From: s 22
To: s 22 ; s 22
Subject: FW: [ATTACHMENT UNSCANNED]Re: TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories [SEC=OFFICIAL]
Date: Monday, 4 March 2024 8:24:48 AM
Attachments: image001.png
Liber Pharmaceuticals - TGA Consultation response - Proposed new requirements for therapeutic vaping devices and accessories.pdf
image002.png

---

s 22
s 22 Scientific Operations Management Section
Scientific Evaluation Branch
Medicines Regulation Division | Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s 22
Location: s 22
PO Box 100, Woden ACT 2606, Australia
The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s 22
Sent: Sunday, March 3, 2024 6:58 PM
To: NVP
Cc: s 22 ; s 22
Subject: [ATTACHMENT UNSCANNED]Re: TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories [SEC=OFFICIAL]

Dear Vaping Reform Team

I have attached a copy of Liber Pharmaceutical's response to the consultation on proposed requirements for therapeutic vaping devices and accessories. We have completed the online survey as requested, however, our written response contains additional context and information which we hope the review team may find useful.

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Regards

s 22

s 22
s 22

Logo

Liber Pharmaceuticals Pty Ltd
s 22

www.liber.com.au

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Thank you for your time and attention.

Best regards

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Health Products Regulation Group
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To: s 22 ; s 22
Subject: FW: [ATTACHMENT UNSCANNED]Re: TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories [SEC=OFFICIAL]
Date: Monday, 4 March 2024 8:26:35 AM
Attachments: image001.png
Liber Pharmaceuticals - TGA Consultation response - Proposed new requirements for therapeutic vaping devices and accessories.pdf
image002.png

Hi s 22,
Can you please reply to this one. thanks

s 22
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From: s 22
To: s 22 s 22
Subject: RE: [ATTACHMENT UNSCANNED]Re: TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories [SEC=OFFICIAL]
Date: Monday, 4 March 2024 9:04:15 AM
Attachments: image001.png
image002.png

Hi s 22,
Will do.
Regards,
s 22 s 22
Devices Specialist Evaluation Section / MDAB / MDPQD
Ext. 3295

From: s 22
Sent: Monday, March 4, 2024 8:26 AM
To: s 22 ; s 22
Subject: FW: [ATTACHMENT UNSCANNED]Re: TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories [SEC=OFFICIAL]

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From:	[redacted]
To:	[redacted] [redacted]
Cc:	NVP
Subject:	TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories [SEC=OFFICIAL]
Date:	Monday, 4 March 2024 9:22:08 AM
Attachments:	ATTACHMENT UNSCANNEDRe TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories SECOFFICIAL.msg ATTACHMENT UNSCANNEDRe TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories SECOFFICIAL.msg ATTACHMENT UNSCANNEDRe TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories SECOFFICIAL.msg ATTACHMENT UNSCANNEDRe TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories SECOFFICIAL.msg image001.png

---

Good morning [redacted] and [redacted],

Please see attached emails from [redacted] (query about submission date) and [redacted] - Liber (containing submission).

Thank you.

Kind regards,

[redacted] [redacted]
[redacted] – Vaping Legislative Reform Branch
Health Products Regulation Group
Australian Government, Department of Health and Aged Care
[redacted]
P.O. Box 100, Woden ACT 2606, Australia

From: s 22
To: NVP
Cc: s 22 ; s 22
Subject: [ATTACHMENT UNSCANNED]Re: TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories [SEC=OFFICIAL]
Date: Sunday, 3 March 2024 11:04:55 PM
Attachments: image001.png
Liber Pharmaceuticals - TGA Consultation response - Proposed new requirements for therapeutic vaping devices and accessories.pdf **Please note: this attachment is the consultation response of Liber Pharmaceuticals, which is provided at Document 40.**

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From: s 22
Sent: Monday, 4 March 2024 12:37 PM
To: s 22
Cc: s 22
Subject: FW: [ATTACHMENT UNSCANNED]Re: TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories [SEC=OFFICIAL]
Attachments: Liber Pharmaceuticals - TGA Consultation response - Proposed new requirements for therapeutic vaping devices and accessories.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

For info.

Regards,
s 22 – s 22
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

From: s 22
Sent: Monday, March 4, 2024 8:25 AM
To: s 22
Subject: FW: [ATTACHMENT UNSCANNED]Re: TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories [SEC=OFFICIAL]

s 22
s 22 Scientific Operations Management Section
Scientific Evaluation Branch

Medicines Regulation Division | Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s 22
PO Box 100, Woden ACT 2606, Australia

From: s 22
Sent: Sunday, March 3, 2024 6:58 PM
To: NVP <NVP@Health.gov.au>
Cc: s 22 ; s 22
Subject: [ATTACHMENT UNSCANNED]Re: TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories [SEC=OFFICIAL]

The URL Reputation Scanner encountered an error and was unable to determine the reputation of one or more URLs contained within the e-mail message. Use caution when clicking on URLs contained within an e-mail message that has been sent to you by an unfamiliar sender.Dear Vaping Reform Team

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To: NVP; s 22
Cc: s 22
Subject: FW: [ATTACHMENT UNSCANNED]Re: TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories [SEC=OFFICIAL]
Date: Monday, 4 March 2024 4:07:18 PM
Attachments: image001.png
~WRD2940.jpg

Hi s 22 ,
Response for s 22

Good afternoon s 22 ,
Thank you for your email regarding the targeted consultation on proposed requirements for therapeutic vaping devices and accessories.
We appreciate your detailed response to the survey and also your additional written response. This information will help inform the proposed regulatory changes for therapeutic vaping devices and accessories.
We also appreciate the time you have taken to provide additional technical information and acknowledge the specific passages marked as 'Commercial in confidence'.
Thank you for taking to time to engage with us on this matter.

Regards,
s 22 – s 22
Devices Specialist Evaluation Section / MDAB / MDPQD
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[redacted]
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Cc: s 22 ; s 22 ; NVP
Subject: RE: [ATTACHMENT UNSCANNED]Re: TGA - Reminder to complete survey by 3 March 2024 - Targeted consultation on proposed requirements for therapeutic vaping devices and accessories [SEC=OFFICIAL]
Date: Monday, 4 March 2024 4:11:12 PM
Attachments: ~WRD0844.jpg
image001.png
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To: s 22 ; s 22
Cc: s 22 ; s 22 ; s 22 ; s 22
Subject: FOR INFO: quick update on vaping reforms - early stage survey results and possible direction of the MDSO [SEC=OFFICIAL]
Date: Tuesday, 5 March 2024 6:13:34 PM
Attachments: image001.png

Hi s 22, s 22,

A quick, early update on vaping device reforms. Whilst there is some way to go with the survey analysis (and the survey is still open), I am sharing the current thinking on the MDSO based on where things stand today noting it may change.

We have extended the stakeholder survey to COB 8 March due to a lack of responses late last week, however since then we have now received responses from the four major sponsors of therapeutic vapes (of those that have notified so far). This puts us in a much better position to consider the final requirements for the MDSO.

Survey

The following key sponsors have responded (as at today). We assume these sponsors are likely to represent the majority of vapes to be supplied from March – Dec 2024:

- Liber Pharmaceuticals Pty Ltd
- s 22
- s 22
- s 22

s 22

Preliminary thinking on MDSO

From the preliminary analysis at appears Liber s 22 s 22 could meet the following requirements for s 47 which are broadly in line with our workshop last week:

Possible MDSO requirements – for December 2024:

- IFU, Labelling, Plain packaging (mixed views about plain packaging but overall support even from most sponsors)
- s 47
- s 47
- Battery standards – including several options (most of these overlap, some significantly) – any one of the following:
  - s 47
  - s 47
  - s 47
  - (we'll need to decide if there should be any more options at this stage)
- Possible fundamental device safety requirements yet to be decided (e.g. interlocked activation – to prevent unintentional activation of the device when in transit/storage – this would need to come from a standard such as UL 8139)
- Compliance with other regulatory requirements for electrical and battery products such as:
  - ACCC requirements for button batteries (if appliable, none have indicated they use button batteries)
  - Various AS/NZS electrical requirements (e.g. for chargers)
  - ACMA requirements for EMC

  These may not reside in the MDSO but our guidance may direct sponsors to them

if/as appliable.

[redacted]

Possible stage 2: MDSO for December 2025 (or thereabouts)

Based on the responses from Liber, [redacted] they may be able to comply with the following by late 2025:

- All of the above plus:
- Toxicological risk analysis for the device – some claim to have already completed this including for the device ([redacted] Liber)
- [redacted] ([redacted] Liber [redacted])

Implementing these standards would increase stringency further but likely could not be implemented for this year without pushing some/several sponsors out and therefore risking the policy objective to ensure a therapeutic pathway for vapes.

There is still a significant gap between this stage 2 and what we would expect for ARTG inclusion.

Gap to ARTG inclusion (briefly):

- *Clinical evidence*
- Electrical standards for medical devices - IEC 60601-1-11:2015
- Software – IEC 62304

These are very significant in terms of timeframe to comply.

- Durability – Transport & storage requirements.
- Probably more

We'll provide a further update on Friday at the check-in meeting.

Kind Regards,

[redacted] – [redacted]
Devices Specialist Evaluation Section /
MDAB / MDPQD
[redacted]

From: s 22
To: s 22
Cc: s 22
Subject: RE: FOR INFO: quick update on vaping reforms - early stage survey results and possible direction of the MDSO [SEC=OFFICIAL]
Date: Tuesday, 5 March 2024 8:06:22 PM
Attachments: image001.png

Thanks s 22 for the update.
Re the batteries – I am increasingly become concerned about this. There has been media today around Australia's first deaths as a result of lithium batteries catching alight. I think we need to ensure we capture that well.
s 22

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Sent: Tuesday, March 5, 2024 6:14 PM
To: s 22
Cc: s 22
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- Toxicological risk analysis for the device – some claim to have already completed this including for the device ([redacted] Liber)
- [redacted] Liber[redacted])

Implementing these standards would increase stringency further but likely could not be implemented for this year without pushing some/several sponsors out and therefore risking the policy objective to ensure a therapeutic pathway for vapes.

There is still a significant gap between this stage 2 and what we would expect for ARTG inclusion.

Gap to ARTG inclusion (briefly):

- *Clinical evidence*
- Electrical standards for medical devices - IEC 60601-1-11:2015
- Software – IEC 62304

These are very significant in terms of timeframe to comply.

- Durability – Transport & storage requirements.
- Probably more

We'll provide a further update on Friday at the check-in meeting.

Kind Regards,

[redacted] – [redacted]
Devices Specialist Evaluation Section /
MDAB / MDPQD
[redacted]

From: s 22
To: s 22
Cc: s 22
Subject: RE: FOR INFO: quick update on vaping reforms - early stage survey results and possible direction of the MDSO [SEC=OFFICIAL]
Date: Wednesday, 6 March 2024 9:26:10 AM
Attachments: image001.png

Hi s 22 ,
We most certainly will be implementing standards for batteries including lithium batteries.
We are also investigating specific controls for the charger independent of the batteries because it is possible for a poor charger to cause a good battery to fail (catch fire or worse). There are several existing laws that cover requirements for chargers so we will be exploring if we either defer to those or apply them for vaping devices.
Regards,
s 22 – s 22
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

From: s 22
Sent: Tuesday, March 5, 2024 8:06 PM
To: s 22
Cc: s 22

Subject: RE: FOR INFO: quick update on vaping reforms - early stage survey results and possible direction of the MDSO [SEC=OFFICIAL]
Thanks s 22 for the update.
Re the batteries – I am increasingly become concerned about this. There has been media today around Australia's first deaths as a result of lithium batteries catching alight. I think we need to ensure we capture that well.
s 22

From: s 22
Sent: Tuesday, March 5, 2024 6:14 PM
To: s 22 s 22
Cc: s 22

Subject: FOR INFO: quick update on vaping reforms - early stage survey results and possible direction of the MDSO [SEC=OFFICIAL]
Hi s 22
A quick, early update on vaping device reforms. Whilst there is some way to go with the survey analysis (and the survey is still open), I am sharing the current thinking on the MDSO based on where things stand today noting it may change.
We have extended the stakeholder survey to COB 8 March due to a lack of responses late last week, however since then we have now received responses from the four major sponsors of therapeutic vapes (of those that have notified so far). This puts us in a much better position to consider the final requirements for the MDSO.
Survey
The following key sponsors have responded (as at today). We assume these sponsors are likely to represent the majority of vapes to be supplied from March – Dec 2024:

Liber Pharmaceuticals Pty Ltd

- s 22
- [redacted]
- [redacted]

s 22 [redacted]

Preliminary thinking on MDSO

From the preliminary analysis at appears Liber s 22 could meet the following requirements for s 47 which are broadly in line with our workshop last week:

Possible MDSO requirements – for December 2024:

- IFU, Labelling, Plain packaging (mixed views about plain packaging but overall support even from most sponsors)
- s 47
- s 47
- Battery standards – including several options (most of these overlap, some significantly) – any one of the following:
  - s 47
  - s 47
  - s 47
  - (we'll need to decide if there should be any more options at this stage)
- Possible fundamental device safety requirements yet to be decided (e.g. interlocked activation – to prevent unintentional activation of the device when in transit/storage – this would need to come from a standard such as UL 8139)
- Compliance with other regulatory requirements for electrical and battery products such as:
  - ACCC requirements for button batteries (if appliable, none have indicated they use button batteries)
  - Various AS/NZS electrical requirements (e.g. for chargers)
  - ACMA requirements for EMC

  These may not reside in the MDSO but our guidance may direct sponsors to them if/as appliable.

s 22 [redacted]

Possible stage 2: MDSO for December 2025 (or thereabouts)

Based on the responses from Liber s 22 they may be able to comply with the following by late 2025:

- All of the above plus:
- Toxicological risk analysis for the device – some claim to have already completed this including for the device (s 22 Liber)
- s 47 (s 22 Liber s 47 s 22)

Implementing these standards would increase stringency further but likely could not be implemented for this year without pushing some/several sponsors out and therefore risking the policy objective to ensure a therapeutic pathway for vapes.

There is still a significant gap between this stage 2 and what we would expect for ARTG

inclusion.

Gap to ARTG inclusion (briefly):

- *Clinical evidence*
- Electrical standards for medical devices - IEC 60601-1-11:2015
- Software – IEC 62304

These are very significant in terms of timeframe to comply.

- Durability – Transport & storage requirements.
- Probably more

We'll provide a further update on Friday at the check-in meeting.

Kind Regards,

Regards,

s 22 – s 22
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

From: s 22
To: s 22
Cc: s 22
Subject: RE: FOR INFO: quick update on vaping reforms - early stage survey results and possible direction of the MDSO [SEC=OFFICIAL]
Date: Wednesday, 6 March 2024 9:33:40 AM
Attachments: image001.png

Hi s 22 and team,
Great update and summary, thank you. Glad we're getting some strong buy-in and acknowledging the work you and the team have done on this.
Kind regards,
s 22

From: s 22
Sent: Wednesday, March 6, 2024 9:26 AM
To: s 22
Cc: s 22

Subject: RE: FOR INFO: quick update on vaping reforms - early stage survey results and possible direction of the MDSO [SEC=OFFICIAL]
Hi s 22 ,
We most certainly will be implementing standards for batteries including lithium batteries.
We are also investigating specific controls for the charger independent of the batteries because it is possible for a poor charger to cause a good battery to fail (catch fire or worse). There are several existing laws that cover requirements for chargers so we will be exploring if we either defer to those or apply them for vaping devices.
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s 22 – s 22
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

From: s 22
Sent: Tuesday, March 5, 2024 8:06 PM
To: s 22
Cc: s 22

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Re the batteries – I am increasingly become concerned about this. There has been media today around Australia's first deaths as a result of lithium batteries catching alight. I think we need to ensure we capture that well.
s 22

From: s 22
Sent: Tuesday, March 5, 2024 6:14 PM
To: s 22
Cc: s 22

[redacted]

Subject: FOR INFO: quick update on vaping reforms - early stage survey results and possible direction of the MDSO [SEC=OFFICIAL]

Hi [redacted],

A quick, early update on vaping device reforms. Whilst there is some way to go with the survey analysis (and the survey is still open), I am sharing the current thinking on the MDSO based on where things stand today noting it may change.

We have extended the stakeholder survey to COB 8 March due to a lack of responses late last week, however since then we have now received responses from the four major sponsors of therapeutic vapes (of those that have notified so far). This puts us in a much better position to consider the final requirements for the MDSO.

Survey

The following key sponsors have responded (as at today). We assume these sponsors are likely to represent the majority of vapes to be supplied from March – Dec 2024:

- Liber Pharmaceuticals Pty Ltd
- [redacted]
- [redacted]
- [redacted]

[redacted]

Preliminary thinking on MDSO

From the preliminary analysis at appears Liber[redacted] could meet the following requirements for [redacted] which are broadly in line with our workshop last week:

Possible MDSO requirements – for December 2024:

- IFU, Labelling, Plain packaging (mixed views about plain packaging but overall support even from most sponsors)
- [redacted]
- [redacted]
- Battery standards – including several options (most of these overlap, some significantly) – any one of the following:
  - [redacted]
  - [redacted]
  - [redacted]
  - (we'll need to decide if there should be any more options at this stage)
- Possible fundamental device safety requirements yet to be decided (e.g. interlocked activation – to prevent unintentional activation of the device when in transit/storage – this would need to come from a standard such as UL 8139)
- Compliance with other regulatory requirements for electrical and battery products such as:
  - ACCC requirements for button batteries (if appliable, none have indicated they use button batteries)
  - Various AS/NZS electrical requirements (e.g. for chargers)
  - ACMA requirements for EMC

  These may not reside in the MDSO but our guidance may direct sponsors to them if/as appliable.

[redacted]

[redacted]

Possible stage 2: MDSO for December 2025 (or thereabouts)

Based on the responses from Liber [redacted] they may be able to comply with the following by late 2025:

- All of the above plus:
- Toxicological risk analysis for the device – some claim to have already completed this including for the device ([redacted] and perhaps Liber)
- [redacted] ([redacted] Liber [redacted], [redacted])

Implementing these standards would increase stringency further but likely could not be implemented for this year without pushing some/several sponsors out and therefore risking the policy objective to ensure a therapeutic pathway for vapes.

There is still a significant gap between this stage 2 and what we would expect for ARTG inclusion.

Gap to ARTG inclusion (briefly):

- *Clinical evidence*
- Electrical standards for medical devices - IEC 60601-1-11:2015
- Software – IEC 62304

These are very significant in terms of timeframe to comply.

- Durability – Transport & storage requirements.
- Probably more

We'll provide a further update on Friday at the check-in meeting.

Kind Regards,

[redacted] – [redacted]

Devices Specialist Evaluation Section / MDAB / MDPQD

[redacted]

From: s 22
To: s 22
Cc: s 22
Subject: Vaping check-in mtg for 8 March - Updates [SEC=OFFICIAL]
Date: Thursday, 7 March 2024 4:07:00 PM

Hi s 22
I have prepared a status update for tomorrow which I hope will be helpful. Feel free to make updates as required and add anything else that I may have missed.
As tomorrow is my non-working day, I will not be able to attend the vaping-check in mtg. I have also communicated this to s 22 's EA for s 22 awareness.
Kind regards
s 22

- Progress status:
  - We have delivered the Standards checklist, RegTech presentation & internal workshop focused on options for the updated MDSO ahead of the survey results and was great to understand consensus around non-negotiable requirements such as labelling.
  - Survey: Out for consultation, closing on 10 March 2024 (deadline extended):
    - Summary of preliminary analysis: 15 responses to date and include submissions from s 22 , s 22 Liber s 22) and s 22 claim they will be able to meet s 47 , IFU & labelling requirements by s 47 . There are slightly mixed responses around plain packaging. [feel free to add more detail, perhaps it may be worthwhile to get s 22 to provide this input]
  - Brief to Tracey is being prepared to support the MDSO finalisation, likely to be ready next week for feedback by John and s 22 ?
- Critical considerations/decisions:
  - In relation to the MDSO, we are addressing the battery safety risk by including relevant battery standards as options and further to that, we are also considering charging standards to also address the electrical safety risk. We have identified that there are particular electrical and electronic equipment standards that all electrical equipment with 240V or more must meet in Australia.
    - Do you want us to contact the Electrical Regulatory Authorities Council in relation to the electrical safety requirement for electrical equipment?
  - Flagging there may be potential delay in publication of the MDSO and TGO to mid-April due to RLSB being busy with the changes to the Act occurring next week – this is yet to be confirmed. We'll keep you posted as soon as we know more.
  - MDSO approval process – John to flag with Tracey that this is coming when she returns from IMDRF (if possible check with John if he's had the discussion with Tracey on what the MDSO approval process looks like)
- MDSO Drafting:
  - We have had a follow-up discussed with RLSB to commence drafting of the MDSO. RLSB will be busy next week with the Bill, so drafting is likely to occur from the week of the 18th.
- Project timeline for key elements:

Key tasks to deliver Updated MDSO	Due Date	Comments
Survey	Complete, 19 Feb 2024	Will close on 10 March (extended deadline)
Brainstorming workshop	Complete, 28 Feb 2024	
Survey analysis and preliminary position on MDSO	Underway, 4-11 March 2024	
Final position on MDSO and briefing upwards	11-15 March 2024	
MDSO clearance/approval (inc. Brief to Tracey)	18-22 March 2024	
EP/Standards checklist	Complete, 27 Feb 2024	Published on our website
Reg Tech Presentation	Complete, 27 Feb 2024	

From: s 22
To: s 22
Cc: s 22
Subject: RE: Vaping check-in mtg for 8 March - Updates [SEC=OFFICIAL]
Date: Thursday, 7 March 2024 4:23:05 PM

Thanks very much s 22 !
Regards,
s 22 – s 22
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

From: s 22
Sent: Thursday, March 7, 2024 4:08 PM
To: s 22
Cc: s 22
Subject: Vaping check-in mtg for 8 March - Updates [SEC=OFFICIAL]

Hi s 22
I have prepared a status update for tomorrow which I hope will be helpful. Feel free to make updates as required and add anything else that I may have missed.
As tomorrow is my non-working day, I will not be able to attend the vaping-check in mtg. I have also communicated this to s 22 's EA for s 22 awareness.
Kind regards
s 22

- Progress status:
  - We have delivered the Standards checklist, RegTech presentation & internal workshop focused on options for the updated MDSO ahead of the survey results and was great to understand consensus around non-negotiable requirements such as labelling.
  - Survey: Out for consultation, closing on 10 March 2024 (deadline extended):
    - Summary of preliminary analysis: 15 responses to date and include submissions from s 22 (s 22 Liber s 22) and s 22 claim they will be able to meet s 47 , IFU & labelling requirements by s 47 . There are slightly mixed responses around plain packaging. [feel free to add more detail, perhaps it may be worthwhile to get s 22 to provide this input]
  - Brief to Tracey is being prepared to support the MDSO finalisation, likely to be ready next week for feedback by John and s 22 ?
- Critical considerations/decisions:
  - In relation to the MDSO, we are addressing the battery safety risk by including relevant battery standards as options and further to that, we are also considering charging standards to also address the electrical safety risk. We have identified that there are particular electrical and electronic equipment standards that all electrical equipment with 240V or more must meet in Australia.
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  - Flagging there may be potential delay in publication of the MDSO and TGO to mid-April due to RLSB being busy with the changes to the Act occurring next week – this is yet to be confirmed. We'll keep you posted as soon as we know more.
  - MDSO approval process – John to flag with Tracey that this is coming when she returns from IMDRF (if possible check with John if he's had the discussion with Tracey on what the MDSO approval process looks like)
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MDSO clearance/approval (inc. Brief to Tracey)	18-22 March 2024	
EP/Standards checklist	Complete, 27 Feb 2024	Published on our website
Reg Tech Presentation	Complete, 27 Feb 2024	

From: s 22
To: s 22
Cc: s 22
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]
Date: Friday, 8 March 2024 10:41:36 AM
Attachments: image001.png
image002.png
image007.png
image008.png
image009.png
image010.png
image011.png

Hi s 22 ,
Here is the short feedback from survey about battery standards for your consideration during your research. Interesting to note that Liber s 22 claim their devices are s 47 .

	UL 8139	When can you comply?	Additional Comments	Lithium Batteries	Do you comply with any other standards?	Views on any other standard?
s 22						
Liber Pharmaceuticals Pty Ltd	s 47	s 47	UL is US centric but s 47	Yes	s 47	UN 38.3 and IEC 62133-2 Have provided table of comparison with other listed standards
s 22						
s 22						

Regards,
s 22
s 22
s 22

Devices Specialist Evaluation Section | Medical Devices and Product Quality Division | Medical Devices Branch | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Dr Fairbairn
Phone: s 22
PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s 22
Sent: Thursday, March 7, 2024 5:04 PM
To: s 22
Cc: s 22
Subject: Battery and charger standards - update [SEC=OFFICIAL]
Hi s 22 and team,
For battery safety the following is recommended:

Note

A. **Primary batteries – single use**
B. **Secondary batteries – rechargeable**

- **For Lithium batteries**
  - **General safety:** UL 1642 UL Standard for Safety Lithium Batteries **or**
    - **Secondary cells and batteries** containing alkaline or other non-acid electrolytes IEC 62133-2 - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems or
    - **Primary batteries safety:** IEC 60086 – 4 - Safety of lithium batteries
  - UN 38.3 – Transportation testing for Lithium metal and lithium-ion batteries (maybe should be requirement as needed for transport by air) **or** IEC 62281 Safety of primary and secondary lithium cells and batteries during transport (*extra drop test vs UN standard*)
- For **Nickel systems batteries: IEC 62133-1** (general safety and seems to cover sufficiently transport impacts by vibration, fall, crush, temperature cycling) - Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 1: Nickel systems.
- **For Primary batteries (safety and transport)** IEC 60086 (series) or UL 2054

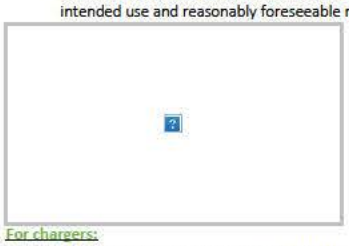
Further notes:

In the United States, two standards are commonly used for the evaluation of lithium batteries: UL 1642, the standard for Lithium Batteries, and UL 2054, Standard for Household and Commercial Batteries, (**UL 2054 refers to UL 1642** testing required for cells). UL2054 requires the cells to be certified UL1642 (if Lithium batteries).

UL 2054 - cover portable primary (nonchargeable) and secondary (rechargeable) batteries for use as power sources in products.
UL 2054 test is performed on a battery that is fully discharged, while the IEC 62133 test is done on a set of fully charged batteries.
ACCC report: Lithium batteries - In summary recommendation:
Demonstrable compliance of lithium-ion batteries to either IEC 62133 (portable applications) ... is promoted through a combination of additional guidance in standards (such as in AS 62368.1)
requirements of the ADGC (Dangerous Goods) on batteries imported into Australia, and potentially integrated into new equipment, meet the requirements of UN 38.3.
The overlap between requirements of IEC 62133 ... and UN 38.3 will simplify the required compliance (i.e., testing) pathway for manufacturers, importers....
(differences summary – with caution to be considered difference between UN 38.3 and IEC 62133.docx)
IEC 60086 (1, 2 and if applicable 4): covers markings, transport, safety aspects of primary batteries (non-rechargeable)
- Part 1: standardize primary batteries with respect to dimensions, nomenclature, terminal configurations, markings, test methods, typical performance, safety and environmental aspects.

- Part 2: Physical and electrical specifications
- Part 4: Safety of lithium batteries
- Part 6: Guidance on environmental aspects (possible less of priority at moment so therefore part 1, 2 and 4 is only recommended)

IEC 62133-1 specifies requirements and tests for the safe operation of portable sealed secondary nickel cells and batteries containing alkaline electrolyte, under intended use and reasonably foreseeable misuse. Inclusion of button cell requirements.



For chargers:

The following three standards are linked within them and also required under EESS requirements. The first two seem most important, third one is linked to second standard.

AS/NZS 3820 - Essential safety requirements for electrical equipment

This Standard sets out requirements for electrical equipment, to ensure that electrical equipment is constructed in accordance with good engineering practice in regard to safety such that it does not endanger the safety of persons (including children, the elderly and people with disabilities), domestic animals or property, when properly installed and maintained and used in applications for which it was made.

Australian Standard AS/NZS 4417 Marking of electrical products (Part 1 and 2)

General rules for use of the mark provides general requirements for the use of the RCM including location of the marking on the equipment and its dimensional requirements. Part 2 also covers ACMA requirements (e.g EMC, EMR etc).

IEC 60335-1: Household and similar electrical appliances - Safety - Part 1: General requirements -

Battery charger (Power supply or charger) require compliance with AS/NZS 60335 – particular 2.29 (as **listed under AS/NZS 4417.2 – clause B.2.49**).

Note: IEC 60601 is the medical devices electrical safety standard series, but this standard may impact on supply therefore at least the above seems reasonable to be expected.

The following are now additionally available for download:

What I have so far....any comments are welcome...

overlap between requirements of IEC 62133 ... and UN 38.3 needs still to be looked at...

s 22 [redacted]
s 22

Devices Specialist Evaluations Sections | Medical Devices Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location Fairbairn
Phone: s 22

PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s 22
To: s 22
Cc: s 22
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]
Date: Friday, 8 March 2024 10:48:34 AM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
image006.png
image007.png

In summary, if we add general safety on Litium batteries s 22 . Tbc if only transport Un38.3 or IEC 62281 line should be listed first.....to ensure supply....

s 22
s 22

Devices Specialist Evaluations Sections | Medical Devices Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location Fairbairn
Phone: s 22

PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s 22
Sent: Friday, March 8, 2024 10:42 AM
To: s 22
Cc: s 22
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]

Hi s 22
Here is the short feedback from survey about battery standards for your consideration during your research. Interesting to note that Liber and s 22 claim their devices are UN 38.3 and IEC 62133-2 **certified.**

	UL 8139	When can you comply?	Additional Comments	Lithium Batteries	Do you comply with any other standards?	Views on any other standard?
s 22						
Liber Pharmaceuticals Pty Ltd	s 47	s 47	UL is US centric but s 47	Yes	s 47	UN 38.3 and IEC 62133-2 Have provided table of comparison with other listed standards
s 22						
s 22						

Regards,

s 22
s 22
s 22

Devices Specialist Evaluation Section | Medical Devices and Product Quality Division | Medical Devices Branch | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Dr Fairbairn
Phone: s 22
PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s 22
Sent: Thursday, March 7, 2024 5:04 PM
To: s 22
Cc: s 22
Subject: Battery and charger standards - update [SEC=OFFICIAL]

Hi s 22 and team,
For battery safety the following is recommended:

Note

A. **Primary batteries – single use**
B. **Secondary batteries – rechargeable**

- **For Lithium batteries**
  - **General safety:** UL 1642 UL Standard for Safety Lithium Batteries **or**
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Further notes:

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Demonstrable compliance of lithium-ion batteries to either IEC 62133 (portable applications) … is promoted through a combination of additional guidance in standards (such as in AS 62368.1)
requirements of the ADGC (Dangerous Goods) on batteries imported into Australia, and potentially integrated into new equipment, meet the requirements of UN 38.3.
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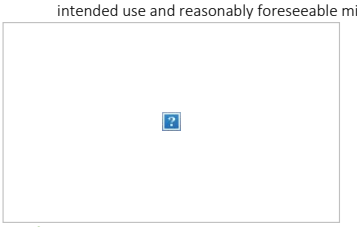
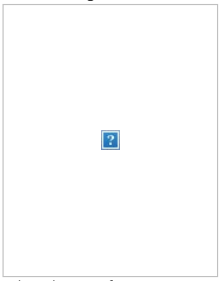


For chargers:
The following three standards are linked within them and also required under EESS requirements. The first two seem most important, third one is linked to second standard.

AS/NZS 3820 - Essential safety requirements for electrical equipment
This Standard sets out requirements for electrical equipment, to ensure that electrical equipment is constructed in accordance with good engineering practice in regard to safety such that it does not endanger the safety of persons (including children, the elderly and people with disabilities), domestic animals or property, when properly installed and maintained and used in applications for which it was made.
Australian Standard AS/NZS 4417 Marking of electrical products (Part 1 and 2)
General rules for use of the mark provides general requirements for the use of the RCM including location of the marking on the equipment and its dimensional requirements. Part 2 also covers ACMA requirements (e.g EMC, EMR etc).

IEC 60335-1: Household and similar electrical appliances - Safety - Part 1: General requirements -
Battery charger (Power supply or charger) require compliance with AS/NZS 60335 – particular 2.29 (as **listed under AS/NZS 4417.2 – clause B.2.49**).

Note: IEC 60601 is the medical devices electrical safety standard series, but this standard may impact on supply therefore at least the above seems reasonable to be expected.
The following are now additionally available for download:



What I have so far….any comments are welcome…
overlap between requirements of IEC 62133 … and UN 38.3 needs still to be looked at…

s 22 [redacted]
s 22

Devices Specialist Evaluations Sections | Medical Devices Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location Fairbairn
Phone: s 22

PO Box 100, Woden ACT 2606
www.tga.gov.au
The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our

From: s 22
To: s 22
Cc: s 22
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]
Date: Friday, 8 March 2024 10:57:37 AM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
image006.png
image007.png

Liber had interesting comment which we expcted that
In the unusual circumstance that the TGA elected not to mandate UN 38.3, Liber would still elect to have the lithium-ion batteries used in its devices tested and certified to meet UN 38.3 because:
- UN 38.3 has been adopted by regulators and competent authorities around the world, making it a requirement for global market access.
- UN 38.3 certification is a mandatory requirement for the transportation of lithium-ion batteries under the Australian Dangerous Goods Code.
Regards,

s 22
s 22
s 22

Devices Specialist Evaluation Section | Medical Devices and Product Quality Division | Medical Devices Branch | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Dr Fairbairn
Phone: s 22
PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s 22
Sent: Friday, March 8, 2024 10:49 AM
To: s 22
Cc: s 22
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]
In summary, if we add general safety on Litium batteries s 22 . Tbc if only transport Un38.3 or IEC 62281 line should be listed first.....to ensure supply....

s 22
s 22

Devices Specialist Evaluations Sections | Medical Devices Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location Fairbairn
Phone: s 22

PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s 22
Sent: Friday, March 8, 2024 10:42 AM
To: s 22
Cc: s 22
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]
Hi s 22
Here is the short feedback from survey about battery standards for your consideration during your research. Interesting to note that Liber and s 22 claim their devices are UN 38.3 and IEC 62133-2 **certified.**

	UL 8139	When can you comply?	Additional Comments	Lithium Batteries	Do you comply with any other standards?	Views on any other standard?
s 22						
Liber Pharmaceuticals Pty Ltd	s 47	s 47	UL is US centric but s 47	Yes	s 47	UN 38.3 and IEC 62133-2 Have provided table of comparison with other listed standards
s 22						

Regards,

s 22
s 22
s 22

Devices Specialist Evaluation Section | Medical Devices and Product Quality Division | Medical Devices Branch | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Dr Fairbairn
Phone: 02 s 22
PO Box 100, Woden ACT 2606

From: [redacted]
Sent: Thursday, March 7, 2024 5:04 PM
To: [redacted]
Cc: [redacted]
Subject: Battery and charger standards - update [SEC=OFFICIAL]

Hi [redacted] and team,

For battery safety the following is recommended:

Note

A. **Primary batteries – single use**
B. **Secondary batteries – rechargeable**

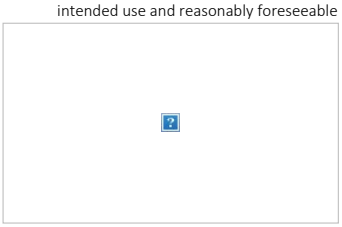
- **For Lithium batteries**
  - **General safety:** UL 1642 UL Standard for Safety Lithium Batteries **or**
    - **Secondary cells and batteries** containing alkaline or other non-acid electrolytes IEC 62133-2 - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems or
    - **Primary batteries safety:** IEC 60086 – 4 - Safety of lithium batteries
  - UN 38.3 – Transportation testing for Lithium metal and lithium-ion batteries (maybe should be requirement as needed for transport by air) **or** IEC 62281 Safety of primary and secondary lithium cells and batteries during transport (*extra drop test vs UN standard*)
- For **Nickel systems batteries: IEC 62133-1** (general safety and seems to cover sufficiently transport impacts by vibration, fall, crush, temperature cycling) - Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 1: Nickel systems.
- **For Primary batteries (safety and transport)** IEC 60086 (series) or UL 2054

Further notes:

In the United States, two standards are commonly used for the evaluation of lithium batteries: UL 1642, the standard for Lithium Batteries, and UL 2054, Standard for Household and Commercial Batteries, (**UL 2054 refers to UL 1642** testing required for cells). UL2054 requires the cells to be certified UL1642 (if Lithium batteries).

UL 2054 - cover portable primary (nonchargeable) and secondary (rechargeable) batteries for use as power sources in products.
UL 2054 test is performed on a battery that is fully discharged, while the IEC 62133 test is done on a set of fully charged batteries.
ACCC report: Lithium batteries - In summary recommendation:
Demonstrable compliance of lithium-ion batteries to either IEC 62133 (portable applications) … is promoted through a combination of additional guidance in standards (such as in AS 62368.1)
requirements of the ADGC (Dangerous Goods) on batteries imported into Australia, and potentially integrated into new equipment, meet the requirements of UN 38.3.
The overlap between requirements of IEC 62133 … and UN 38.3 will simplify the required compliance (i.e., testing) pathway for manufacturers, importers….
(differences summary – with caution to be considered difference between UN 38.3 and IEC 62133.docx)
IEC 60086 (1, 2 and if applicable 4): covers markings, transport, safety aspects of primary batteries (non-rechargeable)
- Part 1: standardize primary batteries with respect to dimensions, nomenclature, terminal configurations, markings, test methods, typical performance, safety and environmental aspects.
- Part 2: Physical and electrical specifications
- Part 4: Safety of lithium batteries
- Part 6: Guidance on environmental aspects (possible less of priority at moment so therefore part 1, 2 and 4 is only recommended)

IEC 62133-1 specifies requirements and tests for the safe operation of portable sealed secondary nickel cells and batteries containing alkaline electrolyte, under intended use and reasonably foreseeable misuse. Inclusion of button cell requirements.



For chargers:

The following three standards are linked within them and also required under EESS requirements. The first two seem most important, third one is linked to second standard.

AS/NZS 3820 - Essential safety requirements for electrical equipment

This Standard sets out requirements for electrical equipment, to ensure that electrical equipment is constructed in accordance with good engineering practice in regard to safety such that it does not endanger the safety of persons (including children, the elderly and people with disabilities), domestic animals or property, when properly installed and maintained and used in applications for which it was made.

Australian Standard AS/NZS 4417 Marking of electrical products (Part 1 and 2)

General rules for use of the mark provides general requirements for the use of the RCM including location of the marking on the equipment and its dimensional requirements. Part 2 also covers ACMA requirements (e.g EMC, EMR etc).

IEC 60335-1: Household and similar electrical appliances - Safety - Part 1: General requirements -
Battery charger (Power supply or charger) require compliance with AS/NZS 60335 – particular 2.29 (as **listed under AS/NZS 4417.2 – clause B.2.49**).

Note: IEC 60601 is the medical devices electrical safety standard series, but this standard may impact on supply therefore at least the above seems reasonable to be expected.
The following are now additionally available for download:

What I have so far....any comments are welcome...

overlap between requirements of IEC 62133 ... and UN 38.3 needs still to be looked at...

s 22
s 22

Devices Specialist Evaluations Sections | Medical Devices Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location Fairbairn
Phone: s 22

PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s 22
To: s 22
Cc: s 22
Subject: RE: Vaping Devices - Check In [SEC=OFFICIAL]
Date: Friday, 8 March 2024 12:11:34 PM
Attachments: image001.png
FOR INFO quick update on vaping reforms - early stage survey results and possible direction of the MDSO SECOFFICIAL.msg
Battery and charger standards - update SECOFFICIAL.msg

Please note that the attachments to this email are provided elsewhere in the schedule of documents at Documents 08 and 16 respectively.

Hi all,

Please see below update on the vaping device reform work:

- Progress status:
  - **We have delivered** the
    - Standards checklist (now on the web)
    - RegTech presentation
    - internal workshop focused on options for the updated MDSO ahead of the survey results. It was great to understand consensus around non-negotiable requirements such as labelling.
  - **Timeframe and resource dependencies are critical risks** – On the current schedule we have 9 business days to have an MDSO cleared through Tracey (MDPQD approved), to enable final clearance and registration before the end of march.
    - Whilst we have more resources on board and MDSO considerations are progressing, schedule remains a major risk.
    - RLSB availability to undertake drafting may lead to delays. Drafting is likely to occur from the week of the 18th which means the brief will be going to Tracey late in the week.
  - **Survey update:** now closing on 10 March 2024 (deadline extended):
    - Summary of preliminary analysis: 15 responses so far and include submissions from s 22 (s 22 , Liber s 22) and s 22 claim they will be able to meet s 47 , IFU & labelling, and certain battery requirements by s 47 . There are slightly mixed responses around plain packaging. No major changes from my email on Tuesday (attached for reference) s 22
    - We did have a slight error with closure dates on one of the extension emails but we have addressed that with follow up communications.
  - **Brief to Tracey is in very early draft** to support the MDSO finalisation, and we are hoping to get this to both s 22 and s 22 next week if everything goes to plan.
- **Critical considerations/decisions:**
  - In relation to the MDSO, we are currently considering battery and charger safety risk in detail by including relevant battery and charger standards as options (see attached email for more info). We have identified that there are particular electrical and electronic equipment standards that all electrical equipment with 240V or more must meet in Australia (see below in blue text)
    - Do you want us to contact the Electrical Regulatory Authorities Council in relation to the electrical safety requirement for electrical equipment? and/or ACMA regarding EMC?
  - Flagging there may be potential delay in publication of the MDSO and TGO to mid-April due to RLSB being busy with the changes to the Act occurring next week – this is yet to be confirmed. I checked with Tony today, no update yet, we'll keep you posted as soon as we know more.
  - MDSO approval process – s 22 to flag with Tracey that this is coming when she returns from IMDRF (if there is no delay).
- **MDSO Drafting:**
  - We have had a follow-up discussed with RLSB to commence drafting of the MDSO. RLSB will be busy next week with the Bill, so drafting is likely to occur from the week of the 18th
- **Project timeline for key elements:**

Key tasks to deliver Updated MDSO	Due Date	Comments
Survey	Complete, 19 Feb 2024	Will close on 10 March (extended deadline)
Brainstorming workshop	Complete, 28 Feb 2024	

Survey analysis and preliminary position on MDSO	Underway, 4-11 March 2024	Underway
Final position on MDSO and briefing upwards	11-15 March 2024	Underway
MDSO clearance/approval (inc. Brief to Tracey)	18-22 March 2024	Pending
MDSO final clearance through Tony and Registration	25-29 March	Pending, (RLSB action)
EP/Standards checklist	Complete, 27 Feb 2024	Published on our website
Reg Tech Presentation	Complete, 27 Feb 2024	

Possible MDSO requirements – for December 2024:

- IFU, Labelling, Plain packaging (mixed views about plain packaging but overall support even from most sponsors)
- ISO 13485 (QMS)
- ISO 14971 – Risk management for medical devices
- Battery standards – including several options (most of these overlap, some significantly) – any one of the following:
  - IEC 62133
  - IEC 62281
  - UN38.3
  - (we'll need to decide if there should be any more options at this stage)
- Possible fundamental device safety requirements yet to be decided (e.g. interlocked activation – to prevent unintentional activation of the device when in transit/storage – this would need to come from a standard such as UL 8139)
- Compliance with other regulatory requirements for electrical and battery products such as:
  - ACCC requirements for button batteries (if appliable, none have indicated they use button batteries)
  - Various AS/NZS electrical requirements (e.g. for chargers)
    - **AS/NZS 3820 - Essential safety requirements for electrical equipment**
      This Standard sets out requirements for electrical equipment, to ensure that electrical equipment is constructed in accordance with good engineering practice in regard to safety such that it does not endanger the safety of persons (including children, the elderly and people with disabilities), domestic animals or property, when properly installed and maintained and used in applications for which it was made.
    - **Australian Standard AS/NZS 4417 Marking of electrical products (Part 1 and 2)**
      General rules for use of the mark provides general requirements for the use of the RCM including location of the marking on the equipment and its dimensional requirements. Part 2 also covers ACMA requirements (e.g EMC, EMR etc).
  - ACMA requirements for EMC

These may not reside in the MDSO but our guidance may direct sponsors to them if/as appliable.

Regards,
s 22 – s 22
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

-----Original Appointment-----
From: s 22
Sent: Wednesday, February 14, 2024 1:31 PM
To: s 22
Cc: s 22
Subject: Vaping Devices - Check In
When: Friday, 8 March 2024 1:30 PM-2:30 PM (UTC+10:00) Canberra, Melbourne, Sydney.
Where: Webex / s 22 Office

Hi All,
Moving this from s 22 diary to s 22 ,
As usual
Weekly standing meeting as a check in for the different pieces of work we need to get done:

- Survey (s 22)
- Expectations for MDSO and EPs (checklist) (s 22)
- Guidance (s 22)
- Etc.

Thanks

s 22

-- Do not delete or change any of the following text. --

From: s 22
To: s 22
Cc: s 22
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]
Date: Friday, 8 March 2024 2:41:44 PM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
image006.png
image007.png
s 22

Certification to UN38.3 questions:

Australian Dangerous Goods Code: "….Component cells of the battery shall be of a type proved to meet the respective testing requirements of the Manual of Tests and Criteria, part III, sub-section 38.3"

Some make these interpretation:

- s 22
- *UN 38.3 certification is a mandatory requirement for the transportation of lithium-ion batteries under the Australian Dangerous Goods Code.*
- s 22

Recommendation 1:

Lithium battery containing vaping devices to be certified to UN38.3 by an accredited third party test laboratory.

This ensures safe transport and compliance with Australian Dangerous Goods Code and international travel requirements.

IEC 62281 is not mandated or listed as alternative, therefore inclusion of this standard is not recommended

BATTERIES or devices to be labelled with appropriate UN battery classification (e.g UN 3481 for lithium-ion batteries supplied within a vaping device)

Certification IEC 62133-2 or any other battery standard listed question:

There are Certification bodies worldwide to certify the relevant IEC standards.

s 22

The exclusion of additional general safety standards means there is only a safety requirement on lithium batteries. This may be an temporary acceptable risk as other battery types are not likely used and of very small safety risk and therefore not listed in Dangerous goods code.

Recommendation 2: Introduction of any additional battery safety standards at a later stage, 12 month timeframe (IEC 62133-2).

Further Background:

The European Union (EU) adopted 62133-2 in March, 2021. New portable lithium ion batteries in the EU must comply with these requirements.

US and Canada have adopted ANSI/UL 62133-2 and CSA C22.2 No. 62133-2:20 with transition timelines for enforcement of these versions.

s 22
s 22

Devices Specialist Evaluations Sections | Medical Devices Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location Fairbairn
Phone: s 22

PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s 22
Sent: Friday, March 8, 2024 10:58 AM
To: s 22
Cc: s 22
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]

Liber had interesting comment which we expcted that

In the unusual circumstance that the TGA elected not to mandate UN 38.3, Liber would still elect to have the lithium-ion batteries used in its devices tested and certified to meet UN 38.3 because:

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s 22
s 22

Devices Specialist Evaluation Section | Medical Devices and Product Quality Division | Medical Devices Branch | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Dr Fairbairn
Phone: s 22
PO Box 100, Woden ACT 2606
www.tga.gov.au

From s 22
Sent: Friday, March 8, 2024 10:49 AM
To: s 22
Cc: s 22
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]

In summary, if we add general safety on Litium batteries s 22. Tbc if only transport Un38.3 or IEC 62281 line should be listed first…..to ensure supply….

s 22
s 22

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Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location Fairbairn
Phone: s 22

PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s 22
Sent: Friday, March 8, 2024 10:42 AM
To: s 22
Cc: s 22
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]

Hi s 22 ,
Here is the short feedback from survey about battery standards for your consideration during your research. Interesting to note that Liber s 22 claim their devices are s 47 .

	UL 8139	When can you comply?	Additional Comments	Lithium Batteries	Do you comply with any other standards?	Views on any other standard?
s 22						
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s 22						

Regards,
s 22
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Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Dr Fairbairn
Phone: s 22
PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s 22
Sent: Thursday, March 7, 2024 5:04 PM
To: s 22
Cc: s 22
Subject: Battery and charger standards - update [SEC=OFFICIAL]

Hi s 22 and team,
For battery safety the following is recommended:

Note

A. **Primary batteries – single use**
B. **Secondary batteries – rechargeable**

- **For Lithium batteries**
  - **General safety:** UL 1642 UL Standard for Safety Lithium Batteries **or**
    - **Secondary cells and batteries** containing alkaline or other non-acid electrolytes IEC 62133-2 - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems or
    - **Primary batteries safety:** IEC 60086 – 4 - Safety of lithium batteries
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- **For Primary batteries (safety and transport)** IEC 60086 (series) or UL 2054

Further notes:

In the United States, two standards are commonly used for the evaluation of lithium batteries: UL 1642, the standard for Lithium Batteries, and UL 2054, Standard for Household and Commercial Batteries, (**UL 2054 refers to UL 1642** testing required for cells). UL2054 requires the cells to be certified UL1642 (if Lithium batteries).

UL 2054 - cover portable primary (nonchargeable) and secondary (rechargeable) batteries for use as power sources in products.
UL 2054 test is performed on a battery that is fully discharged, while the IEC 62133 test is done on a set of fully charged batteries.
ACCC report: Lithium batteries - In summary recommendation:
Demonstrable compliance of lithium-ion batteries to either IEC 62133 (portable applications) … is promoted through a combination of additional guidance in

standards (such as in AS 62368.1)
requirements of the ADGC (Dangerous Goods) on batteries imported into Australia, and potentially integrated into new equipment, meet the requirements of UN 38.3.
The overlap between requirements of IEC 62133 ... and UN 38.3 will simplify the required compliance (i.e., testing) pathway for manufacturers, importers....
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IEC 60086 (1, 2 and if applicable 4): covers markings, transport, safety aspects of primary batteries (non-rechargeable)

- Part 1: standardize primary batteries with respect to dimensions, nomenclature, terminal configurations, markings, test methods, typical performance, safety and environmental aspects.
- Part 2: Physical and electrical specifications
- Part 4: Safety of lithium batteries
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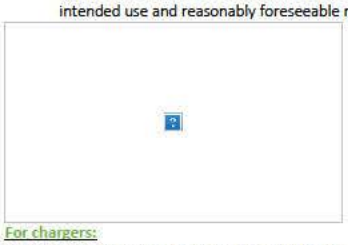


For chargers:

The following three standards are linked within them and also required under EESS requirements. The first two seem most important, third one is linked to second standard.

AS/NZS 3820 - Essential safety requirements for electrical equipment

This Standard sets out requirements for electrical equipment, to ensure that electrical equipment is constructed in accordance with good engineering practice in regard to safety such that it does not endanger the safety of persons (including children, the elderly and people with disabilities), domestic animals or property, when properly installed and maintained and used in applications for which it was made.

Australian Standard AS/NZS 4417 Marking of electrical products (Part 1 and 2)

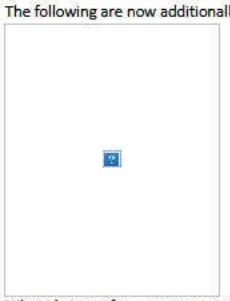
General rules for use of the mark provides general requirements for the use of the RCM including location of the marking on the equipment and its dimensional requirements. Part 2 also covers ACMA requirements (e.g EMC, EMR etc).

IEC 60335-1: Household and similar electrical appliances - Safety - Part 1: General requirements -

Battery charger (Power supply or charger) require compliance with AS/NZS 60335 – particular 2.29 (as **listed under AS/NZS 4417.2 – clause B.2.49**).

Note: IEC 60601 is the medical devices electrical safety standard series, but this standard may impact on supply therefore at least the above seems reasonable to be expected.

The following are now additionally available for download:



What I have so far....any comments are welcome...

overlap between requirements of IEC 62133 ... and UN 38.3 needs still to be looked at...

s 22 [redacted]
s 22

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Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location Fairbairn
Phone: s 22

PO Box 100, Woden ACT 2606
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From: s 22
To: s 22
Cc: s 22
Subject: RE: Vaping Devices - Check In [SEC=OFFICIAL]
Date: Friday, 8 March 2024 6:51:30 PM
Attachments: image001.png
image002.png
RE Battery and charger standards - update SECOFFICIAL.msg

Hi all,
Following the meeting earlier today, a quick update on battery standards.
Big thanks to s 22 and the team for fast work on this.
The likely requirement will be:
For December 2024:

Lithium batteries:

- **Compliance with UN 38.3** (to enable air and road transport of the batteries, and most of the vape device sponsors have indicated they already comply)

For secondary/rechargeable batteries:

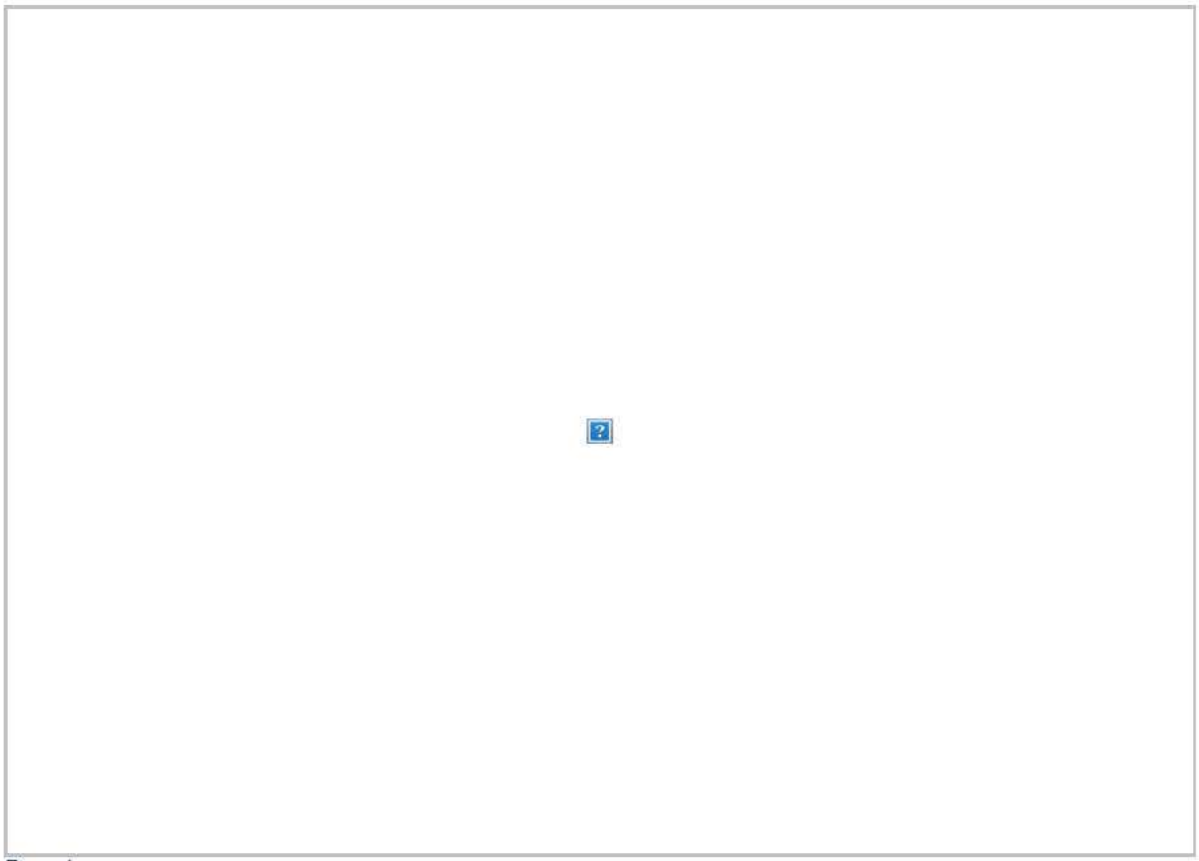
- **Lithium: Certification to IEC 62133 by an accredited third party laboratory.**
  - The CSIRO report on lithium batteries implies that this is a preferred standard because it has a test for internal short circuit where many other standard currently do not.
  - Most manufacturers indicated they could comply with this standard even if they don't currently (and as they all meet 38.3 they should be bale to obtain compliance to this standard). Liber indicated this is the preferred standard and referenced the CSIRO report.
  - We understand both the EU and US have adopted this standard.
  - Our initial investigations indicate testing and certification can be achieved within 1-2 months (though this is likely to be testing in the US or EU). Note the ACCC report indicates there is no testing capability for some of these electrical standards in Australia this may be sensitivity for any prospective Australian manufacturers if (any) of these standards are mandated through the MDSO, however at this stage we are not aware of any Australian manufacturers.

s 22 There is an option to require compliance to UN 38.3 from December, and have delayed implementation of a requirement for certification to IEC 62133 until perhaps July-Dec 2025.

We are not aware that any manufacturers that use nickel system batteries or non-rechargeable batteries but for completeness we propose to include these as options:

- **Nickel systems batteries**: Certification to IEC 62133-1 by an accredited third party laboratory. Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 1: Nickel systems.
- **For Primary/non-rechargeable batteries:**
  - Compliance to IEC 60086 (series as applicable to battery type)

We are in the process of procuring the relevant UL standards for lithium batteries. However they do not include internal short circuit testing and therefore it is unlikely that we would provide them as options for compliance.
Excerpt from CSIRO report:
A detailed review of the abuse testing standards for lithium-ion batteries in electric and hybrid electric vehicles was published in 2018 by members of the European Union.53 A key recommendation of that review was that tests for internal short circuits (and by implication, standards that include them) be more widely adopted in the legislative landscape



Regards,
s 22 – s 22
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

-----Original Appointment-----
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Sent: Wednesday, February 14, 2024 1:31 PM
To: s 22
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Subject: Vaping Devices - Check In [SEC=OFFICIAL]
When: Friday, 8 March 2024 1:30 PM-2:30 PM (UTC+10:00) Canberra, Melbourne, Sydney.
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Hi All,

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* Survey (s 22)
* Expectations for MDSO and EPs (checklist) (s 22)
* Guidance (s 22)
* Etc.

Thanks

s 22

From: s 22
To: s 22
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]
Date: Friday, 8 March 2024 3:42:00 PM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
image006.png
image007.png

Thanks s 22 , great work.
Regards,
s 22 – s 22
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

From: s 22
Sent: Friday, March 8, 2024 2:42 PM
To: s 22
Cc: s 22
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]

Certification to UN38.3 questions:

Australian Dangerous Goods Code: "….Component cells of the battery shall be of a type proved to meet the respective testing requirements of the Manual of Tests and Criteria, part III, sub-section 38.3"
Some make these interpretation:

- s 22
- s 22
- *UN 38.3 certification is a mandatory requirement for the transportation of lithium-ion batteries under the Australian Dangerous Goods Code.*
- s 22

Recommendation 1:

Lithium battery containing vaping devices to be certified to UN38.3 by an accredited third party test laboratory.

This ensures safe transport and compliance with Australian Dangerous Goods Code and international travel requirements.
IEC 62281 is not mandated or listed as alternative, therefore inclusion of this standard is not recommended
BATTERIES or devices to be labelled with appropriate UN battery classification (e.g UN 3481 for lithium-ion batteries supplied within a vaping device)

Certification IEC 62133-2 or any other battery standard listed question:

There are Certification bodies worldwide to certify the relevant IEC standards.
s 22
The exclusion of additional general safety standards means there is only a safety requirement on lithium batteries. This may be an temporary acceptable risk as other battery types are not likely used and of very small safety risk and therefore not listed in Dangerous goods code.

Recommendation 2: Introduction of any additional battery safety standards at a later stage, 12 month timeframe (IEC 62133-2).

Further Background:

The European Union (EU) adopted 62133-2 in March, 2021. New portable lithium ion batteries in the EU must comply with these requirements.
US and Canada have adopted ANSI/UL 62133-2 and CSA C22.2 No. 62133-2:20 with transition timelines for enforcement of these versions.

s 22
s 22

Devices Specialist Evaluations Sections | Medical Devices Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location Fairbairn
Phone: s 22

PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s 22
Sent: Friday, March 8, 2024 10:58 AM
To: s 22
Cc: s 22
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]

Liber had interesting comment which we expcted that
In the unusual circumstance that the TGA elected not to mandate UN 38.3, Liber would still elect to have the lithium-ion batteries used in its devices tested and certified to meet UN 38.3 because:
- UN 38.3 has been adopted by regulators and competent authorities around the world, making it a requirement for global market access.
- UN 38.3 certification is a mandatory requirement for the transportation of lithium-ion batteries under the Australian Dangerous Goods Code.
Regards,
s 22
s 22
s 22

Devices Specialist Evaluation Section | Medical Devices and Product Quality Division | Medical Devices Branch | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Dr Fairbairn
Phone: s 22
PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s 22
Sent: Friday, March 8, 2024 10:49 AM
To: s 22
Cc: s 22

Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]

[redacted]

Devices Specialist Evaluations Sections | Medical Devices Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location Fairbairn
Phone: [redacted]

PO Box 100, Woden ACT 2606
www.tga.gov.au

From: [redacted]
Sent: Friday, March 8, 2024 10:42 AM
To: [redacted]
Cc: [redacted]
Subject: RE: Battery and charger standards - update [SEC=OFFICIAL]

Hi [redacted], [redacted] and [redacted],
Here is the short feedback from survey about battery standards for your consideration during your research. Interesting to note that Liber [redacted] claim their devices are UN 38.3 and IEC 62133-2 **certified.**

	UL 8139	When can you comply?	Additional Comments	Lithium Batteries	Do you comply with any other standards?	Views on any other standard?
[redacted]						
Liber Pharmaceuticals Pty Ltd	[redacted]	[redacted]	UL is US centric but [redacted]	Yes	[redacted]	UN 38.3 and IEC 62133-2 Have provided table of comparison with other listed standards
[redacted]						

Regards,
[redacted]

Devices Specialist Evaluation Section | Medical Devices and Product Quality Division | Medical Devices Branch | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Dr Fairbairn
Phone: [redacted]
PO Box 100, Woden ACT 2606
www.tga.gov.au

From: [redacted]
Sent: Thursday, March 7, 2024 5:04 PM
To: [redacted]
Cc: [redacted]
Subject: Battery and charger standards - update [SEC=OFFICIAL]

Hi [redacted] and team,
For battery safety the following is recommended:

Note

A. **Primary batteries – single use**
B. **Secondary batteries – rechargeable**

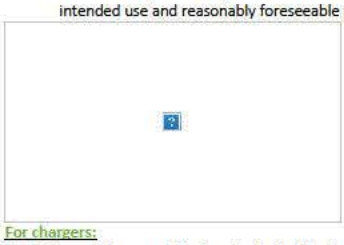
- **For Lithium batteries**
  - **General safety:** UL 1642 UL Standard for Safety Lithium Batteries **or**
    - **Secondary cells and batteries** containing alkaline or other non-acid electrolytes IEC 62133-2 - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems or
    - **Primary batteries safety:** IEC 60086 – 4 - Safety of lithium batteries
  - UN 38.3 – Transportation testing for Lithium metal and lithium-ion batteries (maybe should be requirement as needed for transport by air) **or** IEC 62281 Safety of primary and secondary lithium cells and batteries during transport (*extra drop test vs UN standard*)
- For **Nickel systems batteries: IEC 62133-1** (general safety and seems to cover sufficiently transport impacts by vibration, fall, crush, temperature cycling) - Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 1: Nickel systems.
- **For Primary batteries (safety and transport)** IEC 60086 (series) or UL 2054

Further notes:

In the United States, two standards are commonly used for the evaluation of lithium batteries: UL 1642, the standard for Lithium Batteries, and UL 2054, Standard for Household and Commercial Batteries, (**UL 2054 refers to UL 1642** testing required for cells). UL2054 requires the cells to be certified UL1642 (if Lithium batteries).

UL 2054 - cover portable primary (nonchargeable) and secondary (rechargeable) batteries for use as power sources in products.
UL 2054 test is performed on a battery that is fully discharged, while the IEC 62133 test is done on a set of fully charged batteries.
ACCC report: Lithium batteries - In summary recommendation:
Demonstrable compliance of lithium-ion batteries to either IEC 62133 (portable applications) ... is promoted through a combination of additional guidance in standards (such as in AS 62368.1)
requirements of the ADGC (Dangerous Goods) on batteries imported into Australia, and potentially integrated into new equipment, meet the requirements of UN 38.3.
The overlap between requirements of IEC 62133 ... and UN 38.3 will simplify the required compliance (i.e., testing) pathway for manufacturers, importers....
(differences summary – with caution to be considered difference between UN 38.3 and IEC 62133.docx)
IEC 60086 (1, 2 and if applicable 4): covers markings, transport, safety aspects of primary batteries (non-rechargeable)
- Part 1: standardize primary batteries with respect to dimensions, nomenclature, terminal configurations, markings, test methods, typical performance, safety and environmental aspects.
- Part 2: Physical and electrical specifications
- Part 4: Safety of lithium batteries
- Part 6: Guidance on environmental aspects (possible less of priority at moment so therefore part 1, 2 and 4 is only recommended)

IEC 62133-1 specifies requirements and tests for the safe operation of portable sealed secondary nickel cells and batteries containing alkaline electrolyte, under intended use and reasonably foreseeable misuse. Inclusion of button cell requirements.



For chargers:
The following three standards are linked within them and also required under EESS requirements. The first two seem most important, third one is linked to second standard.

AS/NZS 3820 - Essential safety requirements for electrical equipment
This Standard sets out requirements for electrical equipment, to ensure that electrical equipment is constructed in accordance with good engineering practice in regard to safety such that it does not endanger the safety of persons (including children, the elderly and people with disabilities), domestic animals or property, when properly installed and maintained and used in applications for which it was made.
Australian Standard AS/NZS 4417 Marking of electrical products (Part 1 and 2)
General rules for use of the mark provides general requirements for the use of the RCM including location of the marking on the equipment and its dimensional requirements. Part 2 also covers ACMA requirements (e.g EMC, EMR etc).

IEC 60335-1: Household and similar electrical appliances - Safety - Part 1: General requirements -
Battery charger (Power supply or charger) require compliance with AS/NZS 60335 – particular 2.29 (as **listed under AS/NZS 4417.2 – clause B.2.49**).

Note: IEC 60601 is the medical devices electrical safety standard series, but this standard may impact on supply therefore at least the above seems reasonable to be expected.
The following are now additionally available for download:

What I have so far....any comments are welcome...
overlap between requirements of IEC 62133 ... and UN 38.3 needs still to be looked at...

s 22 [redacted]
s 22

Devices Specialist Evaluations Sections | Medical Devices Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location Fairbairn
Phone: s 22

PO Box 100, Woden ACT 2606
www.tga.gov.au

From: JAMIESON, John
To: s 22
Cc: s 22
Subject: RE: Vaping Devices - Check In [SEC=OFFICIAL]
Date: Friday, 8 March 2024 1:40:48 PM
Attachments: image001.png

Hi s 22
As a former official observer member of ERAC (when I was at the ACCC) I suggest they would be unable to respond quickly to us. They are no more than a meeting of State and Territory regulators (they don't actually exist as an entity) and they meet infrequently etc. and are typically reluctant to state a position on anything – preferring for the regulator members to make the calls separately.
In any case, State and territory requirements for anything that plugs into 240v are solid and we do not need to replicate those requirements in our framework.
For electromagnetic compatibility (EMC) and the ACMA, let's also not go there with this MDSO. These are simple low electrical power products – so electromagnetic risk is very small. If this becomes an issue later we can address further but please do not spend time on this now.
We can address both these issues in guidance:
- the battery chargers must comply with State and Territory electrical safety laws
- the charger and vapes must comply with ACMA requirements
- non-compliance with those laws would mean the product did not comply with our Essential Principles.
Let me know if you want to discuss further
Regards
John

From: s 22
Sent: Friday, March 8, 2024 12:12 PM
To: s 22 ; JAMIESON, John
Cc: s 22
Subject: RE: Vaping Devices - Check In [SEC=OFFICIAL]
Hi all,
Please see below update on the vaping device reform work:

- Progress status:
  - **We have delivered** the
    - Standards checklist (now on the web)
    - RegTech presentation
    - internal workshop focused on options for the updated MDSO ahead of the survey results. It was great to understand consensus around non-negotiable requirements such as labelling.
  - **Timeframe and resource dependencies are critical risks** – On the current schedule we have 9 business days to have an MDSO cleared through Tracey (MDPQD approved), to enable final clearance and registration before the end of march.
    - Whilst we have more resources on board and MDSO considerations are progressing, schedule remains a major risk.
    - RLSB availability to undertake drafting may lead to delays. Drafting is likely to occur from the week of the 18th which means the brief will be going to Tracey late in the week.
  - **Survey update:** now closing on 10 March 2024 (deadline extended):
    - Summary of preliminary analysis: 15 responses so far and include submissions from the s 22 (s 22 , Liber s 22) and s 22 claim they will be able to meet s 47 , IFU & labelling, and certain battery requirements by s 47 . There are slightly mixed responses around plain packaging. No major changes from my email on Tuesday (attached for reference) s 22
    - We did have a slight error with closure dates on one of the extension emails but we have addressed that with follow up communications.
  - **Brief to Tracey is in very early draft** to support the MDSO finalisation, and we are hoping to get this to both John and s 22 next week if everything goes to plan.
- **Critical considerations/decisions:**

- In relation to the MDSO, we are currently considering battery and charger safety risk in detail by including relevant battery and charger standards as options (see attached email for more info). We have identified that there are particular electrical and electronic equipment standards that all electrical equipment with 240V or more must meet in Australia (see below in blue text)
    - Do you want us to contact the Electrical Regulatory Authorities Council in relation to the electrical safety requirement for electrical equipment? and/or ACMA regarding EMC?
- Flagging there may be potential delay in publication of the MDSO and TGO to mid-April due to RLSB being busy with the changes to the Act occurring next week – this is yet to be confirmed. I checked with s 22 today, no update yet, we'll keep you posted as soon as we know more.
- MDSO approval process – John to flag with Tracey that this is coming when she returns from IMDRF (if there is no delay).

- **MDSO Drafting:**
    - We have had a follow-up discussed with RLSB to commence drafting of the MDSO. RLSB will be busy next week with the Bill, so drafting is likely to occur from the week of the 18th
- **Project timeline for key elements:**

Key tasks to deliver Updated MDSO	Due Date	Comments
Survey	Complete, 19 Feb 2024	Will close on 10 March (extended deadline)
Brainstorming workshop	Complete, 28 Feb 2024	
Survey analysis and preliminary position on MDSO	Underway, 4-11 March 2024	Underway
Final position on MDSO and briefing upwards	11-15 March 2024	Underway
MDSO clearance/approval (inc. Brief to Tracey)	18-22 March 2024	Pending
MDSO final clearance through Tony and Registration	25-29 March	Pending, (RLSB action)
EP/Standards checklist	Complete, 27 Feb 2024	Published on our website
Reg Tech Presentation	Complete, 27 Feb 2024	

Possible MDSO requirements – for December 2024:

- IFU, Labelling, Plain packaging (mixed views about plain packaging but overall support even from most sponsors)
- ISO 13485 (QMS)
- ISO 14971 – Risk management for medical devices
- Battery standards – including several options (most of these overlap, some significantly) – any one of the following:
    - IEC 62133
    - IEC 62281
    - UN38.3
    - (we'll need to decide if there should be any more options at this stage)
- Possible fundamental device safety requirements yet to be decided (e.g. interlocked activation – to prevent unintentional activation of the device when in transit/storage – this would need to come from a standard such as UL 8139)
- Compliance with other regulatory requirements for electrical and battery products such as:
    - ACCC requirements for button batteries (if appliable, none have indicated they use button batteries)
    - Various AS/NZS electrical requirements (e.g. for chargers)
        - **AS/NZS 3820 - Essential safety requirements for electrical equipment**
          This Standard sets out requirements for electrical equipment, to ensure that electrical equipment is constructed in accordance with good engineering practice in regard to safety such that it does not endanger the safety of persons (including children, the elderly and people with disabilities), domestic animals or property, when properly installed and maintained and used in applications for which it was made.
        - **Australian Standard AS/NZS 4417 Marking of electrical products (Part 1 and 2)**
          General rules for use of the mark provides general requirements for the use of the RCM including location of the marking on the equipment and its dimensional requirements. Part 2 also covers ACMA requirements (e.g EMC, EMR etc).
    - ACMA requirements for EMC

These may not reside in the MDSO but our guidance may direct sponsors to them if/as appliable.

Regards,
s 22 – s 22
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22
-----Original Appointment-----
From: s 22
Sent: Wednesday, February 14, 2024 1:31 PM
To: s 22 JAMIESON, John; s 22
Cc: s 22
Subject: Vaping Devices - Check In
When: Friday, 8 March 2024 1:30 PM-2:30 PM (UTC+10:00) Canberra, Melbourne, Sydney.
Where: Webex / s 22 Office
Hi All,
Moving this from s 22 diary to s 22 ,
As usual
Weekly standing meeting as a check in for the different pieces of work we need to get done:

- Survey (s 22)
- Expectations for MDSO and EPs (checklist) (s 22)
- Guidance (s 22)
- Etc.

Thanks
s 22
-- Do not delete or change any of the following text. --

From: s 22
To: s 22
Subject: RE: Vaping check-in mtg for 8 March - Updates [SEC=OFFICIAL]
Date: Tuesday, 12 March 2024 9:37:04 AM

Thanks this was very helpful.
Regards,
s 22 – s 22
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

From: s 22
Sent: Thursday, March 7, 2024 4:08 PM
To: s 22
Cc: s 22
Subject: Vaping check-in mtg for 8 March - Updates [SEC=OFFICIAL]

Hi s 22
I have prepared a status update for tomorrow which I hope will be helpful. Feel free to make updates as required and add anything else that I may have missed.
As tomorrow is my non-working day, I will not be able to attend the vaping-check in mtg. I have also communicated this to s 22 's EA for s 22 awareness.
Kind regards
s 22

- Progress status:
  - We have delivered the Standards checklist, RegTech presentation & internal workshop focused on options for the updated MDSO ahead of the survey results and was great to understand consensus around non-negotiable requirements such as labelling.
  - Survey: Out for consultation, closing on 10 March 2024 (deadline extended):
    - Summary of preliminary analysis: 15 responses to date and include submissions from the s 22 (s 22 , Liber s 22) and s 22 claim they will be able to meet s 47 , IFU & labelling requirements by s 47 . There are slightly mixed responses around plain packaging. [feel free to add more detail, perhaps it may be worthwhile to get s 22 to provide this input]
  - Brief to Tracey is being prepared to support the MDSO finalisation, likely to be ready next week for feedback by John and s 22 ?
- Critical considerations/decisions:
  - In relation to the MDSO, we are addressing the battery safety risk by including relevant battery standards as options and further to that, we are also considering charging standards to also address the electrical safety risk. We have identified that there are particular electrical and electronic equipment standards that all electrical equipment with 240V or more must meet in Australia.
    - Do you want us to contact the Electrical Regulatory Authorities Council in relation to the electrical safety requirement for electrical equipment?
  - Flagging there may be potential delay in publication of the MDSO and TGO to mid-April due to RLSB being busy with the changes to the Act occurring next week – this is yet to be confirmed. We'll keep you posted as soon as we know more.
  - MDSO approval process – John to flag with Tracey that this is coming when she returns from IMDRF (if possible check with John if he's had the discussion with Tracey on what the MDSO approval process looks like)
- MDSO Drafting:
  - We have had a follow-up discussed with RLSB to commence drafting of the MDSO. RLSB will be busy next week with the Bill, so drafting is likely to occur from the week of the 18th.
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MDSO clearance/approval (inc. Brief to Tracey)	18-22 March 2024	
EP/Standards checklist	Complete, 27 Feb 2024	Published on our website
Reg Tech Presentation	Complete, 27 Feb 2024	

From: s 22
To: s 22
Subject: RE: Vaping check-in mtg for 8 March - Updates [SEC=OFFICIAL]
Date: Tuesday, 12 March 2024 2:55:00 PM

Thanks s 22, pleased to hear it was. Will aim to do this in future where I can.
Kind regards
s 22

From: s 22
Sent: Tuesday, March 12, 2024 9:37 AM
To: s 22
Subject: RE: Vaping check-in mtg for 8 March - Updates [SEC=OFFICIAL]
Thanks this was very helpful.
Regards,
s 22 – s 22
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

From: s 22
Sent: Thursday, March 7, 2024 4:08 PM
To: s 22
Cc: s 22
Subject: Vaping check-in mtg for 8 March - Updates [SEC=OFFICIAL]
Hi s 22
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EP/Standards checklist	Complete, 27 Feb 2024	Published on our website
Reg Tech Presentation	Complete, 27 Feb 2024	

From: s 22
To: s 22
JAMIESON, John
Cc: s 22
Subject: VAPING REFORMS - draft MDSO requirement for feedback - please provide feedback by the morning of Thursday 14 March [SEC=OFFICIAL:Sensitive]
Date: Tuesday, 12 March 2024 3:38:00 PM
Attachments: image001.png
RE Vaping Devices - Check In SECOFFICIAL.msg
image002.png
Importance: High

Hi Everyone,
We are working to finalise the proposed requirements for an updated Medical Device Standards Order (MDSO) for vaping devices. The draft requirement is set out below and we would **appreciate your input and feedback by 9am Thursday 14 March.** My apologies for the short turnaround time but it is required to enable us to progress with this work given the very tight schedule (including clearance and legal drafting of a new MDSO). This MDSO is intended to be made in March and implemented in December 2024.

Background

How does this fit into the strategy for regulating vapes?
"These changes will protect Australians, particularly young people, from the harms of vaping and nicotine dependence, *while ensuring those with a legitimate need to access therapeutic vapes can continue to do so, where clinically appropriate*." - The Hon Mark Butler MP, Minister for Health and Aged Care. In line with the broader vape reforms, the MDSO requirement drafted below is intended to increase the stringency of the existing MDSO by implementing product specific standards (and removing some options) whilst balancing that against the need for patient access to therapeutic vaping devices to support the broader reform program. Please also note that there are two pathways for sponsors of nicotine vaping devices through the existing exemptions, they may claim compliance to the MDSO (if eligible) or they may claim compliance with the EPs directly and we have recently published the Standards for therapeutic vaping devices checklist to support sponsors (and assessment of those claims).

Survey update

We previously sought feedback on a stakeholder survey (D24-645284) and that survey closed last night, 10 March. The detailed analysis is being completed. However a high level summary is:

- Five manufacturers of vaping devices responded and some responses provided detailed information and views on the technical standards for vaping devices. s 47
- s 22
-

Raw data output of the survey is available here: export-2024-03-04-10-11-02.xlsx

Draft MDSO requirement:

Please note there are many reasons why we have elected for certain requirements over others and its probably best to discuss these. If you are interested please contact me or s 22.

- Quality Management Systems requirements
    - **ISO 13485 certification** for the manufacture of the device, issued by one of the following:

(i) an IAF accredited organisation;

(ii) a notified body;

(iii) an auditing organisation recognised by Health Canada;

(iv) an Australian conformity assessment body determined under the Regulations;

- **Removing the option of certification to ISO 9001**

- Product requirements (for detail refer to the draft requirement below)
  - **Instructions for Use**
  - **Labelling**
  - **Plain packaging**
- Meet the following product standards:
  - **ISO 14971 – Application of risk management to medical devices** (compliance only, not certification)
  - Battery standards:
    - Lithium batteries:
      - **Certification to, or independent test reports demonstrating compliance with, UN/DOT 38.3** – UN Manual of tests and criteria section 38.3 concerning the testing of lithium cells and batteries for transport safety.
      - **Certification to IEC 62133 -2**: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems. Certification by an accredited third party laboratory.

        Note: there is considerable overlap in test requirements, however both of these requirements service different purposes. The intent is to impose relevant requirements without imposing unnecessary regulatory burden, therefore requiring certification to IEC 62133 -2 whilst allowing test reports demonstrating compliance to 38.3 would enable manufacturers to meet the MDSO requirement without needing (costly) certification to both of these standards.
    - Nickel systems batteries: Certification to IEC 62133-1 - Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 1: Nickel systems. Certification by an accredited third party laboratory.
    - For primary (non-rechargeable) batteries: Certification to IEC 60086 - Primary batteries (parts 1, 2, and 4 or 5 if applicable). Certification by an accredited third party laboratory.

      For much more background on batteries please see the attached emails.
- **If applicable to the device, compliance with relevant Commonwealth and State or Territory legislation related to consumer goods** including the following:
  - Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020

(where applicable)
    - Electrical safety of consumer goods (if/where applicable):
        - Australian Standard AS/NZS 3820 - Essential safety requirements for electrical equipment (if applicable – for the charger)
        - Australian Standard AS/NZS 4417 Marking of electrical products (if applicable – for the charger)
            - As a result power supplies or battery chargers may require compliance with AS/NZS 60335 - Household and similar electrical appliances – Safety – Part 1: General requirements
- **Removal of the option to use user consumer grade e-cigarettes evidence** (schedule 1, item c, of the current MDSO)
- **Retaining the option to use certain evidence of compliance for a vape as a therapeutic good** (schedule 1, item d, of the current MDSO)
- **Specific safety requirements:**
    - **Preventing accidental activation**- The device is required to incorporate a means to minimise the likelihood of accidental activation. The method used to prevent accidental activation may be aligned with the requirements of section 13 of UL 8139:2020, or may be other means as appropriate to the design of the device.

Appreciate your review and feedback.
Kind Regards,
s 22

Product requirements - Instructions for Use

Therapeutic vaping devices and accessories must be supplied with Instructions For Use (IFU). This IFU must be in English but may also be written in other languages, and may be supplied in paper or electronic format provided it is readily accessible to patients.
IFUs must include the following information:

- device manufacturer's name, or trading name, and address
- intended purpose and the intended user of the device
- device name
- batch code, lot number or serial number of the device, if this is not provided on the device or its packaging
- particular handling or storage requirements applying to the device including acceptable storage conditions (e.g. a temperature range)
- any warnings, restrictions, or precautions that may apply in relation to the use of the device, such as:

    - a statement that informs the user if the device is not functioning correctly, to seek advice from a healthcare professional

    - if it is a selected-dose device, only the user shall be able to select the correct dose

    - if it is a selected-dose device, how the device operates when the amount of medication available is less than the dose the user intends to select

    - if it contains button or coin batteries, include warning information about the risks associated with button or coin batteries by complying with the Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020

    - Consumers need to know about the risks that button or coin batteries can pose,

and what to do if they suspect that someone has swallowed or inserted a battery

- special operating instructions for the use of the device including:

  - appropriate actions that need to be performed prior to use (e.g. shaking, priming, device orientation, selecting the dose, etc.);

  - instructions on how the operator is to use the device (e.g. inhalation, exhalation, actuation, inspiratory effort, duration, breath holding, repetition of inhalation);
- any preparatory actions for first-time use (e.g. battery loading, function testing) or instructions for assembly or for use with an accessory
- any cleaning requirements for the device and, where applicable, reusable containers holding e-liquid
- Information about the replacement of consumable components of the device during its lifetime
- Information about precautions that should be taken by a patient and the user if there are special or unusual risks associated with the disposal of the device including:

  - instructions on how to dispose of the device or its parts at the end of its used life

  - type and identifier of replaceable batteries, if used, and instructions about how to recycle the used batteries.

Labelling requirements

Therapeutic vaping devices must be labelled in English and include the following information:

- Sponsor name and address
- Manufacturer name and address
- Device name (brand, model etc.)
- Batch code, lot number or serial number of the device
- *Risk of fire or explosion. Replace only with battery [manufacturer, model or series].*

Where a label containing the above information cannot be affixed directly on the device itself, then it is expected to be included on the packaging used for the device.

Packaging requirements

Packaging for Therapeutic Vaping Devices must:

- be predominantly in white background with only black and grey lettering permitted
- not include certain [prohibited or restricted] product names, logos or brand names
- include health warnings being:
  "KEEP OUT OF REACH OF CHILDREN"
- if it contains button or coin batteries, include warnings that comply with the Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020 such as:
  "Warning: Contains button or coin cell battery. Hazardous if swallowed – see instructions"

Kind Regards,

s 22 – s 22
Devices Specialist
Evaluation Section /
MDAB / MDPQD
s 22

From: s 22
To: s 22
Cc: s 22
Subject: FW: VAPING REFORMS - draft MDSO requirement for feedback [SEC=OFFICIAL:Sensitive]
Date: Tuesday, 12 March 2024 3:49:00 PM
Attachments: image001.png
RE Vaping Devices - Check In SECOFFICIAL.msg
image002.png

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Sent: Tuesday, March 12, 2024 3:39 PM
To: s 22 ; JAMIESON, John
Cc: s 22
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- Five manufacturers of vaping devices responded and some responses provided detailed information and views on the technical standards for vaping devices. s 47

[redacted] s 22

- [redacted]

Raw data output of the survey is available here: export-2024-03-04-10-11-02.xlsx

Draft MDSO requirement:

Please note there are many reasons why we have elected for certain requirements over others and its probably best to discuss these. If you are interested please contact me or Tania.

- Quality Management Systems requirements
  - **ISO 13485 certification** for the manufacture of the device, issued by one of the following:

    (i) an IAF accredited organisation;

    (ii) a notified body;

    (iii) an auditing organisation recognised by Health Canada;

    (iv) an Australian conformity assessment body determined under the Regulations;
  - **Removing the option of certification to ISO 9001**
- Product requirements (for detail refer to the draft requirement below)
  - **Instructions for Use**
  - **Labelling**
  - **Plain packaging**
- Meet the following product standards:
  - **ISO 14971 – Application of risk management to medical devices** (compliance only, not certification)
  - Battery standards:
    - Lithium batteries:
      - **Certification to, or independent test reports demonstrating compliance with, UN/DOT 38.3** – UN Manual of tests and criteria section 38.3 concerning the testing of lithium cells and batteries for transport safety.
      - **Certification to IEC 62133 -2**: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems. Certification by an accredited third party laboratory.

        Note: there is considerable overlap in test requirements, however both of these requirements service different purposes. The intent is to impose relevant requirements without imposing unnecessary regulatory burden, therefore requiring certification to IEC 62133 -2 whilst allowing test reports demonstrating compliance to 38.3 would enable manufacturers to meet the MDSO requirement without needing (costly) certification to both of these standards.
    - Nickel systems batteries: Certification to IEC 62133-1 - Secondary cells

and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 1: Nickel systems. Certification by an accredited third party laboratory.

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For much more background on batteries please see the attached emails.

- **If applicable to the device, compliance with relevant Commonwealth and State or Territory legislation related to consumer goods** including the following:
  - Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020 (where applicable)
  - Electrical safety of consumer goods (if/where applicable):
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    - Australian Standard AS/NZS 4417 Marking of electrical products (if applicable – for the charger)
      - As a result power supplies or battery chargers may require compliance with AS/NZS 60335 - Household and similar electrical appliances – Safety – Part 1: General requirements
- **Removal of the option to use user consumer grade e-cigarettes evidence** (schedule 1, item c, of the current MDSO)
- **Retaining the option to use certain evidence of compliance for a vape as a therapeutic good** (schedule 1, item d, of the current MDSO)
- **Specific safety requirements:**
  - **Preventing accidental activation**- The device is required to incorporate a means to minimise the likelihood of accidental activation. The method used to prevent accidental activation may be aligned with the requirements of section 13 of UL 8139:2020, or may be other means as appropriate to the design of the device.

Appreciate your review and feedback.
Kind Regards,
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Product requirements - Instructions for Use

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IFUs must include the following information:

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- intended purpose and the intended user of the device
- device name
- batch code, lot number or serial number of the device, if this is not provided on the device or its packaging
- particular handling or storage requirements applying to the device including acceptable storage conditions (e.g. a temperature range)
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  - a statement that informs the user if the device is not functioning correctly, to seek

advice from a healthcare professional

- if it is a selected-dose device, only the user shall be able to select the correct dose

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Devices Specialist
Evaluation Section /
MDAB / MDPQD
s 22

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Date: Tuesday, 12 March 2024 3:49:20 PM
Attachments: image001.png
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- device name
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Cc: s 22
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Date: Tuesday, 12 March 2024 3:58:00 PM
Attachments: image001.png
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Devices Specialist
Evaluation Section /
MDAB / MDPQD
s 22

From: s 22
To: s 22
Cc: s 22

Subject: FW: Supply chain survey 1-8/3 summary of 8 responses [SEC=OFFICIAL]
Date: Tuesday, 12 March 2024 5:36:18 PM
Attachments: No 1 Supply chain survey 1 to 8 March 2024 Report.docx
image001.png
image003.png

Hi all,
Attached is the data from the first supply survey (a success) that s 22 has pulled together, but here are the main takeaway messages:

- **STOP DRIP-FEEDING THE CHANGES** (very clear message!) – sponsors trying to supply the legal pathways are really struggling to keep up with the regular changes. It is impossible to keep re-formulating to meet the moving goal posts, to make any sort of supply plan (education of all in the supply chain) and the costs are adding up. They need clear communication of all changes impacting their operations in the short and longer term, and then they need it not to change for a period of time. This lack of clarity is materially affecting buy in, particularly the willingness of pharmacies to buy and hold stock, which is necessary for immediate dispensing. Until this is resolved, there will be continued disruptions to the supply chain.
- **Current sales are increasing, but still well below predictions** and the 'black market' is still winning. For example, the major online sellers of iGets for instance is running promotions and discounts for bulk purchases. Major retail also continue to sell black market products under the guise of 0 nicotine which is not the case. They don't see this subsiding for the next 6-12 months.
- **Concerns of the ability to sell the product we've already shipped to Australia** [especially the banned flavours and by 1 July] has been raised.
- There is still significant black-market products.
- **Lack of public awareness of the legal pathway.** Vapers are only hearing the media headlines that vaping is now "banned". There is minimal awareness on the legal pathway. A public education campaign is necessary to ensure awareness and correct understanding of the legal pathway. The inability for pharmacies & doctors to advertise [communicate?] is further negatively impacting the medical model.

I will follow up on a few issues with calls (with s 22), but generally this survey is the baseline and there is not anything too concerning or surprising.
The plan is that we will include a summary of 'actions against the feedback' to participants at the time we reach out and ask them to complete the next survey. This is to demonstrate that we are listening and taking action against their input, so it is worth their continued survey engagement.
Let me know if you have any feedback or questions.
Regards

s 22
, Scientific Operations Management Section
Scientific Evaluation Branch
Medicines Regulation Division | Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s 22
Location: Level 1, 27 Scherger Drive Fairbairn, ACT 2609
PO Box 100, Woden ACT 2606, Australia
The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s 22

Sent: Tuesday, March 12, 2024 12:17 PM
To: s 22 y
Subject: Supply chain survey 1-8/3 summary of 8 responses

FYI

s 22

s 22 | Vaping Implementation and Enforcement Branch

Health Products Regulation Group
Australian Government Department of Health
s 22
Location: 27 Scherger Drive Fairbairn ACT
PO Box 100, Woden ACT 2606, Australia
The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

Supply chain survey – 1 March 2024 to 8 March 2024

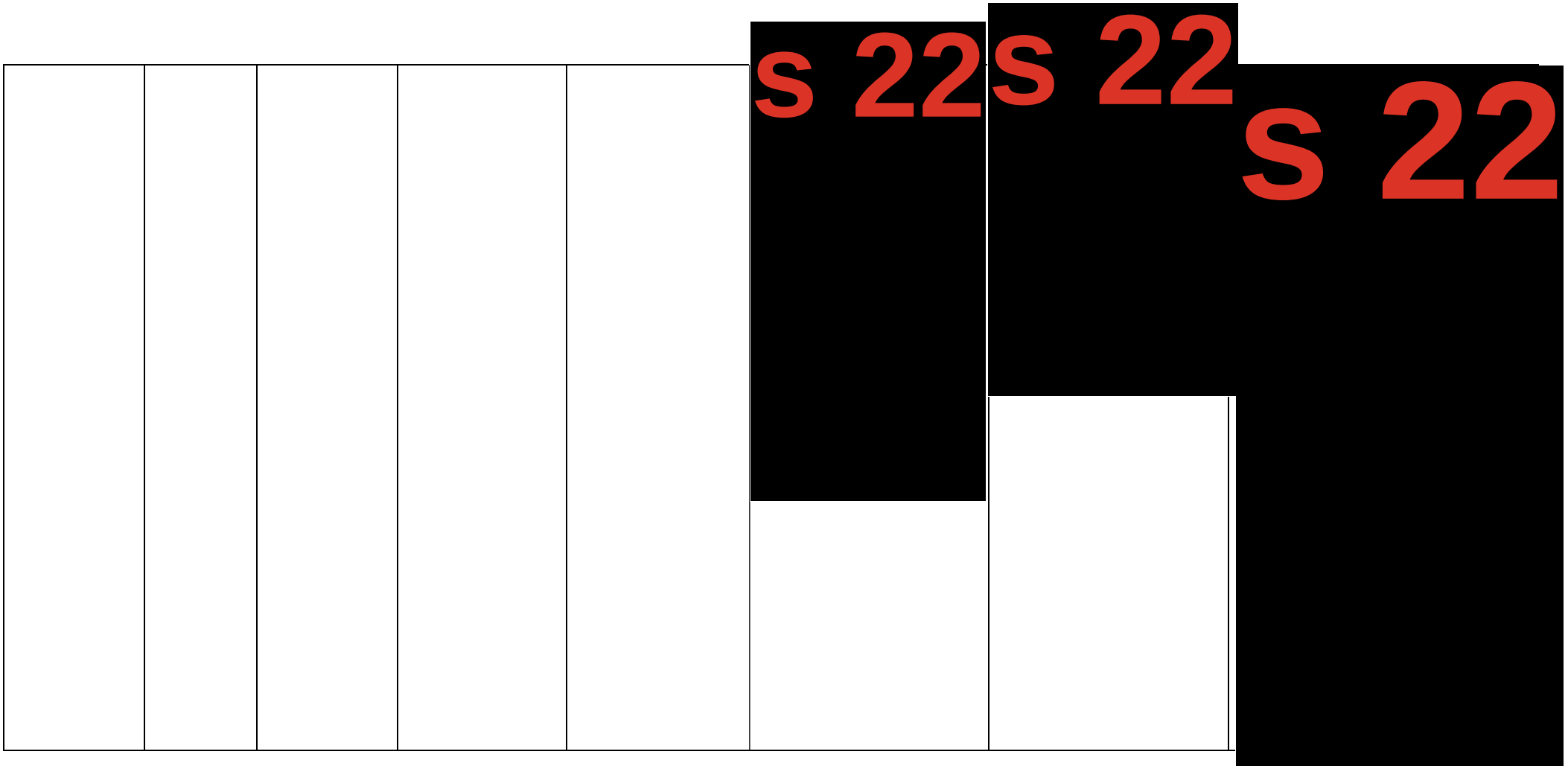
s 22

Sponsors/Importers

Number of respondents: 6

Question/ Survey date	1.	2.	3.	4.	5.	6.	7.
	Do you have sufficient stock to meet retailer demand?	**Has demand for supply of vapes increased or decreased since 1 January 2024?**	**Have you been able to readily import your goods where a permit is provided with the consignment?** If no describe:	**How much stock do you hold in the country?** ***3-6 months,*** ***6-12 months*** ***+12 months***	**Do you foresee any supply chain challenges that may affect your vape supply in Australia in the next 6 months? Please describe the challenges e.g. if they are distinct to the device or e-liquid**	**Do you have a plan of how to respond to vape shortages or product line discontinuations?** **If Yes, please describe your plan**	**Do you have any other comments or feedback for us - either from yourself or your stakeholders?**

	5/6 Yes	4/6 Increased	4/6 Yes 1. still working on the product notification details prior we can apply for import permit (6-12 months supply) 2, we have not as yet imported further goods (3-6 months supply)	4/6 s 47 2/6 s 47 (Liber is one)	4/6 yes 1. It becomes a surprise to us and our pharmacy partners that fruity flavours nicotine vaping products can only be dispensed until 1st July 2024. This is an item of significance that should be highlighted to the industry during the webinar and TGA vaping hut, rather than just sitting in the updated TGO110. We also have not been provided the details of future TGO 110 requirements, including packaging and nicotine limit, which makes it very hard to have an accurate production plan and add more risks from an inventory planning perspective 2. Forecasting the effect of illicit trade. 3. Lack of clarity from CSO wholesalers in terms of allowing pharmacies to hold stock before scripts are presented. (from Liber)	4/6 Yes 1. Liber is currently holding 6-9 months of stock onshore, and proposes to launch s 47 s 47 a new fully notified NVP, with three permitted flavours in each of three nicotine concentrations s 22 [redacted] to meet demand.	s 22 2. (liber) s 47 [redacted] lack of certainty about future changes makes it almost impossible to plan future supply or train stakeholders in terms of prescribing, distributing and dispensing. This lack of clarity is materially affecting buy in, particularly the willingness of pharmacies to buy and hold stock, which is necessary for immediate dispensing. Until this is resolved, there will be continued disruptions to the supply chain. s 22 [redacted]


s 22
s 22
s 22

From: s 22
To: s 22
Cc: s 22
Subject: RE: Supply chain survey 1-8/3 summary of 8 responses [SEC=OFFICIAL]
Date: Wednesday, 13 March 2024 9:00:00 AM
Attachments: image002.png
image003.png

Hi s 22
Thank you for sharing the stakeholder feedback.
The first point is a critical one for us to take note of and another one is about supply. Good to hear insights from Liber indicating they have sufficient stock to maintain supply unless there is an unforeseen surge in which case they expect supply issues to be limited to s 47. Both useful insights for the upcoming MDSO update.
Kind regards
s 22

From: s 22
Sent: Tuesday, March 12, 2024 5:36 PM
To: s 22 ; GILMOUR-WALSH, Bridget ; s 22 ; JAMIESON, John
Cc: s 22

Subject: FW: Supply chain survey 1-8/3 summary of 8 responses [SEC=OFFICIAL]
Hi all,
Attached is the data from the first supply survey (a success) that s 22 has pulled together, but here are the main takeaway messages:

- **STOP DRIP-FEEDING THE CHANGES** (very clear message!) – sponsors trying to supply the legal pathways are really struggling to keep up with the regular changes. It is impossible to keep re-formulating to meet the moving goal posts, to make any sort of supply plan (education of all in the supply chain) and the costs are adding up. They need clear communication of all changes impacting their operations in the short and longer term, and then they need it not to change for a period of time. This lack of clarity is materially affecting buy in, particularly the willingness of pharmacies to buy and hold stock, which is necessary for immediate dispensing. Until this is resolved, there will be continued disruptions to the supply chain.
- **Current sales are increasing, but still well below predictions** and the 'black market' is still winning. For example, the major online sellers of iGets for instance is running promotions and discounts for bulk purchases. Major retail also continue to sell black market products under the guise of 0 nicotine which is not the case. They don't see this subsiding for the next 6-12 months.
- **Concerns of the ability to sell the product we've already shipped to Australia** [especially the banned flavours and by 1 July] has been raised.
- There is still significant black-market products.
- **Lack of public awareness of the legal pathway.** Vapers are only hearing the media headlines that vaping is now "banned". There is minimal awareness on the legal pathway. A public education campaign is necessary to ensure awareness and correct understanding of the legal pathway. The inability for pharmacies & doctors to advertise [communicate?] is further negatively impacting the medical model.

I will follow up on a few issues with calls (with s 22), but generally this survey is the baseline and there is not anything too concerning or surprising.

The plan is that we will include a summary of 'actions against the feedback' to participants at the time we reach out and ask them to complete the next survey. This is to demonstrate that we are listening and taking action against their input, so it is worth their continued survey engagement. Let me know if you have any feedback or questions.

Regards

s 22
s 22 , Scientific Operations Management Section
Scientific Evaluation Branch
Medicines Regulation Division | Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s 22
Location: Level 1, 27 Scherger Drive Fairbairn, ACT 2609
PO Box 100, Woden ACT 2606, Australia
The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s 22
Sent: Tuesday, March 12, 2024 12:17 PM
To: s 22
Subject: Supply chain survey 1-8/3 summary of 8 responses

FYI

s 22

s 22 | Vaping Implementation and Enforcement Branch

Health Products Regulation Group
Australian Government Department of Health
s 22
Location: 27 Scherger Drive Fairbairrn ACT
PO Box 100, Woden ACT 2606, Australia
The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s 22
To: s 22
Subject: For assistance please - Survey analysis - Due: 10.30am Monday 18 [SEC=OFFICIAL]
Date: Sunday, 17 March 2024 6:38:00 PM
Importance: High

Hi s 22 ,

Could I please ask you to provide summary of the survey analysis kindly. I have drafted below and would appreciate your input where X is marked and anything else you believe would be value add. Grateful if it could be provided by 10.30am Monday 18th please? I'd like to include this summary in the update Vaping check-in meeting in the morning.

- Total number of respondents: 15?
- Respondents include:
  - s 22 manufacturers/sponsors including s 22 , Liber s 22 , s 22 claiming to meet s 47 , IFU & labelling, and certain battery standards by s 47 .
  - X wholesalers/importers including XX, s 22 claim to comply with the requirements of s 47 or any of the device standards, although battery standards such as s 47 or s 47 were mentioned by s 22 . The unique 'pharmaceutical-like packaging' requirement was claimed to have some impact on their business.
  - s 22 [redacted]
  - [redacted]

Thank you

s 22

From: s 22
To: s 22
Subject: RE: For assistance please - Survey analysis - Due: 10.30am Monday 18 [SEC=OFFICIAL]
Date: Monday, 18 March 2024 10:21:16 AM
Attachments: image001.png

Hi s 22,

Summary below for your review.

- Total number of respondents: 21
- Respondents include:
  - manufacturers/sponsors including s 22, Liber s 22 claiming to meet s 47, IFU & labelling, and certain battery standards by s 47.
  - s 22
  - s 22 s 22
  - s 22
  - s 22
  - s 22

Regards,

s 22

Devices Specialist Evaluation Section | Medical Devices and Product Quality Division | Medical Devices Branch | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Dr Fairbairn
Phone: s 22
PO Box 100, Woden ACT 2606
www.tga.gov.au

From: s 22

Sent: Sunday, March 17, 2024 6:39 PM
To: s 22
Subject: For assistance please - Survey analysis - Due: 10.30am Monday 18 [SEC=OFFICIAL]
Importance: High

Hi s 22 ,

Could I please ask you to provide summary of the survey analysis kindly. I have drafted below and would appreciate your input where X is marked and anything else you believe would be value add. Grateful if it could be provided by 10.30am Monday 18th please? I'd like to include this summary in the update Vaping check-in meeting in the morning.

- Total number of respondents: 15?
- Respondents include:
  - [redacted] manufacturers/sponsors including s 22 , Liber, s 22 claiming to meet s 47 , IFU & labelling, and certain battery standards by s 47 .
  - X wholesalers/importers including XX, s 22 claim to comply with the requirements of s 47 or any of the device standards, although battery standards such as s 47 or s 47 were mentioned by some. The unique 'pharmaceutical-like packaging' requirement was claimed to have some impact on their business.
  - s 22 [redacted]
  - [redacted]

Thank you

s 22

From: s 22
To: s 22 JAMIESON, John
Cc: s 22
Subject: RE: Vaping Devices - Check In - Update 18 March 2024 [SEC=OFFICIAL]
Date: Monday, 18 March 2024 10:30:00 AM
Attachments: FW FOR ENDORSEMENT - VAPING REFORMS - proposed final MDSO requirement SECOFFICIALSensitive.msg

Hi all,
Please see below update on the vaping device reform work.

- **Progress status:**
  - **We have:**
    - completed survey analysis (see below)
    - developed a final position on the MDSO for Dec 2024 - have consulted internally and sought endorsement (see attached email)
    - Other matters:
      - For the Dep Sec presentation at AusMedtech 2024, prepared slides to provide update on vaping reforms
      - Provided input into the costings work for capturing effort on vaping reforms
  - **Survey update:**
    - Closed on 10 March 2024
    - Summary of analysis:
    - Total number of respondents: 21
    - Respondents include:
      - manufacturers/sponsors including s 22, Liber, s 22 claiming to meet s 47, IFU & labelling, and certain battery standards by s 47.
      - s 22
  - **Brief to Tracey is in draft** to support MDSO finalisation, and hoping to get this to John and Marcelle by tomorrow.
  - **Timeframe and resource dependencies are critical risks** – On the current schedule we have 4 business days to have an MDSO cleared through Tracey (MDPQD approved), to enable final clearance and registration before the end of march.
    - Schedule remains a major risk along with RLSB availability to undertake drafting which may lead to delays.
- **Critical considerations/decisions:**
  - MDSO approval process – John to flag with Tracey that this is coming when she returns from IMDRF (if there is no delay).
  - We will work with s 22 about plain packaging aspects to get consistency where possible
  - We will circle back to Labs and other MDSB colleagues to manage expectations
- **MDSO Drafting:**
  - We have had a follow-up discussion with RLSB on Thursday and answered questions to commence

drafting of the MDSO.

- **Project timeline for key elements:**

Key tasks to deliver Updated MDSO	Due Date	Comments
Survey	Complete, 19 Feb 2024	Closed on 10 March 2024
Brainstorming workshop	Complete, 28 Feb 2024	
Survey analysis and draft final position on MDSO	Complete, 15 March 2024	
Final position on MDSO and briefing upwards	11-15 March 2024 (see attached email)	Complete
MDSO clearance/approval (inc. Brief to Tracey)	18-22 March 2024	Pending
MDSO final clearance through Tony and Registration	25-29 March	Pending, (RLSB action)
EP/Standards checklist	Complete, 27 Feb 2024	Published on our website
Reg Tech Presentation	Complete, 27 Feb 2024	
Dep Sec presentation at AusMedtech 2024	Completed slides preparation, 15 March 2024	

Kind regards

s 22

-----Original Appointment-----

From: s 22

Sent: Wednesday, February 14, 2024 1:31 PM

To: s 22 ; JAMIESON, John; s 22

Cc: s 22

Subject: Vaping Devices - Check In [SEC=OFFICIAL]

When: Monday, 18 March 2024 12:00 PM-1:00 PM (UTC+10:00) Canberra, Melbourne, Sydney.

Where: Webex / s 22 Office

Hi All,

Moving this from s 22 diary to s 22 ,

As usual

Weekly standing meeting as a check in for the different pieces of work we need to get done:

* Survey (s 22)
* Expectations for MDSO and EPs (checklist) (s 22)
* Guidance (s 22)
* Etc.

Thanks

s 22

From: s 22
To: s 22
Subject: RE: For assistance please - Survey analysis - Due: 10.30am Monday 18 [SEC=OFFICIAL]
Date: Monday, 18 March 2024 10:48:00 AM
Attachments: image001.png

Thanks very much, s 22 . This is perfect!
Kind regards
s 22

From: s 22
Sent: Monday, March 18, 2024 10:21 AM
To: s 22
Subject: RE: For assistance please - Survey analysis - Due: 10.30am Monday 18 [SEC=OFFICIAL]

Hi s 22 ,
Summary below for your review.

- Total number of respondents: 21
- Respondents include:
  - [redacted] manufacturers/sponsors including s 22 Liber, s 22 claiming to meet s 47 , IFU & labelling, and certain battery standards by s 47 .
  - s 22 [redacted]
  - [redacted]
  - [redacted]
  - [redacted]

Regards,
s 22
s 22

Devices Specialist Evaluation Section | Medical Devices and Product Quality Division | Medical Devices Branch | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

27 Scherger Dr Fairbairn
Phone: s 22
PO Box 100, Woden ACT 2606

From: s 22
Sent: Sunday, March 17, 2024 6:39 PM
To: s 22
Subject: For assistance please - Survey analysis - Due: 10.30am Monday 18 [SEC=OFFICIAL]
Importance: High

Hi s 22 ,

Could I please ask you to provide summary of the survey analysis kindly. I have drafted below and would appreciate your input where X is marked and anything else you believe would be value add. Grateful if it could be provided by 10.30am Monday 18th please? I'd like to include this summary in the update Vaping check-in meeting in the morning.

- Total number of respondents: 15?
- Respondents include:
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  - s 22 [redacted]
  - [redacted]
  - [redacted]

Thank you

s 22

From: s 22
To: s 22
Subject: FW: Vaping Devices - Check In - Update 18 March 2024 [SEC=OFFICIAL]
Date: Monday, 18 March 2024 12:03:00 PM
Attachments: FW FOR ENDORSEMENT - VAPING REFORMS - proposed final MDSO requirement SECOFFICIALSensitive.msg

---

From: s 22
Sent: Monday, March 18, 2024 10:31 AM
To: s 22 ; JAMIESON, John
Cc: s 22
Subject: RE: Vaping Devices - Check In - Update 18 March 2024 [SEC=OFFICIAL]

Hi all,

Please see below update on the vaping device reform work.

- **Progress status:**
  - **We have:**
    - completed survey analysis (see below)
    - developed a final position on the MDSO for Dec 2024 - have consulted internally and sought endorsement (see attached email)
    - Other matters:
      - For the Dep Sec presentation at AusMedtech 2024, prepared slides to provide update on vaping reforms
      - Provided input into the costings work for capturing effort on vaping reforms
  - **Survey update:**
    - Closed on 10 March 2024
    - Summary of analysis:
      - Total number of respondents: 21
      - Respondents include:

        - manufacturers/sponsors including s 22, Liber, s 22 claiming to meet s 47, IFU & labelling, and certain battery standards by s 47.

        - 3 wholesalers/importers including s 22, none claim to comply with the requirements of ISO 13485 or any of the device standards, although battery standards such as UN38.3 or IEC 62133-2 were mentioned by some. The unique 'pharmaceutical-like packaging' requirement was claimed to have some impact on their business.

        - s 22
  - **Brief to Tracey is in draft** to support MDSO finalisation, and hoping to get this to John and s 22 by tomorrow.
  - **Timeframe and resource dependencies are critical risks** – On the current schedule we have 4 business days to have an MDSO cleared through Tracey (MDPQD approved), to enable final clearance and registration before the end of march.
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  - MDSO approval process – John to flag with Tracey that this is coming when she returns from IMDRF (if there is no delay).

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- We will circle back to Labs and other MDSB colleagues to manage expectations

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EP/Standards checklist	Complete, 27 Feb 2024	Published on our website
Reg Tech Presentation	Complete, 27 Feb 2024	
Dep Sec presentation at AusMedtech 2024	Completed slides preparation, 15 March 2024	

Kind regards

s 22

-----Original Appointment-----

From: s 22

Sent: Wednesday, February 14, 2024 1:31 PM

To: s 22

Cc: s 22

Subject: Vaping Devices - Check In [SEC=OFFICIAL]

When: Monday, 18 March 2024 12:00 PM-1:00 PM (UTC+10:00) Canberra, Melbourne, Sydney.

Where: Webex / s 22 Office

Hi All,

Moving this from s 22 diary to s 22,

As usual

Weekly standing meeting as a check in for the different pieces of work we need to get done:

* Survey (s 22)
* Expectations for MDSO and EPs (checklist) (s 22)
* Guidance s 22)
* Etc.

Thanks

s 22

From: s 22
To: s 22
Subject: FW: FOR ENDORSEMENT - VAPING REFORMS - proposed final MDSO requirement [SEC=OFFICIAL:Sensitive]
Date: Friday, 15 March 2024 8:41:51 AM
Attachments: image001.png
image002.png
image003.png

For info and records.

Regards,
s 22 – Director
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

From: s 22
Sent: Friday, March 15, 2024 7:36 AM
To: s 22
Subject: RE: FOR ENDORSEMENT - VAPING REFORMS - proposed final MDSO requirement [SEC=OFFICIAL:Sensitive]

Hi s 22
I endorse this, with s 22 's feedback to be included.
Regards
s 22

From: s 22
Sent: Friday, March 15, 2024 7:29 AM
To: s 22
Subject: Re: FOR ENDORSEMENT - VAPING REFORMS - proposed final MDSO requirement [SEC=OFFICIAL:Sensitive]

Thanks s 22

One change –
From = "for implementation in June 2026"
To = "for implementation by no later than 30 June 2026"

Perhaps we could also require them to inform us once they have implemented ISO 20072 so that we can pass that information onto our post-market colleagues.

From: s 22
Date: Thursday, 14 March 2024 at 18:26
To: s 22

Subject: FOR ENDORSEMENT - VAPING REFORMS - proposed final MDSO requirement [SEC=OFFICIAL:Sensitive]

Hi s 22 ,

Thanks for your time earlier today to discuss the MDSO requirement.

As discussed, our legal colleagues have started drafting the MDSO so we need to finalise the requirement ASAP. The MDSO needs to be MDPQD cleared/endorsed by the end of next week to meet the overall timeframes for the Vaping project to have 'product standards' (MDSO + TGO) legislative instruments made by the end of March.

We agreed a staged approach would be best to balance the need to introduce new product standards versus the risk of introducing requirements that are too stringent and cause undue risk to the overall therapeutic vaping reforms.

Proposed MDSO requirement

For implementation in December 2024 (no change to my email of 12 March):

- Quality Management Systems requirements
    - ISO 13485 certification for the manufacture of the device, issued by one of the following:
    - Removing the option of certification to ISO 9001
- Product requirements (for detail refer to the draft requirement below)
    - Instructions for Use
    - Labelling
    - Plain packaging
- Meet the following product standards:
        - ISO 14971 – Application of risk management to medical devices (compliance only, not certification)
        - Battery standards:
            - Lithium batteries:
                - Certification to, or independent test reports demonstrating compliance with, UN/DOT 38.3 – UN Manual of tests and criteria section 38.3 concerning the testing of lithium cells and batteries for transport safety.
                - Certification to IEC 62133 -2: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems. Certification by an accredited third party laboratory.
            - Nickel systems batteries: Certification to IEC 62133-1 - Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 1: Nickel systems. Certification by an accredited third party laboratory.
            - For primary (non-rechargeable) batteries: Certification to IEC 60086 - Primary batteries (parts 1, 2, and 4 or 5 if applicable). Certification by

an accredited third party laboratory.

- If applicable to the device, compliance with relevant Commonwealth and State or Territory legislation related to consumer goods including the following:
    - Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020 (where applicable)
    - Electrical safety of consumer goods (if/where applicable):
        - Australian Standard AS/NZS 3820 - Essential safety requirements for electrical equipment (if applicable – for the charger)
        - Australian Standard AS/NZS 4417 Marking of electrical products (if applicable – for the charger)
            - As a result power supplies or battery chargers may require compliance with AS/NZS 60335 - Household and similar electrical appliances – Safety – Part 1: General requirements
- Removal of the option to use user consumer grade e-cigarettes evidence (schedule 1, item c, of the current MDSO)
- Retaining the option to use certain evidence of compliance for a vape as a therapeutic good (schedule 1, item d, of the current MDSO) – we would limit this certification to that of a class II medical device.
- Specific safety requirements: Preventing accidental activation

AND for implementation in June 2026 (this is the addition/change)

- ISO 20072 – Aerosol drug delivery device design verification, requirements and test methods

Please note that I had a very useful discussion with MDPQD Directors (and s 22 and s 22) this morning on the MDSO and during that meeting a range of concerns were expressed about the timing of implementing additional product standards in the MDSO. There was a strong preference to implement additional product standards for December 2024. Per the email below I prepared some options and asked for further comments. Most comments from Directors support introducing further products standards in December 2024. However we are unsure if sponsors can fully implement many product specific standards by that time, particularly because stakeholder demonstrated a varying level of understanding of these industry standards (though a small number of sponsors clearly do understand the standards in detail).

A staged approach to introducing requirements in the MDSO (as outlined above) would:

- increase stringency of the requirement beyond the initial changes proposed for December 2024
- indicate the direction we are taking with the broader reform – to align with international standards for medical devices
- provide time for industry to become fully educated on the technical requirements of relevant standards (as some are comprehensive and detailed) and develop/update their products in order to be compliant

Regards,
s 22 – Director
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

From: s 22

Sent: Thursday, March 14, 2024 11:41 AM
To: s 22
Cc: s 22
Subject: RE: VAPING REFORMS - draft MDSO requirement for feedback - please provide feedback by the morning of Thursday 14 March [SEC=OFFICIAL:Sensitive]
Importance: High

Hi all,

Thanks for the discussion this morning. I have updated the Draft MDSO requirement - 12 March 2024.docx to include a table of possible options. If you have views on these please provide them using comments in SharePoint by 2.00 pm today.

Thanks,
Regards,
s 22 – Director
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

From: s 22
Sent: Wednesday, March 13, 2024 3:52 PM
To: s 22
Cc: s 22
Subject: RE: VAPING REFORMS - draft MDSO requirement for feedback - please provide feedback by the morning of Thursday 14 March [SEC=OFFICIAL:Sensitive]

Hi all,

Firstly, thank you for taking the time to review and comment on the draft MDSO requirements.

There have been a number of comments and I have tried to respond to all of these and provide some clarity on the specifics and/or the tricky tension with the policy settings – we are aiming to set more stringent requirements that we have a reasonable expectation that a significant number sponsors can/should be able to meet whilst mitigating the risk of significantly impacting

supply of therapeutic vapes (which could lead to policy failure if the therapeutic vaping devices become unavailable or too expensive). There have been some very helpful comments and we have few items to follow up on and/or check with our legal colleagues.

I'm happy to book a meeting to discuss the draft requirement first thing tomorrow (~9-10am) if there is interest in that? Please respond to let me know if that discussion would be helpful.

Apologies again for the very short timeframe for feedback on this.

Regards,
s 22 – Director
Devices Specialist Evaluation Section / MDAB / MDPQD
s 22

From: s 22
Sent: Tuesday, March 12, 2024 4:47 PM
To: s 22
Cc: s 22
Subject: RE: VAPING REFORMS - draft MDSO requirement for feedback - please provide feedback by the morning of Thursday 14 March [SEC=OFFICIAL:Sensitive]

Hi Everyone,

I have put the draft MDSO requirement into a SharePoint document here: Draft MDSO requirement - 12 March 2024.docx

Please include your comments in this document.

Thanks,
s 22

From: s 22
Sent: Tuesday, March 12, 2024 3:39 PM
To: s 22
Cc: s 22
Subject: VAPING REFORMS - draft MDSO requirement for feedback - please provide feedback by

the morning of Thursday 14 March [SEC=OFFICIAL:Sensitive]
Importance: High

Hi Everyone,

We are working to finalise the proposed requirements for an updated Medical Device Standards Order (MDSO) for vaping devices. The draft requirement is set out below and we would **appreciate your input and feedback by 9am Thursday 14 March.** My apologies for the short turnaround time but it is required to enable us to progress with this work given the very tight schedule (including clearance and legal drafting of a new MDSO). This MDSO is intended to be made in March and implemented in December 2024.

Background

How does this fit into the strategy for regulating vapes?
"These changes will protect Australians, particularly young people, from the harms of vaping and nicotine dependence, *while ensuring those with a legitimate need to access therapeutic vapes can continue to do so, where clinically appropriate*." - The Hon Mark Butler MP, Minister for Health and Aged Care. In line with the broader vape reforms, the MDSO requirement drafted below is intended to increase the stringency of the existing MDSO by implementing product specific standards (and removing some options) whilst balancing that against the need for patient access to therapeutic vaping devices to support the broader reform program. Please also note that there are two pathways for sponsors of nicotine vaping devices through the existing exemptions, they may claim compliance to the MDSO (if eligible) or they may claim compliance with the EPs directly and we have recently published the Standards for therapeutic vaping devices checklist to support sponsors (and assessment of those claims).

Survey update

We previously sought feedback on a stakeholder survey (D24-645284) and that survey closed last night, 10 March. The detailed analysis is being completed. However a high level summary is:

- s 22 manufacturers of vaping devices responded and some responses provided detailed information and views on the technical standards for vaping devices. s 47 [redacted]
- s 22 [redacted]
- [redacted]

Raw data output of the survey is available here: export-2024-03-04-10-11-02.xlsx

Draft MDSO requirement:

Please note there are many reasons why we have elected for certain requirements over others and its probably best to discuss these. If you are interested please contact me or Tania.

- Quality Management Systems requirements
  - **ISO 13485 certification** for the manufacture of the device, issued by one of the following:

    (i) an IAF accredited organisation;

(ii) a notified body;

(iii) an auditing organisation recognised by Health Canada;

(iv) an Australian conformity assessment body determined under the Regulations;

- **Removing the option of certification to ISO 9001**

- Product requirements (for detail refer to the draft requirement below)
  - **Instructions for Use**
  - **Labelling**
  - **Plain packaging**
- Meet the following product standards:
  - **ISO 14971 – Application of risk management to medical devices** (compliance only, not certification)
  - Battery standards:
    - Lithium batteries:
      - **Certification to, or independent test reports demonstrating compliance with, UN/DOT 38.3** – UN Manual of tests and criteria section 38.3 concerning the testing of lithium cells and batteries for transport safety.
      - **Certification to IEC 62133 -2**: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems. Certification by an accredited third party laboratory.

        Note: there is considerable overlap in test requirements, however both of these requirements service different purposes. The intent is to impose relevant requirements without imposing unnecessary regulatory burden, therefore requiring certification to IEC 62133 -2 whilst allowing test reports demonstrating compliance to 38.3 would enable manufacturers to meet the MDSO requirement without needing (costly) certification to both of these standards.
    - Nickel systems batteries: Certification to IEC 62133-1 - Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 1: Nickel systems. Certification by an accredited third party laboratory.
    - For primary (non-rechargeable) batteries: Certification to IEC 60086 - Primary batteries (parts 1, 2, and 4 or 5 if applicable). Certification by an accredited third party laboratory.

      For much more background on batteries please see the attached emails.
- **If applicable to the device, compliance with relevant Commonwealth and State or Territory legislation related to consumer goods** including the following:
  - Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020 (where applicable)
  - Electrical safety of consumer goods (if/where applicable):

        - Australian Standard AS/NZS 3820 - Essential safety requirements for electrical equipment (if applicable – for the charger)
        - Australian Standard AS/NZS 4417 Marking of electrical products (if applicable – for the charger)
            - As a result power supplies or battery chargers may require compliance with AS/NZS 60335 - Household and similar electrical appliances – Safety – Part 1: General requirements
- **Removal of the option to use user consumer grade e-cigarettes evidence** (schedule 1, item c, of the current MDSO)
- **Retaining the option to use certain evidence of compliance for a vape as a therapeutic good** (schedule 1, item d, of the current MDSO)
- **Specific safety requirements:**
    - **Preventing accidental activation**- The device is required to incorporate a means to minimise the likelihood of accidental activation. The method used to prevent accidental activation may be aligned with the requirements of section 13 of UL 8139:2020, or may be other means as appropriate to the design of the device.

Appreciate your review and feedback.

Kind Regards,
s 22

Product requirements - Instructions for Use
Therapeutic vaping devices and accessories must be supplied with Instructions For Use (IFU). This IFU must be in English but may also be written in other languages, and may be supplied in paper or electronic format provided it is readily accessible to patients.

IFUs must include the following information:

- device manufacturer's name, or trading name, and address
- intended purpose and the intended user of the device
- device name
- batch code, lot number or serial number of the device, if this is not provided on the device or its packaging
- particular handling or storage requirements applying to the device including acceptable storage conditions (e.g. a temperature range)
- any warnings, restrictions, or precautions that may apply in relation to the use of the device, such as:

    a statement that informs the user if the device is not functioning correctly, to seek advice from a healthcare professional

    if it is a selected-dose device, only the user shall be able to select the correct dose

    if it is a selected-dose device, how the device operates when the amount of medication available is less than the dose the user intends to select

    if it contains button or coin batteries, include warning information about the risks associated with button or coin batteries by complying with the Consumer Goods

(Products Containing Button/Coin Batteries) Safety Standard 2020

Consumers need to know about the risks that button or coin batteries can pose, and what to do if they suspect that someone has swallowed or inserted a battery

- special operating instructions for the use of the device including:

  appropriate actions that need to be performed prior to use (e.g. shaking, priming, device orientation, selecting the dose, etc.);

  instructions on how the operator is to use the device (e.g. inhalation, exhalation, actuation, inspiratory effort, duration, breath holding, repetition of inhalation);
- any preparatory actions for first-time use (e.g. battery loading, function testing) or instructions for assembly or for use with an accessory
- any cleaning requirements for the device and, where applicable, reusable containers holding e-liquid
- Information about the replacement of consumable components of the device during its lifetime
- Information about precautions that should be taken by a patient and the user if there are special or unusual risks associated with the disposal of the device including:

  instructions on how to dispose of the device or its parts at the end of its used life

  type and identifier of replaceable batteries, if used, and instructions about how to recycle the used batteries.

Labelling requirements

Therapeutic vaping devices must be labelled in English and include the following information:

- Sponsor name and address
- Manufacturer name and address
- Device name (brand, model etc.)
- Batch code, lot number or serial number of the device
- *Risk of fire or explosion. Replace only with battery [manufacturer, model or series].*

Where a label containing the above information cannot be affixed directly on the device itself, then it is expected to be included on the packaging used for the device.

Packaging requirements

Packaging for Therapeutic Vaping Devices must:

- be predominantly in white background with only black and grey lettering permitted
- not include certain [prohibited or restricted] product names, logos or brand names
- include health warnings being:
  "KEEP OUT OF REACH OF CHILDREN"
- if it contains button or coin batteries, include warnings that comply with the Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020 such as:

  "Warning: Contains button or coin cell battery. Hazardous if swallowed – see instructions"

Kind Regards,
s 22 – Director
Devices Specialist
Evaluation Section /
MDAB / MDPQD
s 22

From: s 22
To: s 22
Subject: [redacted] to comply with EPs - Vaping devices [SEC=OFFICIAL]
Date: Tuesday, 19 March 2024 8:20:24 AM
Attachments: image001.png

s 22
Compliance with s 47 :
s 22
Liber s 47
s 22
s 22

From: s 22
To: s 22
Subject: Attachment ~ to targeted survey on proposed requirements for therapeutic vaping devices.docx [SEC=OFFICIAL]
Date: Tuesday, 26 March 2024 2:01:59 PM
Attachments: Attachment ~ to targeted survey on proposed requirements for therapeutic vaping devices.docx

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I re-saved and deleted highlighter. You could save it via drop and drag into TRIM over the old version. Ta s 22

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Attachment B: Targeted consultation – Analysis of the stakeholder feedback on proposed MDSO requirements

Executive Summary

Targeted consultation was conducted in the form of a survey to understand sector preparedness to meet various device safety, quality, and performance standards. This is in preparation for planned implementation of increased product standards for therapeutic vaping devices complying with the MDSO, refer to D24-645284. The survey also sought stakeholder input on preferences towards relevant standards.

Stakeholders included vaping device manufacturers, vaping wholesalers/importers, academic and research groups as well as healthcare groups. A total of 21 out of 83 stakeholders responded to the survey. Responses were analysed and are summarised **below.**

Preliminary analysis of responses by relevant stakeholder grouping

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Manufacturers:

- [redacted] respondents including [redacted] Liber Pharmaceuticals Pty Ltd [redacted]. All have submitted a notification to the TGA stating that their vaping goods comply with applicable standards for supply in Australia for purposes of smoking cessation or the management of nicotine dependence.
  - [redacted]
  - [redacted]
  - Device safety and performance standards: Manufacturers appears to be aware of the standards specified in the survey with varying levels of compliance. Liber Pharmaceuticals has provided very detailed feedback including their views in support of UN, ISO and IEC standards and views against compliance with region specific standards.
  - [redacted] Liber Pharmaceuticals stated that the CEN/TS 17287 standard is not an appropriate whilst [redacted]
  - [redacted] Liber Pharmaceuticals stated that GB 41700-2022 standard is region specific and not an appropriate standard. [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- [redacted]
- IFU, Labelling and Packaging: [redacted]. The manufacturers do not anticipate any significant impact to the business or supply. [redacted]
- In general, majority of manufacturers appear to possess general awareness about the standards specified in the survey with varying level of compliance.

[redacted]

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

s 22

Table: Detailed analysis of responses from Therapeutic Vaping Device Manufacturers.

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Manufacturer Name	s 47	Will manufacturer comply with IFU, Labelling Packaging requirements by Dec-2024	Specific comments on device related standards	Battery standards recommended by the manufacturers
s 22				
Liber Pharmaceuticals Pty Ltd	s 47	Yes	• Compliance with CEN/TS 17287 would add no additional value to the other standards considered herein. • GB 41700-2022 and UL 8139 are region specific standards. • PAS 54115 - Compliance can be established however, NBs are not issuing certification.	UN 38.3 and IEC 62133-2
s 22				

* The list of device standards specified in the survey included

- ISO 14971 - Medical devices Application of risk management to medical devices
- CEN/TS 17287 - Requirements and test methods for electronic cigarette devices
- GB 41700-2022 – Mandatory National Standards for Electronic Cigarettes
- UL 8139 - Standard for Electrical Systems of Electronic Cigarettes and Vaping Devices
- AS 54115 - Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products. Manufacture, importation, testing and labelling. Guide
- ISO 20072 - Aerosol drug delivery device design verification - Requirements and test methods
- IEC 62304 Medical device software life cycle processes
- Toxicological Risk Assessment

From: s 22
To: GILMOUR-WALSH, Bridget; s 22
s 22
Cc: s 22
s 22
Subject: TGO110 final recommendations

Dated 27/03/2024

Dear all,

Please join us for discussion on recommendations for TGO110 amendment, I will forward a discussion document prior to the meeting next week.

Apologies for some double bookings as it was very difficult to find any window when we all are available, please delegate the meeting if you can't attend.

Kind Regards,

s 22

Dated 05/12/2023

Dear all,

Please find below the discussion points for our meeting today. We would like to discuss inclusion of flavour and transition provisions for TGO110 amendments by the end of year.

Restrictions on flavours

Recommendation:

* Include a restriction on flavours in TGO 110:

* Restrict flavour to mint/menthol and tobacco

* Mint flavour: the taste and aroma commonly associated with herbaceous plants in the Mentha genus of the family Lamiaceae, including for example peppermint, spearmint, horsemint and corn mint. The flavour must be solely an extract, or where a synthetic flavour is formulated it must only mimic a natural flavour. [Suggest a Note to explain the intention of this phrasing is to prevent the use of flavour mixes, such as cherry mint]
* Tobacco flavour: the taste and aroma derived from a combination of substances commonly associated with herbaceous plants in the Nicotiana genus of the family Solanaceae. The flavour must be solely an extract, or where a synthetic flavour is formulated it must only mimic the tobacco flavour. [Suggest a Note to explain the intention of this phrasing is to prevent the use of flavour mixes, such as sweet tobacco]

* Need to carefully amend the mint definition to capture 'menthol' flavour
* Concerned about the loss of Liber products (Classic, cool mint and cherry). Liber does not market a "tobacco" flavour, but instead markets a "classic" variant of Nicovape Q, which is designed to impart a rich, savoury aroma, without attempting to mimic tobacco.
* All other brands appear to have vapes with both of these flavours.
* Starting date:

* Include in TGO110 that commences from 1 Jan, but delayed commencement for restrictions on flavours until 1 March
* Need to allow companies to use up stock
* Notifications need to reference supply from 1 March with new restriction to flavours
* All messaging to date is that this restriction unlikely to commence until end 2024, with other TGO updates

Supplier using Pharmacy channels

Complete flavour profile

s 22

Liber

Classic (tobacco?), coolmint, cherry

s 22

s 22

s 22

Background

* A restriction on flavours is required to reduce appeal of vapes for recreational use and government intention is to implement such restrictions early in 2024.
* Any such restriction needs to consider impact on product availability in case of short or no transition.
* In consultation papers, we proposed to allow Tobacco and mint flavours only, since a flavour other than 'tobacco' should be retained to assist patients trying to move away from tobacco use and mint is not as appealing to recreational users. This proposal was well supported by key stakeholders in both 2022 and 2023 consultations.
* To assist with regulation, definitions of mint and tobacco flavours were proposed in 2023 consultation paper, however several questions were raised in relation to these definitions by consultation respondents.
* Respondents advised to define each flavour in terms of a subset of chemical entities that can be used to create that flavour.
* Identifying chemical subset (to define flavour) and their analytical test methods require some further research work by SMEs.
* Any such restriction will also force manufacturers to change their formulations and hence would require longer transition period.
* To make effective change in flavour profile, it is recommended that flavour definitions are not included, and manufacturers are not forced to make formulation changes.
* Currently suppliers using pharmacy channel do have both Tobacco and mint in their portfolio of products.
* Therefore, in current situation allowing only mint (including spearmint, peppermint coolmint etc) and tobacco will let key suppliers such as Bay, Liber, Phill Morris, FTF and Zefir to continue supply their legal product, while other youth attractive flavours will be effectively banned.
* Strategically, March TGO update will not afford enough time to manufacturer to reformulate or change their product and exploit any loophole in TGO110 such as broad-based definition of flavour.
* The aim should be to tighten up the regulation with next amendment of TGO110 by defining flavours and including labelling requirements.
* Similarly, a restriction on menthol contents as proposed in consultation paper would require formulation changes, hence not suitable for inclusion by end of the year, therefore, recommendation is to not include menthol restrictions now but considered for March rendition of TGO110.

Dated 22/11/2023

Dear all,

I am booking time for our next session on TGO110. I will send the agenda and additional information before the meeting.

Thanks and Regards,

s 22

Dated 8/11/2023

Dear all,

Please see the discussion topics for our meeting as below, please feel free to decline the meeting if the topics are not of your interest of value.

Requirements for zero nicotine vapes:

* Need to change name of std (Therapeutic Goods (Standard for Nicotine Vaping Products))
* Include definition of zero nicotine vapes in TGO110

non-nicotine vaping product means a therapeutic good that:

(a) does not contain nicotine; and

(b) is a finished product; and

(c) is intended to be used with a vaping device for smoking cessation or the treatment of nicotine addiction.

* Change to Application to capture zero-nicotine products – and are the exemptions for starting material and other in schedule 5a still to apply?
* Only 7(3) applies (prohibited ingredients in Schedule 1)
* Section 8 on labels should apply, but in Schedule 2 only Item 1 need apply (not the warning statements or nicotine ingredient labels)
* Section 9 on Child-resistant packaging does not need to apply
* Section 10 (Record keeping) & 11 (alternative conformity) should apply

Requirements for nicotine contents in e liquid:

* An option to reduce nicotine contents from 100 mg/mL to 20 mg/mL was put forward in 2022 consultation, with most of the respondents supported the option (including s 22 . In September 2023 this option was not interrogated however several key stakeholders still provided strong feedback on this topic.
* Proposal options below set out the benefit-risk of each option: 20, 40 or 60 mg/mL

Option 1: Lower the limit to 20 mg/mL as free base or base equivalent.

Benefits:

* The product will be safer than high concentration e-liquids (especially for open systems).
* Most respondents to the 2022 consultation supported the option (s 22)
* s 22 provided a very strong argument for this proposal, sighting the positive impact it has shown when Canada restricted nicotine in vapes to 20 mg/mL, the lack of supportive data showing any benefit of increasing nicotine in vapes beyond 20 mg/mL, and that the risk profile increases as nicotine concentration is increased.
* This is consistent with other jurisdiction such as UK, EU, Canada and NZ (except for separate salt form limit).
* Market may be served from vapes that are currently available in other jurisdictions, but it may still require bespoke changes to packaging to make it acceptable in Australia.

Risk:

* Heavy users would need to take more puffs and/or stronger devices to get the same dose, which exposes them to more excipients
* For heavy smokers, the lower concentrations does not provide the same instant hit nicotine as a higher concentration formulation
* Potentially less effective as treatment for cessation, but very little quality data to support this claim.
* GPs want the discretion of choosing right formulation, including concentration, for patients, as strongly argued in the responses from s 22 and s 22
* Manufacturers mentioned that higher concentration of nicotine (in salt form) is most used by GPs to start the treatment and then in subsequent steps the lower concentration products are used – 20 mg/mL is too low and too restrictive for effective treatment of heavy smokers.
* Lower concentration products are used in jurisdictions that use fundamentally different regulation model than Australia
* Under a medical supervision model there is less risk of allowing higher concentration products as use will be under medical supervision.
* For closed systems the exposure risk is not a strong argument, only for open systems [could consider defining different levels for open systems]

Option 2: Lower the limit to 40 mg/mL as free base or base equivalent.

Benefits:

* Address some of the concerns raised by s 22 around having higher concentration options available to Sponsors and reducing puffing frequency for heavy users.
* It will cover the product range from 40 mg/mL nicotine free base up to 75 mg/mL nicotine salicylate.
* Most of the products currently on MIMS will fall within this limit, however, there will be still few that are out of the range such as s 22 and 59 mg/mL e liquid from Liber.
* Under medical supervision, there is limited risk with increasing the available concentration, and justifying a different approach to markets with vapes as consumer products
* Comparatively less disruptive for market than 20 mg/mL limit.

Risk:

* Higher risk of toxic exposure in open systems
* Still does not allow for the most commonly prescribed first dose product of 59 mg/mL
* Potentially higher addiction risks with higher concentration.
* Risks associated with intentional misuse are more for higher concentration vapes.

Option 3: Lower the limit to 60 mg/mL as free base or base equivalent.

Advantages:

* This will be least disruptive to market supply and would support s 22 position to leave it in the hand of the prescriber and their guidance.
* Currently the most prescribed concentration
* GPs have choice to tailor treatment to their patients.
* Potential lower risk of exposure to other toxic excipients.
* Minimal increase in safety if supplied in closed systems
* To date, the FDA has authorized marketing of 45 products, including 23 tobacco-flavoured e-cigarette products and devices, with concentrations from 15-60 mg/mL (1.5 – 6% w/w)

Disadvantages:

* Unacceptable risk for open systems, and would only be appropriate for closed systems
* Ignores clinical advice for other countries that suggest efficacy at 20 mg/mL, so higher concentrations are not justified
* No clinical data to support the need for such high concentrations, apart from anecdotal
* No driver for suppliers to generate data to support the safety and efficacy of this high dose vape for high usage smokers
* Benefit of such high concentration are not yet substantiated but risk of addiction and harmful effects goes higher with concentration.

Dated 7/11/2023

Dear All,

s 22 has requested to move the meeting to Friday and we need her in the room for this meeting, so I have moved it to Friday 10th Nov. Sorry for inconvenience.

Kind Regards

s 22

Date 1/11/2023

Dear all,

Booking time for next session to discuss TGO110 proposal. Will send agenda and discussion document before our meeting, if agenda doesn't include topic of your interest, please feel free to give it a pass, however may I request the decision makers on related topics to please attend the meeting.

Kind Regards,

s 22

Date: 30/10/2023

Dear all,

Please find below the discussion points for the two items (restrictions on flavours and requirements for devices) we would like to discuss in meeting today, if we have enough time we will continue discussing other items included in document: D23-3751921 <el://D23-3751921?db=A7&edit>

1. Restrictions on flavours

Recommendation:

* Allow both mint and tobacco flavour – on labels they must only be labelled as 'mint' or 'classic' flavour, respectively
* Tighten the definitions proposed in the consultation paper to prevent flavour mixes e.g. cherry mint, and put the onus on manufacturers to justify ingredients included in the flavour. For example,:

Mint flavour: the taste and aroma commonly associated with herbaceous plants in the Mentha genus of the family Lamiaceae, including for example peppermint, spearmint, horsemint and corn mint. The flavour must only be an extract, or where a synthetic flavour is formulated it must mimic the natural flavour only. [Suggest a Note to explain the intention of this phrasing is to prevent the use of flavour mixes, such as cherry mint]

Tobacco flavour: the taste and aroma derived from a combination of substances commonly associated with herbaceous plants in the Nicotiana genus of the family Solanaceae. The flavour must be solely an extract, or where a synthetic flavour is formulated it must mimic the tobacco flavour only. [Suggest a Note to explain the intention of this phrasing is to prevent the use of flavour mixes, such as sweet tobacco]

* Limit the % a flavour can be present and the amount of menthol allowed in mint flavours, but higher than the proposed 0.1% (1-5% possible, but waiting on Tox input)

New Justification

* The restrictions and definitions are designed to allow only simple flavours, limit the attractiveness to youth and young adults, and improve the safety of flavours used, while still allowing some choice of consumers using vapes for smoking cessation
* A flavour other than 'tobacco' should be retained to assist patients trying to move away from tobacco use
* Mint flavours are commonly used in vapes (including by youth), but it is not as attractive as other sweet flavours used to target these products at youth and young adults
* Mint flavour, both as extracts and when synthetically formulated, has a relatively well-defined safety profile
* The level of menthol is restricted, to ensure sufficient for the flavour, but is unlikely to result in well-defined physiological effects it can have on the lungs
* We did consider the ability to define flavours by a list of ingredients that can be used to construct them, but the data is not available at this time. This is a direction currently being investigated for restricted use in tobacco products and we will continue to review the need to tighten the definition of flavours used in vapes accordingly

2. Requirements for the medical device components

Agreement:

* s 47

Issues and discussion:

* Feedback in the consultation was very mixed, but it appears that most manufacturers have a poor understanding on the requirements outlined in the consultation paper and are not ready for many of the device requirements to be imposed at this time
* A balance is needed to ensure ongoing supply of vapes, and crafting a journey for manufacturers to manufacture compliant devices – some are looking to move fast to meet requirements, but significant challenges
* This is a similar story to educating manufacturers of inhalers – where we needed to slowly lift standards to allow sector time to mature and generate data, and even with a very engaged and willing sector they struggled to meet compliance
* Unlike for other unapproved medical devices, for vapes the manufacturers must make a declaration of compliance to all applicable standards in the Notification, including the EPs, which lifts the risk of non-compliance
* Consider how quickly GMP standards will be applied to the e-liquid manufacturers
* So, what EPs should apply?
* In the current MDSOs an international standard may be referenced as appropriate for demonstrating compliance to one or more EPs, but these instruments have not previously been used to displace the need to comply with any EPs
* A few options are outlined below, with probably my preferred being Option 2.

Potential options:

* Option 1: no EPs to apply at this time, with review at the end of 12 months following commencement - no EPs apply at the end of 12 months, and the sector has no direction on when they may apply
* Option 2: Selective EPs should apply based on the considered main risks associated with vaping devices, with commencement in 12 months – some EPs will apply at the end of 12 months, but only those considered essential to lifting the level of safety for vape device components; need to consider when the
* Option 3: The full list of EPs should apply, but a longer transition (2 years?) is given to educate the sector and allow them to generate the supporting data – all EPs will apply at the end of the transition, even though they are unapproved goods

Kind Regards,

Dear all,

Booking some time to discuss TGO110 proposal. Will send agenda and discussion document before our meeting.

Kind Regards,

s 22

-- Do not delete or change any of the following text. --

s 22

Analysis of targeted survey responses to Therapeutic Vaping Device requirements

Executive Summary

Preliminary analysis of responses by relevant stakeholder grouping

1. **Manufacturers**
   - Point 1
   - Point 2
   - Point 3
2. **Wholesalers/importers**
   - Point 1
   - Point 2
   - Point 3
3. **Academic/Research community**
   - Point 1
   - Point 2
   - Point 3
4. **Healthcare/medical community**
   - Point 1
   - Point 2
   - Point 3

Appendix:

Detailed analysis of responses

	UL 8139	When?	Additional Comments	Lithium Batteries	Do you comply with any other standards	Views on any other standard?
[redacted]						

s 22

Liber Pharmaceuticals Pty Ltd	s 47	s 47	UL is US centric but s 47	Yes	s 47	UN 38.3 and IEC 62133-2

s 22

Submission: Proposed new requirements for therapeutic vaping devices and accessories

Executive Summary

In a targeted consultation survey to stakeholders released on 20 February 2024 (**Consultation Survey)**, the Therapeutic Goods Administration (**TGA**) sought input concerning proposed requirements for therapeutic vaping devices and accessories for use under prescription in the medical access framework (**MAF**) for nicotine vaping products (**NVPs**).

In the Consultation Survey, the TGA has sought stakeholder feedback on a range of proposals to improve the safety and performance of therapeutic vaping devices and accessories through the introduction of:

- Updated manufacturing standards;
- Requirements for instructions for use, labelling and plain packaging;
- Product-specific standards for the vaping device and batteries; and
- Transition to full compliance with medical device regulatory requirements over time.

Liber supports the consultation process, which allows industry participants who have been operating legally within the MAF to provide feedback on the future direction of regulation of therapeutic vaping devices and the roadmap towards meeting the quality and safety requirements for medical devices included in the Australian Register of Therapeutic Goods (**ARTG**).

In particular, Liber is supportive of the process, to the extent that it will result in improvements to the overall quality and safety of therapeutic vaping devices in the Australian market, as well as seeking to limit market participants to those who are genuinely willing to progress their products towards ARTG registration, as opposed to those focused on short-term commercial opportunities.

However, Liber also strongly believes that the TGA must implement the changes proposed in this consultation and other regulatory changes under consideration quickly and decisively.

Each time the TGA changes the MAF, the potential arises that manufacturers will need to reformulate or repackage their existing products, leading to material market disruption and confusion for prescribing doctors, dispensing pharmacists, and ultimately prescribed patients. This disruption undermines the work undertaken by the TGA and other stakeholders to establish the MAF. It increases the risk that prescribers, pharmacists and patients may consider the new framework in the 'too hard' box.

For example, to provide appropriate products that meet the new flavouring restrictions and packaging requirements implemented at the end of last year, Liber has undertaken an exercise of developing and carrying out appropriate toxicological risk analyses on new flavours, as well as reworking its packaging.

This redevelopment process will likely require 6 to 9 months by the time Liber completes it, followed by a 4 to 6-month transition period where Liber has two versions of its NVP on the market. This transition period is necessary to allow existing patients to secure new scripts and educate doctors on prescribing the new product.

Removing any product from the supply chain is a complicated process, and even more so in this case, given the struggle by CSO wholesalers and dispensing pharmacies to understand tweaks to special access prescribing in the unique context of the MAF. This confusion is resulting in many pharmacies being reluctant to incur the cost and administrative burden associated with holding NVP stock, which in turn is slowing down the supply of NVPs to nicotine-dependent patients and leading to low levels of adoption,

even among willing patients.

As a result, Liber suggests that the TGA should implement any further proposed changes to product requirements in a single, decisive update and not stage them across a series of regulatory updates.

Updated manufacturing standards

Liber supports the TGA's intent to update the manufacturing standards for therapeutic vaping devices and accessories. It is a legitimate expectation of medical professionals that the vaping devices they prescribe are manufactured under ISO 13485 (for example). For the medical community to embrace vaping products as a legitimate therapeutic tool, medical device standards are required to provide them with the necessary level of assurance.

Requirements for instructions for use, labelling and plain packaging

- **Instructions for use (IFU):** Liber supports the proposed IFU requirements, which it considers to be a necessary interim step towards the IFU requirements of the Essential Principles required for ARTG registration.
- **Labelling:** In Liber's view, labelling requirements for therapeutic vaping devices and accessories should be consistent with the requirements for all medical devices, and the proposed changes provide little additional benefit.

  Regarding the proposal that "certain product names, logos or brand names" may not be included (on the packaging), if this proposal is intended to debar the use of product names, logos or brand names associated with tobacco products or NVPs sold in other markets under consumer access regulations, Liber would support such a proposal.

- **Plain packaging:** As noted in previous consultation responses, Liber does not support the requirement for 'plain packaging' of therapeutic vaping devices, which it believes will serve little benefit and will be counterproductive to the extent that it will continue to differentiate the regulation and treatment of NVPs from that of other therapeutic goods.

  Plain packaging is a concept developed to address the marketing appeal of tobacco products, specifically, to stop the cigarette pack itself from being a mobile billboard for tobacco brands. This measure does not logically apply to the packaging of therapeutic vaping devices, which will not be carried by end consumers and cannot be displayed in a retail setting due to State-based tobacco control laws prohibiting the display of vaping devices (where they are deemed as 'tobacco' or 'smoking' products).

Product-specific standards for the vaping device and batteries

- **Device standards:** Where the proposed standards serve to address requirements of medical devices, Liber is generally supportive, including requirements to adhere to:
  - ISO 14971;
  - ISO 20072 (if the TGA determines, during ARTG pre-submission meetings, that this is a requirement for ARTG); and
  - IEC 62304.

  Regarding the timing for manufacturers to adhere to such standards, to the extent that it does not already, Liber anticipates that its NVP [s 47] . Liber also considers that such

an exercise is important as it continues to work towards seeking inclusion on the ARTG.

Liber views certain elements of PAS 54115 (noted in our response to questions below) as providing the basis for an interim product standard that would serve to provide confidence in the products available under the MAF (for example, by mandating toxicological risk assessments) until products are registered on the ARTG.

However, Liber sees the adoption of existing consumer product standards as counterproductive in terms of moving market participants towards medical device standards and would not support the introduction of standards derived from:

- CEN/TS 17287;
- GB 41700-2022; and
- UL 8139.

- **Battery standards:** In Australia, existing electrical standards and the Australian Dangerous Goods Code substantially address the required battery standards. Liber notes that the battery standards proposed in the Consultation Survey were assessed by the CSIRO in the report *Lithium-ion battery safety: A report for the Australian Competition and Consumer Commission (ACCC)*.[1]

  Liber suggests that the TGA be guided by the CSIRO report and maintain compliance with internationally recognised standards when considering appropriate battery safety requirements for therapeutic vaping products.

Transitioning to compliance with medical device regulatory requirements over time

Liber supports the TGA's approach to encourage all market participants to seek ARTG registration for therapeutic NVPs. Liber is fully committed to seeking ARTG registration for its products and looks forward to continued engagement with the TGA.

As the TGA is aware, there are considerable costs associated with compliance for therapeutic goods, and these costs far exceed those required for consumer goods generally. In the current market, the range of notified vaping devices sits across a broad continuum regarding quality and safety and between consumer goods and therapeutic device standards. However, these products compete in the same market.

If it is true that a rising tide carries all boats, increasing the quality and safety standards required for therapeutic vaping devices should serve to bring all market participants to the same level of quality and safety compliance. However, in implementing the updated requirements, the TGA should be mindful that some market participants may, for short-term gain, elect to remain in the market for as long as possible with no intention of complying with new standards before dropping out at the end of any proposed sunset period. This activity would leave those market participants who have already invested considerably in quality and safety compliance at a significant competitive disadvantage.

How important are vaping device standards to ensuring uptake and adoption by medical practitioners and pharmacists?

In the near term, the adoption of NVPs by both medical practitioners and pharmacists is critical in ensuring that illicit vapers and dependent smokers can find clinicians that will prescribe and pharmacies

[1] Best, A, Cavanagh K, Preston C, Webb A, and Howell S (2023) Lithium-ion battery safety: A report for the Australian Competition and Consumer Commission (ACCC). CSIRO, Australia. https://www.productsafety.gov.au/system/files/CSIRO-ACCCLithiumIonBatteries.pdf

that will dispense NVPs.

While appropriate product standards are essential, other issues that will also be critical to the success of the MAF include the following;

- Ensuring that doctors and nurse practitioners understand how to prescribe under special access pathways, including how to access the TGA's SAS dashboard;
- Publishing appropriate guidance to prescribers, including an update of the RACGP's Smoking Cessation Guidelines;
- Ensuring that the pharmaceutical supply chain operates in a manner that ensures that prescribed NVPs can be immediately dispensed by pharmacies when prescribed; and
- Providing guidance to the Australian public on how to access medical practitioners that are educated and willing to consider prescribing NVPs.

1. Changes to manufacturing requirements

Question 8. [If applicable] As a sponsor, have you made or are you intending to make a notification to the TGA to import or supply your therapeutic vaping device or accessory in Australia?

Liber Response:

Liber has completed the notification process for its existing Nicovape Q products, referred to herein as the A1 products, in terms of its device and its three nicotine concentrations (59mg/mL, 35mg/mL and 20mg/mL) cartridges, across two flavours, coolmint and classic [tobacco].

Question 9. [If applicable] If you are intending to notify, provide details about when you expect to lodge a notification and the products to be included in this notification.

Liber Response:

****Commercial in confidence****

s 47

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Question 10. [If applicable] ISO 13485 relates to the requirements for quality management systems for medical devices such as therapeutic vaping devices and accessories. Are you familiar with, and do you currently hold a valid ISO 13485 certificate where the certificate scope covers the manufacturing of therapeutic vaping devices and accessories:

s 47

Liber Response:

Liber is familiar with ISO 13485 s 47

****Commercial in confidence****

s 47

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Question 11. [If applicable] If you do not hold a valid ISO 13485 certificate for the manufacturing of therapeutic vaping devices and accessories, can you get this certificate:

s 47

Liber Response: [note - there is no 'please explain' box for this question in the webform]

Liber's A1 device is currently manufactured in an ISO 9001-certified facility.

****Commercial in confidence****

s 47

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2. Proposed new product requirements

2.1 Instructions for Use

Question 12. Regarding the proposed instructions for use (IFU) requirements, what would impact you as a manufacturer or sponsor to implement an IFU? If you are another stakeholder, do you have views about this change?

Liber Response:

Liber currently provides a CMI with Nicovape Q A1 cartridges and a User Guide with Nicovape Q A1 devices. The IFU requirements outlined will require strengthening of Liber's existing User Guide.

****Commercial in confidence****

s 47

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Question 13. Regarding the proposed IFU requirements, can you meet these requirements:

- ~~Now~~
- by December 2024 - likely sooner
- ~~in 24 months~~
- ~~in more than 24 months~~

Liber Response: [note - there is no 'please explain' box for this question in the webform]

To the extent that Liber is required to amend its existing User Guide, it is confident that it will be able to meet the requirements by December 2024.

****Commercial in confidence****

s 47

[redacted]

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2.2 Labelling & Packaging

Labelling requirements and Packaging requirements

Question 14. Regarding the proposed labelling and packaging requirements, what would be the impact on you as a manufacturer or sponsor to implement these requirements? If you are another stakeholder, do you have views about this change?

Liber Response:

Liber supports packaging requirements consistent with TGO 91 and TGO 95, and which treat NVPs in line with other mainstream medicines. Liber voluntarily decided to design its NVP packaging (including device packaging) to meet the packaging requirements set by TGO 91.

Since TGO 91 governs all prescription medicines, the packaging requirements for vaping devices and

accessories should not extend beyond the parameters set by TGO 91. Liber notes that, in order to ensure that NVPs are treated in line with other medicines, the special MBS codes (consultations for smoking cessation) and the permission for pharmacies to include posters stating "Nicotine Vaping Products available here" have been removed. Liber believes this approach is sensible and that the TGA should apply it consistently.

Liber believes that TGO 91 sufficiently distinguishes medicines from consumer products. As such, a similar and consistent approach to NVP device packaging would ensure that the TGA appropriately addresses any marketing concerns about NVP device packaging.

To the extent that the TGA proposes additional restrictions to the packaging of NVPs, such as a white background with black/grayscale lettering, Liber believes that these serve no benefit and will be counterproductive by appearing to treat NVPs as tobacco products rather than therapeutic goods.

Regarding the proposal that "certain product names, logos or brand names" may not be included (on the packaging), it is challenging to offer commentary on this proposal without understanding what those product names, logos or brand names might be.

However, on the basis that most NVPs are consumer products in all jurisdictions outside of Australia and are marketed directly to consumers via internationally hosted websites and social media platforms, Liber supports restrictions on the use of product names, logos or brand names associated with NVPs marketed and sold as consumer products in other jurisdictions.

Indeed, under s3(5) of the *Therapeutic Goods Act,* such a presentation (i.e., that of a consumer good that can leverage offshore advertising and marketing) may constitute "a purpose that is not in accordance with conditions applicable to the supply of the goods in Australia" and, therefore, already be prohibited.

> *Section 3(5) of the Therapeutic Goods Act 1989* states that:
>
> *"the presentation of therapeutic goods is unacceptable if it is capable of being misleading or confusing as to the content or proper use or identification of the goods and, without limiting the previous words in this subsection, the presentation of therapeutic goods is unacceptable:*
>
> *[..]*
>
> *d) if a form of presentation of the goods may lead to unsafe use of the goods or suggests a purpose that is not in accordance with conditions applicable to the supply of the goods in Australia; or*
>
> *(e) in prescribed cases."*

Question 15. Regarding the proposed labelling and packaging requirements, can you meet these requirements:

- Now — We apply TGO 91 to all packaging
- by December 2024 — If changes beyond TGO 91 were implemented we could meet this
- ~~in 24 months~~
- ~~in more than 24 months~~

Liber Response: [note - there is no 'please explain' box for this question in the webform]

Liber has designed its NVP packaging (including device packaging) to meet the packaging requirements set by TGO 91 – understanding that applying TGO 91 to device packaging (in lieu of any other appropriate standard for NVPs) was a voluntary decision by Liber.

If the TGA imposes additional requirements for NVP packaging in addition to TGO 91, Liber anticipates being able to meet those by the earlier of three months or December 2024, subject to its comment above about time needed to sell down non-compliant stock already in the supply chain to meet demand anticipated by the DoH's impact analysis.

2.3 Product-specific standards

Question 16. ISO 14971 standard relates to the application of risk management to medical devices. Indicate the level of compliance of your therapeutic vaping device against ISO 14971 standard and specify if your vaping devices:

s 47

Liber Response:

****Commercial in confidence****

s 47

s 47

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Question 17. CEN/TS 17287 relates to requirements and test methods for electronic cigarette devices. Indicate the level of compliance of your therapeutic vaping devices against CEN/TS 17287 standard and specify if your vaping devices:

- ~~Fully comply now~~
- ~~Partially comply now but could fully comply by December 2024 (Please provide details)~~
- ~~Do not comply, but could comply in 12 to 24 months (Please provide details)~~
- ~~Do not comply, but could comply in more than 24 months (Please provide details)~~
- Unsure

Liber Response:

CEN/TS 17287 is a consumer product standard and as such, is not, in itself, appropriate for assessing the suitability of NVPs as medical devices. CEN/TS 17287, in particular, lacks the specificity required of a device standard. Where CEN/TS 17287 does provide specific compliance requirements, it does so by deferring to normative references that Australian electrical standards or Therapeutic Goods regulations already provide.

Liber notes that, as a medical device standard, the CEN/TS 17287 requirements can be summarised as:

- **4.2 General requirements:** These are addressed by existing Australian electrical standards and regulations. For example, EN 60335-1 for electromagnetic compatibility..
- **4.3 Power unit:** Addressed by existing Australian electrical standards and regulations. For example, EN 62133 for lithium battery standards.
- **4.4 Atomizer:** Insufficiently prescriptive for a medical device standard.
- **4.5 E-liquid reservoir:** Generally, insufficiently prescriptive for a medical device standard, and regarding microbiological and bacterial safety, already addressed by existing TGA regulations.
- **4.6 Mouthpiece:** Insufficiently prescriptive for a medical device standard.
- **4.7 Child resistance:** Already addressed by existing TGA regulations.
- **5.1 Material (migration):** Insufficiently prescriptive for a medical device standard, and the intent of this section is better served through appropriate toxicological and hazard risk analysis.
- **5.2 Resistance to breakage and protection from leakage:** Insufficiently prescriptive for a medical device standard.
- **5.3 Child resistance:** Already addressed by existing TGA regulations.
- **5.4 Tamper evident:** Already addressed by existing TGA regulations.
- **6 Labelling:** Already addressed by existing TGA regulations.
- **7 Filling mechanism:** Insufficiently prescriptive for a medical device standard and predominantly addresses concerns relating to open-tank devices.
- **8 Instructions and warnings:** Already addressed by existing TGA regulations.

Liber does not consider CEN/TS 17287 appropriate for its products, which are not intended to be distributed as consumer products. Liber considers CEN/TS 17287 insufficient in certifying the design and

manufacture of a medical device and would be concerned if it were used as the basis for a medical device standard.

At this stage of the medical access framework for NVPs, Liber believes that a requirement to comply with CEN/TS 17287 would add no additional value to the other standards considered herein. In contrast, it may undermine the status of NVPs as medicinal products.

Question 18. GB 41700-2022 relates to requirements for electronic cigarette devices. Indicate the level of compliance of your therapeutic vaping devices against GB 41700-2022 standard and specify if your vaping devices:

- ~~Fully comply now~~
- ~~Partially comply now but could fully comply by December 2024 (Please provide details)~~
- ~~Do not comply, but could comply in 12 to 24 months (Please provide details)~~
- ~~Do not comply, but could comply in more than 24 months (Please provide details)~~
- Unsure

Liber Response:

The Consultation paper notes that GB 41700-2022 is the Chinese national standard for manufacturing e-cigarettes for marketing in China. Liber has not, to this point, contemplated compliance with GB 41700-2022 for its products.

Liber does not consider GB 41700-2022 an appropriate standard for the medical access framework in Australia.

In particular, Liber's main concerns are:

- GB 41700-2022 is not recognised in any jurisdiction outside of China, and is therefore unsuitable for the Australian and international markets.
- GB 41700-2022 was developed and implemented by China's State Tobacco Monopoly Administration (STMA), not a medical regulatory body. The industry widely agrees that the STMA's overarching aim is to protect tobacco revenues and the considerable national GDP of tobacco growing, particularly through restricting flavours to tobacco-only.
- The normative references underpinning GB 41700-2022 are Chinese domestic regulations, meaning compliance with GB 41700-2022 requires monitoring and complying with 29 other Chinese domestic regulations.
- GB 41700-2022 is intended as a standard for consumer goods, not therapeutic goods or medical devices (as the case may be).
- All device and battery safety references are already addressed by Australian or international standards (as applied in Australia).
- The 'technical requirements' are insufficiently prescriptive for a medical device standard or are otherwise addressed by Australian standards.
- Any guidance around impurities and emissions are better addressed through appropriate toxicological and hazard risk analysis.

Liber does not consider GB 41700-2022 appropriate for its products, which are not intended to be marketed as consumer products. Liber considers GB 41700-2022 insufficient in certifying the design and manufacture of a medical device and would be concerned if it became the basis for a medical device standard.

At this stage of the medical access framework for NVPs, Liber believes that a requirement to comply with GB 41700-2022 would add no additional value to the other standards considered herein. In contrast, it may undermine the status of NVPs as medicinal products.

Question 19. UL 8139 relates to requirements for electrical systems of electronic cigarettes and vaping devices. Indicate the level of compliance of your therapeutic vaping devices against UL 8139 and specify if your vaping devices:

s 47

Liber Response:

UL 8139 is a US-centric standard for electric systems incorporated into NVP devices and was touted by Altria[2] (among others) as a 'voluntary' industry standard for ECs. In particular, UL 8139 prescribes an approach to evaluate the safety of NVPs' electrical, heating, cell, battery, and charging systems.

Commercial in confidence

s 47

[2] Proposed Product Standards for Reduced Risk Tobacco Products in the United States. Altria Client Services, LLC. March 16, 2021. https://sciences.altria.com/-/media/Project/Altria/Sciences/our-approach/our-approach-to-product-standards/proposed-product-standard-for-reduced-risk-tobacco-products.pdf

[redacted]

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Question 20. PAS 54115 relates to requirements of manufacture, importation, testing and labelling of vaping products, including electronic cigarettes, e-liquids, e-shisha and directly related products. Indicate the level of compliance of your therapeutic vaping devices against PAS 54115 and specify if your vaping devices:

[redacted]

Liber Response:

PAS 54115 was prepared by the British Standards Institution (**BSI**) in collaboration with the Electronic Cigarette Industry Trade Association (**ECITA**) as a voluntary quality control standard for manufacturing and marketing vaping products. In Liber's view, of all consumer good standards for vaping products, PAS 54115 is best suited to serve as or be adapted to serve as an interim standard for NVPs in a medical access framework as market participants segue towards ARTG.

Liber [redacted] having reviewed PAS 54115 notes some strengths of this standard for the Australian market:

- The normative references it uses align with international standards (62133-2, ISO 8317, EuPh, USP) and are either mandatory in the Australian market or compliance is readily achievable.
- The definitions provided readily align with existing TGO 110 definitions (vaping accessory, vaping product).
- The standard consistently refers to EU or international standards, for example, HACCP: Guidance document on implementing specific provisions of Regulation (EC) No 852/2004.
- Unlike other consumer product standards for NVPs, it addresses the importance of process controls and corrective actions, i.e., QMS.
- The standard mandates European or US Pharmacopeia as purity standards for the API and diluents.
- The standard mandates toxicological risk assessment (TRA) focusing on carcinogenic, mutagenic and/or reproductive toxicants (CMRs), which, in Liber's view, should be a market prerequisite.
- Further, the standard articulates the process for conducting TRAs and mandates that TRAs be undertaken by qualified toxicologists.
- For devices specifically, the standard mandates technical dossiers, process controls, risk

management, and TRAs on emissions (with a list of analytes).

Indeed, there are only two sections (labelling/packaging and vaping claims). The Therapeutic Goods regulations already address these, and they may be considered redundant.

PAS 54115, as it currently stands (i.e., until it is formally adopted as a standard), provides guidance and recommendations. However, no notifying bodies can issue certification for compliance with PAS 54115. Nevertheless, it does provide the basis for a comprehensive suite of requirements that would create a robust interim standard between consumer product standards and ARTG-listed products.

****Commercial in confidence****

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Question 21. ISO 20072 relates to requirements and test methods for aerosol drug delivery devices. Indicate the level of compliance of your therapeutic vaping devices against ISO 20072 standard and specify if your vaping devices:

s 47

Liber Response:

s 47

****Commercial in confidence****

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Question 22. IEC 62304 relates to requirements of medical device software. This question is only applicable if your vaping device incorporates software (including firmware). Specifically, this question is applicable if your device utilises a microcontroller, EPROMS, PLC or control unit that is programmable (has firmware). If your vaping devices incorporates software, indicate the level of compliance of your therapeutic vaping devices against IEC 62304 standard and specify if your vaping devices:

[redacted]

Liber Response:

[redacted]

****Commercial in confidence****

[redacted]

Question 23. To mitigate toxicological risks associated with inhaled vapour, specifically, as those risks pertain to vaping devices (but not the e-liquid), have you completed a toxicological risk assessment for your vaping devices?

- Yes (Please provide details)
- ~~Not yet, but could be completed in by December 2024 (Please provide details)~~
- ~~Not yet, but could be completed in 12 to 24 months (Please provide details)~~
- ~~Not yet, but could be completed in more than 24 months (Please provide details)~~
- ~~Unsure~~

Liber Response:

Yes. Liber has previously disclosed information about the toxicological risk assessment completed on its A1 product.

****Commercial in confidence****

[redacted]

Private and confidential
3 March, 2024

Liber

s 47

[redacted]

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2.4 Batteries for Vaping Devices

Question 24. Does your vaping device use lithium batteries and does the device comply with any of the listed standards?

- Yes, uses lithium batteries and complies with listed standards (Please provide details)
- ~~Yes, uses lithium batteries, but does not comply with the listed standards (Please provide details)~~
- ~~No, does not use lithium batteries~~

Liber Response:

- Liber's A1 device is tested and certified to comply with **UN 38.3** and **IEC 62133-2**. On this basis, the testing requirements for **IEC 62281** have already been met. [redacted]
- Liber's A1 device has not been tested and certified to comply with **UL 1642** or **UL 2054** as these standards are only required for North American markets.

****Commercial in confidence****

[redacted]

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Question 25. Do you have views on which standards should be applied to batteries used in vaping devices?

Liber Response:

As the TGA is likely aware, the testing protocols outlined by the proposed standards (UN 38.3, IEC 62133-2, IEC 62281, UL 1642 and UL 2054) are broadly similar. The testing is not exactly the same, in that, parameters and ranges differ between standards, but the intent and subsequent assurance of safety is broadly similar.

In May 2023, the CSIRO released the report *Lithium-ion battery safety: A report for the Australian Competition and Consumer Commission (ACCC)* (**CSIRO report**).[3] This report considered the five battery safety standards proposed by the TGA (the Comparison table has been reproduced below) and in conclusion recommends the application of UN 38.3 and IEC 62133-2.

Liber suggests that the TGA should be guided by established international standards and the Australian electrical standards regulators to determine the best applicable standard.

[3] Best, A, Cavanagh K, Preston C, Webb A, and Howell S (2023) Lithium-ion battery safety: A report for the Australian Competition and Consumer Commission (ACCC). CSIRO, Australia. https://www.productsafety.gov.au/system/files/CSIRO-ACCCLithiumIonBatteries.pdf

UN 38.3

Liber views UN 38.3 as an essential safety standard for lithium-ion batteries. In the unusual circumstance that the TGA elected not to mandate UN 38.3, Liber would still elect to have the lithium-ion batteries used in its devices tested and certified to meet UN 38.3 because:

- UN 38.3 has been adopted by regulators and competent authorities around the world, making it a requirement for global market access.
- UN 38.3 certification is a mandatory requirement for the transportation of lithium-ion batteries under the Australian Dangerous Goods Code.[4]

IEC 62133-2

Liber views IEC 62133-2 as an essential safety standard for lithium-ion batteries.

- IEC 62133-2 is the *de facto* international standard for the safety requirements for portable lithium cells and batteries.
- Likewise, it is the default safety standard of Australian electrical regulators.

IEC 62281

- IEC 62281 applies the same eight (8) test protocols applied by UN 38.3 with the inclusion of an additional test (drop test). Notably, the additional (drop) test is included in the IEC 62133-2 testing protocol.
- IEC 62281 essentially replicates the testing conducted in the UN 38.3 and IEC 62133-2 testing protocols.

UL 1642 and UL 2054

- UL 1642 and UL 2054 are US-centric standards, and while they are a requirement for North American markets, Liber's understanding is that they are not preferred by Australian electrical regulators, who, much like the TGA, defer to European or International standards where required.
- The UL 1642 and UL 2054 testing protocols cover the same scope as UN 38.2 and IEC 62133-2, with the addition of a 'projectile' test and 'fire' test.
- The CSIRO report, in recommending the application of UN 38.3 and IEC 62133-2 instead of the similar UL standards appeared to not consider the additional testing conducted under the UL protocols to be either, necessary, or to significantly improve the safety profile of lithium-ion batteries.
- It is also worth noting that, while UL 1642 and UL 2054 are the default standards in North America for consumer goods, they are not the standard applied to medical devices. Clause 15.4.3.4 of ANSI/AAMI ES 60601-1:2005 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance) requires lithium batteries to comply with IEC 60086-4 (Primary Batteries – Part 4: Safety of Lithium Batteries) or IEC 62133 (Secondary Cells and Batteries Containing Alkaline or Other Non-acid Electrolytes).
- Finally, UL 1642 and UL 2054 are not 'standalone' standards. UL 2054 requires that UL 1642 certification be completed before testing and certification for UL 2054.

[4] Section 2.9.4 - Australian Code for the Transport of Dangerous Goods by Road & Rail (2022). Edition 7.8
https://www.ntc.gov.au/sites/default/files/assets/files/Australian%20Dangerous%20Goods%20Code%20-%207.8.pdf

Comparison table

Test type	UN 38.3	IEC 62133-2	IEC 62281	UL 1642	UL 2054
External short circuit	✓	✓	✓	✓	✓
Abnormal/Over charging	✓	✓	✓	✓	✓
Forced discharge	✓	✓	✓	✓	✓
Crush		✓		✓	✓
Impact	✓		✓	✓	✓
Shock	✓	✓	✓	✓	✓
Vibration	✓	✓	✓	✓	✓
Heating	✓	✓		✓	✓
Temperature cycling	✓		✓	✓	✓
Altitude	✓	✓	✓	✓	
Projectile				✓	✓
Drop		✓	✓		
Penetration					
Internal Short Circuit		✓			
Fire Exposure				✓	✓

Source: CSIRO. Lithium-ion battery safety - A report for the Australian Competition and Consumer Commission (ACCC). May 2023.

Question 26. Does your vaping device use button or coin batteries and does it comply with the Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020?

- ~~Yes, contains button or coin batteries and complies with the Consumer goods Standard~~
- ~~Yes, contains button or coin batteries, but does not comply with the Consumer goods Standard~~
- No, does not contain button or coin batteries

Liber Response:

No, Liber's devices do not contain button or coin batteries.

Question 27. The electronic cigarette pathways include consumer grade e-cigarette authorisations or notifications issued by the US FDA or UK MHRA, or through the EU e-cigarette notification process. If the electronic cigarette pathways are removed as an acceptable form of evidence for importing or supplying therapeutic vaping devices and accessories in Australia, as a manufacturer or sponsor, do you expect to be able to meet the new requirements – being ISO 13485 certification for manufacturing

of the device and compliance with certain product specific standards (canvassed previously)? If you are another stakeholder, do you have views about this change?

Liber Response:

s 47

3. Transition to full TGA approval in the future

3.1 Preparedness for inclusion of products on the ARTG

Question 28. The Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023 is likely to be time-limited with the expectation that manufacturers of vaping devices and accessories will transition to include their devices in the ARTG. Indicate your level of preparedness to make an application to include your therapeutic vaping devices in the ARTG:

s 47

Liber Response:

****Commercial in confidence****

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Question	Response
What is your name? - Name	[redacted]
What is your email address? - Question 2 (Email)	[redacted]
What is your organisation's name? - Question 3 (Organisation)	Liber Pharmaceuticals Pty Ltd
Please choose the activity (or more if it applies) that best describes you or your organisation: - Question 4 (Activity) - designing, producing, packaging, or labelling the therapeutic vaping device or accessory (manufacturer)	designing, producing, packaging, or labelling the therapeutic vaping device or accessory (manufacturer)
Please choose the activity (or more if it applies) that best describes you or your organisation: - Question 4 (Activity) - importing the therapeutic vaping device or accessory to Australia (sponsor)	importing the therapeutic vaping device or accessory to Australia (sponsor)
Please choose the activity (or more if it applies) that best describes you or your organisation: - Question 4 (Activity) - supplying the therapeutic vaping device or accessory in Australia (sponsor)	
Please choose the activity (or more if it applies) that best describes you or your organisation: - Question 4 (Activity) - Other (please specify)	
Please choose the activity (or more if it applies) that best describes you or your organisation: - Question 4 (Activity)	
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group) - manufacturer of therapeutic vaping device or accessory	manufacturer of therapeutic vaping device or accessory
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group) - sponsor of therapeutic vaping device or accessory	sponsor of therapeutic vaping device or accessory
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group) - pharmacy wholesaler	
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group) - pharmacy industry	
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group) - pharmacy industry	
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group) - pharmacy retailer	
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group) - universities, researchers, experts	
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group) - consumer groups and associations	
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group) - schools and other educational institutions	
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group) - government agency	
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group) - vape stores	
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group) - convenience stores	
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group) - other (please specify)	
Please choose one (or more if it applies) of the stakeholder groups that best describes you or your organisation: - Question 5 (Stakeholder Group)	
Which best describes your response? - Question 6	I am responding on behalf of an organisation
This question relates to any actual or perceived conflict of interest you or your organisation has (or previously had) with the tobacco and/or the e-cigarette industry.	No
This question relates to any actual or perceived conflict of interest you or your organisation has (or previously had) with the tobacco and/or the e-cigarette industry.	n/a
[If applicable] As a sponsor, have you made or are you intending to make a notification to the TGA to import or supply your therapeutic vaping device or accessory in Australia? - Question 8 (Notifications)	Yes, notified (Go to Question 10)

[If applicable] If you are intending to notify, provide details about when you expect to lodge a notification and the products to be included in this notification. - Question 9 (Notification)	**Commercial in confidence** s 47 [redacted] **
[If applicable] ISO 13485 relates to the requirements for quality management systems for medical devices such as therapeutic vaping devices and accessories. Are you familiar with, and do you currently hold a valid ISO 13485 certificate where the certificate scope covers the manufacturing of therapeutic vaping devices and accessories: - Question 10 (ISO 13485)	s 47 [redacted]
[If applicable] If you do not hold a valid ISO 13485 certificate for the manufacturing of therapeutic vaping devices and accessories, can you get this certificate: - Question 11 (ISO 13485)	s 47 [redacted]
Regarding the proposed instructions for use (IFU) requirements, what would be the impact on you as a manufacturer or sponsor to implement an IFU? If you are another stakeholder, do you have views about this change? - Question 12 (IFU)	Liber currently provides a CMI with Nicovape Q A1 cartridges and a User Guide with Nicovape Q A1 devices. The IFU requirements outlined will require strengthening of Liber's existing User Guide. **Commercial in confidence** s 47 [redacted] ** To the extent that Liber is required to amend its existing User Guide, it is confident that it will be able to meet the requirements by December 2024. **Commercial in confidence** s 47 [redacted] **
Regarding the proposed IFU requirements, can you meet these requirements: - Question 13 (IFU)	by December 2024
Regarding the proposed labelling and packaging requirements, what would be the impact on you as a manufacturer or sponsor to implement these requirements? If you are another stakeholder, do you have views about this change? - Question 14 (Labelling&Packaging)	Liber supports packaging requirements consistent with TGO 91 and TGO 95, and which treat NVPs in line with other mainstream medicines. Liber voluntarily decided to design its NVP packaging (including device packaging) to meet the packaging requirements set by TGO 91. While TGO 91 is directed to prescription medicines, the packaging requirements for vaping devices and accessories should not extend beyond the parameters set by TGO 91. Notably, the special MBS codes (consultations for smoking cessation) and the permission for pharmacies to include posters stating "Nicotine Vaping Products available here" have been removed to bring the treatment of NVPs in line with other medicines. Liber believes this approach is sensible and that the TGA should apply it consistently. Liber believes that TGO 91 sufficiently distinguishes medicines from consumer products. As such, a similar and consistent approach to NVP device packaging would ensure that the TGA appropriately addresses any marketing concerns about NVP device packaging. To the extent that the TGA proposes additional restrictions to the packaging of NVPs, such as a white background with black/grayscale lettering, Liber believes that these serve no benefit and will be counterproductive by appearing to treat NVPs as tobacco products rather than therapeutic goods. Regarding the proposal that "certain product names, logos or brand names" may not be included (on the packaging), it is challenging to offer commentary on this proposal without understanding what those product names, logos or brand names might be.

	However, on the basis that most NVPs are consumer products in all jurisdictions outside of Australia and are marketed directly to consumers via internationally hosted websites and social media platforms, Liber supports restrictions on the use of product names, logos or brand names associated with NVPs marketed and sold as consumer products in other jurisdictions. Indeed, under s3(5) of the Therapeutic Goods Act, such a presentation (i.e., that of a consumer good that can leverage offshore advertising and marketing) may constitute "a purpose that is not in accordance with conditions applicable to the supply of the goods in Australia". Section 3(5) of the Therapeutic Goods Act 1989 states that: "the presentation of therapeutic goods is unacceptable if it is capable of being misleading or confusing as to the content or proper use or identification of the goods and, without limiting the previous words in this subsection, the presentation of therapeutic goods is unacceptable: [..] d) if a form of presentation of the goods may lead to unsafe use of the goods or suggests a purpose that is not in accordance with conditions applicable to the supply of the goods in Australia; or (e) in prescribed cases." Context to Liber's response to Q 15 below: Liber has designed its NVP packaging (including device packaging) to meet the packaging requirements set by TGO 91 – understanding that applying TGO 91 to device packaging (in lieu of any other appropriate standard for NVPs) was a voluntary decision by Liber. If the TGA imposes additional requirements for NVP packaging in addition to TGO 91, Liber anticipates being able to meet those by the earlier of three months or December 2024, subject to its comment above about time needed to sell down non-compliant stock already in the supply chain to meet demand anticipated by the DoH's impact analysis.
Regarding the proposed labelling and packaging requirements, can you meet these requirements: - Question 15 (Labelling&Packaging)	
ISO 14971 standard relates to the application of risk management to medical devices. Indicate the level of compliance of your therapeutic vaping device against ISO 14971 standard and specify if your vaping devices: - Question 16 (ISO 14971)	s 47 [redacted]
ISO 14971 standard relates to the application of risk management to medical devices. Indicate the level of compliance of your therapeutic vaping device against ISO 14971 standard and specify if your vaping devices: - Question 16 (ISO 14971)	**Commercial in confidence** s 47 [redacted] **
CEN/TS 17287 relates to requirements and test methods for electronic cigarette devices. Indicate the level of compliance of your therapeutic vaping devices against CEN/TS 17287 standard and specify if your vaping devices: - Question 17 (CEN/TS 17287)	Unsure
CEN/TS 17287 relates to requirements and test methods for electronic cigarette devices. Indicate the level of compliance of your therapeutic vaping devices against CEN/TS 17287 standard and specify if your vaping devices: - Question 17 (CEN/TS 17287)	"CEN/TS 17287 is a consumer product standard and as such, is not, in itself, appropriate for assessing the suitability of NVPs as medical devices. CEN/TS 17287, in particular, lacks the specificity required of a device standard. Where CEN/TS 17287 does provide specific compliance requirements, it does so by deferring to normative references that Australian electrical standards or Therapeutic Goods regulations already provide. Liber notes that, as a medical device standard, the CEN/TS 17287 requirements can be summarised as: 4.2 General requirements: These are addressed by existing Australian electrical standards and regulations. For example, EN 60335-1 for electromagnetic compatibility. 4.3 Power unit: Addressed by existing Australian electrical standards and regulations. For example, EN 62133 for lithium battery standards. 4.4 Atomizer: Insufficiently prescriptive for a medical device standard.

	4.5 E-liquid reservoir: Generally, insufficiently prescriptive for a medical device standard, and regarding microbiological and bacterial safety, already addressed by existing TGA regulations. 4.6 Mouthpiece: Insufficiently prescriptive for a medical device standard. 4.7 Child resistance: Already addressed by existing TGA regulations. 5.1 Material (migration): Insufficiently prescriptive for a medical device standard, and the intent of this section is better served through appropriate toxicological and hazard risk analysis. 5.2 Resistance to breakage and protection from leakage: Insufficiently prescriptive for a medical device standard. 5.3 Child resistance: Already addressed by existing TGA regulations. 5.4 Tamper evident: Already addressed by existing TGA regulations. 6 Labelling: Already addressed by existing TGA regulations. 7 Filling mechanism: Insufficiently prescriptive for a medical device standard and predominantly addresses concerns relating to open-tank devices. 8 Instructions and warnings: Already addressed by existing TGA regulations. Liber does not consider CEN/TS 17287 appropriate for its products, which are not intended to be distributed as consumer products. Liber considers CEN/TS 17287 insufficient in certifying the design and manufacture of a medical device and would be concerned if it were used as the basis for a medical device standard. At this stage of the medical access framework for NVPs, Liber believes that a requirement to comply with CEN/TS 17287 would add no additional value to the other standards considered herein. In contrast, it may undermine the status of NVPs as medicinal products."
GB 41700-2022 relates to requirements for electronic cigarette devices. Indicate the level of compliance of your therapeutic vaping devices against GB 41700-2022 standard and specify if your vaping devices: - Question 18 (GB 41700-2022)	Unsure
GB 41700-2022 relates to requirements for electronic cigarette devices. Indicate the level of compliance of your therapeutic vaping devices against GB 41700-2022 standard and specify if your vaping devices: - Question 18 (GB 41700-2022)	The Consultation paper notes that GB 41700-2022 is the Chinese national standard for manufacturing e-cigarettes for marketing in China. Liber has not, to this point, contemplated compliance with GB 41700-2022 for its products. Liber does not consider GB 41700-2022 an appropriate standard for the medical access framework in Australia. In particular, Liber's main concerns are: - GB 41700-2022 is not recognised in any jurisdiction outside of China, and is therefore unsuitable for the Australian and international markets. - GB 41700-2022 was developed and implemented by China's State Tobacco Monopoly Administration (STMA), not a medical regulatory body. The industry widely agrees that the STMA's overarching aim is to protect tobacco revenues and the considerable national GDP of tobacco growing, particularly through restricting flavours to tobacco-only. - The normative references underpinning GB 41700-2022 are Chinese domestic regulations, meaning compliance with GB 41700-2022 requires monitoring and complying with 29 other Chinese domestic regulations. - GB 41700-2022 is intended as a standard for consumer goods, not therapeutic goods or medical devices (as the case may be). - All device and battery safety references are already addressed by Australian or international standards (as applied in Australia). - The 'technical requirements' are insufficiently prescriptive for a medical device standard or are otherwise addressed by Australian standards. - Any guidance around impurities and emissions are better addressed through appropriate toxicological and hazard risk analysis. Liber does not consider GB 41700-2022 appropriate for its products, which are not intended to be marketed as consumer products. Liber considers GB 41700-2022 insufficient in certifying the design and manufacture of a medical device and would be concerned if it became the

	basis for a medical device standard. At this stage of the medical access framework for NVPs, Liber believes that a requirement to comply with GB 41700-2022 would add no additional value to the other standards considered herein. In contrast, it may undermine the status of NVPs as medicinal products.
UL 8139 relates to requirements for electrical systems of electronic cigarettes and vaping devices. Indicate the level of compliance of your therapeutic vaping devices against UL 8139 and specify if your vaping devices: - Question 19 (UL 8139)	[redacted] s 47 (Please provide details)
UL 8139 relates to requirements for electrical systems of electronic cigarettes and vaping devices. Indicate the level of compliance of your therapeutic vaping devices against UL 8139 and specify if your vaping devices: - Question 19 (UL 8139)	UL 8139 is a US-centric standard for electric systems incorporated into NVP devices and was touted by Altria (among others) [see: Proposed Product Standards for Reduced Risk Tobacco Products in the United States. Altria Client Services, LLC. March 16, 2021. https://sciences.altria.com/-/media/Project/Altria/Sciences/our-approach/our-approach-to-product-standards/proposed-product-standard-for-reduced-risk-tobacco-products.pdf] as a 'voluntary' industry standard for ECs. In particular, UL 8139 prescribes an approach to evaluate the safety of NVPs' electrical, heating, cell, battery, and charging systems. **Commercial in confidence** [redacted] s 47 **
PAS 54115 relates to requirements of manufacture, importation, testing and labelling of vaping products, including electronic cigarettes, e-liquids, e-shisha and directly related products. Indicate the level of compliance of your therapeutic vaping devices against PAS 54115 and specify if your vaping devices: - Question 20 (PAS 54115)	[redacted] s 47 (Please provide details)
PAS 54115 relates to requirements of manufacture, importation, testing and labelling of vaping products, including electronic cigarettes, e-liquids, e-shisha and directly related products. Indicate the level of compliance of your therapeutic vaping devices against PAS 54115 and specify if your vaping devices: - Question 20 (PAS 54115)	PAS 54115 was prepared by the British Standards Institution (BSI) in collaboration with the Electronic Cigarette Industry Trade Association (ECITA) as a voluntary quality control standard for manufacturing and marketing vaping products. In Liber's view, of all consumer good standards for vaping products, PAS 54115 is best suited to serve as or be adapted to serve as an interim standard for NVPs in a medical access framework as market participants segue towards ARTG. Liber [redacted] s 47 notes some strengths of this standard for the Australian market: - The normative references it uses align with international standards (62133-2, ISO 8317, EuPh, USP) and are either mandatory in the Australian market or compliance is readily achievable. - The definitions provided readily align with existing TGO 110 definitions (vaping accessory, vaping product). - The standard consistently refers to EU or international standards, for example, HACCP: Guidance document on implementing specific provisions of Regulation (EC) No 852/2004. - Unlike other consumer product standards for NVPs, it addresses the importance of process controls and corrective actions, i.e., QMS. - The standard mandates European or US Pharmacopeia as purity standards for the API and diluents.

	- The standard mandates toxicological risk assessment (TRA) focusing on carcinogenic, mutagenic and/or reproductive toxicants (CMRs), which, in Liber's view, should be a market prerequisite. - Further, the standard articulates the process for conducting TRAs and mandates that TRAs be undertaken by qualified toxicologists. - For devices specifically, the standard mandates technical dossiers, process controls, risk management, and TRAs on emissions (with a list of analytes). Indeed, there are only two sections (labelling/packaging and vaping claims). The Therapeutic Goods regulations already address these, and they may be considered redundant. PAS 54115, as it currently stands (i.e., until it is formally adopted as a standard), provides guidance and recommendations. However, no notifying bodies can issue certification for compliance with PAS 54115. Nevertheless, it does provide the basis for a comprehensive suite of requirements that would create a robust interim standard between consumer product standards and ARTG-listed products. **Commercial in confidence** s 47 [redacted] **
ISO 20072 relates to requirements and test methods for aerosol drug delivery devices. Indicate the level of compliance of your therapeutic vaping devices against ISO 20072 standard and specify if your vaping devices: - Question 21 (ISO 20072)	s 47 (Please provide details)
ISO 20072 relates to requirements and test methods for aerosol drug delivery devices. Indicate the level of compliance of your therapeutic vaping devices against ISO 20072 standard and specify if your vaping devices: - Question 21 (ISO 20072)	s 47 **Commercial in confidence** s 47 [redacted] **
IEC 62304 relates to requirements of medical device software. This question is only applicable if your vaping device incorporates software (including firmware). Specifically, this question is applicable if your device utilises a microcontroller, EPROMS, PLC or control unit that is programmable (has firmware).	s 47 (Please provide details)
IEC 62304 relates to requirements of medical device software. This question is only applicable if your vaping device incorporates software (including firmware). Specifically, this question is applicable if your device utilises a microcontroller, EPROMS, PLC or control unit that is programmable (has firmware).	s 47 **Commercial in confidence** s 47 [redacted] **
To mitigate toxicological risks associated with inhaled vapour, specifically as those risks pertain to vaping devices (but not the e-liquid), have you completed a toxicological risk assessment for your vaping devices? - Question 23 (Toxicological risks)	Yes (Please provide details)
To mitigate toxicological risks associated with inhaled vapour, specifically as those risks pertain to vaping devices (but not the e-liquid), have you completed a toxicological risk assessment for your vaping devices? - Question 23 (Toxicological risks)	Yes. Liber has previously disclosed information about the toxicological risk assessment completed on its A1 product. **Commercial in confidence** s 47 [redacted]

	s 47 [redacted] **
Does your vaping device use lithium batteries and does the device comply with any of the listed standards? - Question 24 (Batteries)	Yes, uses lithium batteries and complies with listed standards (Please provide details)
Does your vaping device use lithium batteries and does the device comply with any of the listed standards? - Question 24 (Batteries)	s 47 [redacted] **Commercial in confidence** s 47 [redacted] **
Do you have views on which standards should be applied to batteries used in vaping devices? - Question 25 (Battery std)	As the TGA is likely aware, the testing protocols outlined by the proposed standards (UN 38.3, IEC 62133-2, IEC 62281, UL 1642 and UL 2054) are broadly similar. The testing is not exactly the same, in that, parameters and ranges differ between standards, but the intent and subsequent assurance of safety is broadly similar. In May 2023, the CSIRO released the report Lithium-ion battery safety: A report for the Australian Competition and Consumer Commission

	(ACCC) (CSIRO report: Best, A, Cavanagh K, Preston C, Webb A, and Howell S (2023) Lithium-ion battery safety: A report for the Australian Competition and Consumer Commission (ACCC). CSIRO, Australia. https://www.productsafety.gov.au/system/files/CSIRO-ACCCLithiumIonBatteries.pdf). This report considered the five battery safety standards proposed by the TGA (the Comparison table has been reproduced below) and in conclusion recommends the application of UN 38.3 and IEC 62133-2. Liber suggests that the TGA should be guided by established international standards and the Australian electrical standards regulators to determine the best applicable standard. UN 38.3 Liber views UN 38.3 as an essential safety standard for lithium-ion batteries. In the unusual circumstance that the TGA elected not to mandate UN 38.3, Liber would still elect to have the lithium-ion batteries used in its devices tested and certified to meet UN 38.3 because: - UN 38.3 has been adopted by regulators and competent authorities around the world, making it a requirement for global market access. - UN 38.3 certification is a mandatory requirement for the transportation of lithium-ion batteries under the Australian Dangerous Goods Code. IEC 62133-2 Liber views IEC 62133-2 as an essential safety standard for lithium-ion batteries. - IEC 62133-2 is the de facto international standard for the safety requirements for portable lithium cells and batteries. - Likewise, it is the default safety standard of Australian electrical regulators. IEC 62281 - IEC 62281 applies the same eight (8) test protocols applied by UN 38.3 with the inclusion of an additional test (drop test). Notably, the additional (drop) test is included in the IEC 62133-2 testing protocol. - IEC 62281 essentially replicates the testing conducted in the UN 38.3 and IEC 62133-2 testing protocols. UL 1642 and UL 2054 - UL 1642 and UL 2054 are US-centric standards, and while they are a requirement for North American markets, Liber's understanding is that they are not preferred by Australian electrical regulators, who, much like the TGA, defer to European or International standards where required. - The UL 1642 and UL 2054 testing protocols cover the same scope as UN 38.2 and IEC 62133-2, with the addition of a 'projectile' test and 'fire' test. - The CSIRO report, in recommending the application of UN 38.3 and IEC 62133-2 instead of the similar UL standards appeared to not consider the additional testing conducted under the UL protocols to be either, necessary, or to significantly improve the safety profile of lithium-ion batteries. - It is also worth noting that, while UL 1642 and UL 2054 are the default standards in North America for consumer goods, they are not the standard applied to medical devices. Clause 15.4.3.4 of ANSI/AAMI ES 60601-1:2005 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance) requires lithium batteries to comply with IEC 60086-4 (Primary Batteries – Part 4: Safety of Lithium Batteries) or IEC 62133 (Secondary Cells and Batteries Containing Alkaline or Other Non-acid Electrolytes). - Finally, UL 1642 and UL 2054 are not 'standalone' standards. UL 2054 requires that UL 1642 certification be completed before testing and certification for UL 2054. Please see a Comparison table of UN 38.3, IEC 62133-2, IEC 62281, UL 1642 and UL 2054 in the attached submission document.
Does your vaping device use button or coin batteries and does it comply with the Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020? - Question 26 (Coin Battery Std)	No, does not contain button or coin batteries
The electronic cigarette pathways include consumer grade e-cigarette authorisations or notifications issued by the US FDA or UK MHRA, or through the EU e-cigarette notification process. If the electronic cigarette pathways are removed as an acceptable form of evidence for importing or supplying therapeutic vaping devices and accessories in Australia, as a manufacturer or sponsor, do you expect to be able to meet the new requirements – being ISO 13485 certification for manufacturing of the device and compliance with certain product specific standards (canvassed previously)? If you are another stakeholder, do you have views about this change? - Question 27 (Ecigarette pathway)	s 47 [redacted]
The Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023 is likely to be time-limited with the expectation that manufacturers of vaping devices and accessories will transition to include their devices in the ARTG. Indicate your level of	s 47 [redacted] (Please provide details)

preparedness to make an application to include your therapeutic vaping devices in the ARTG: - Question 28 (TGA Approval)	
The Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023 is likely to be time-limited with the expectation that manufacturers of vaping devices and accessories will transition to include their devices in the ARTG. Indicate your level of preparedness to make an application to include your therapeutic vaping devices in the ARTG: - Question 28 (TGA Approval)	**Commercial in confidence** s 47 [redacted] **
Response ID	s 22
Created Date	
Submitted Date	
Last Modified Date	
IP Address	
Browser Identification	
Activity State	
Citizen Space Version	
Visited Pages - Introduction	
Visited Pages - 1. Changes to manufacturing requirements	
Visited Pages - 2. Proposed new product requirements	
Visited Pages - 2. Proposed new product requirements (cont.)	
Visited Pages - 2. Proposed new product requirements (cont.)	
Visited Pages - 2. Proposed new product requirements (cont.)	
Visited Pages - 3. Transition to full TGA approval in the future	