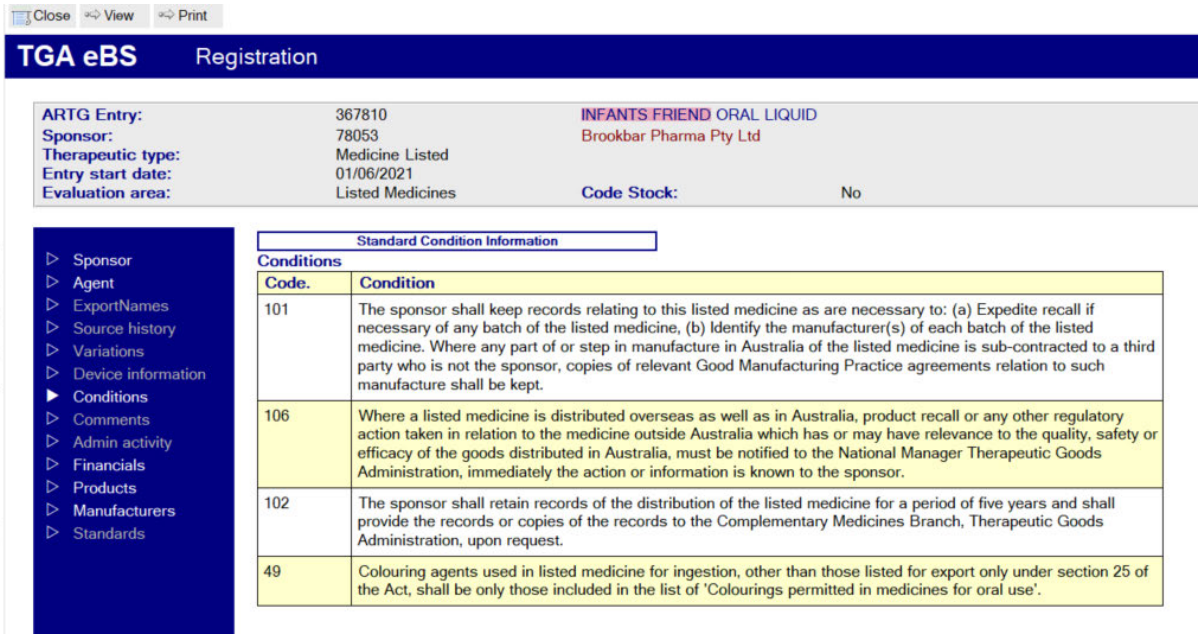
Listed medicine must comply with all validation rules relating the ingredients, indications, dosage forms, routes of administration etc. There is no pre-market assessment, therefore no safety data provided by the sponsor.

B - conditions which the TGA has imposed on the Sponsor and/or undertakings the TGA required the sponsor to give

Conditions imposed at the time of listing:

- 101
- 106

- 102
- 49



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TGA eBS Registration

ARTG Entry:	367810	INFANTS FRIEND ORAL LIQUID	
Sponsor:	78053	Brookbar Pharma Pty Ltd	
Therapeutic type:	Medicine Listed		
Entry start date:	01/06/2021		
Evaluation area:	Listed Medicines	**Code Stock:**	No

- Sponsor
- Agent
- ExportNames
- Source history
- Variations
- Device information
- ▶ Conditions
- Comments
- Admin activity
- Financials
- Products
- Manufacturers
- Standards

Standard Condition Information

Conditions

Code.	Condition
101	The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.
106	Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.
102	The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.
49	Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

C - company information regarding the Sponsor including the names of its directors (noting it was only registered early this year after the liquidation of the former sponsor company), and

Company details on TGA's client database:

- organisation no 78053
- contacts [redacted]
- ABN 37 649 149 360

D - correspondence relating to any of the above..."

Search of trim did not bring up any correspondence between TGA and the sponsor Brookbar Pharma Pty Ltd after September 2020 until the 1 December 2021.

There has been an FOI request – 1984 and correspondence between TGA and Infant's Friend Pty Ltd.