



**Proposed TPs:**

There is a global shortage for IV fluids, like saline, due to global supply limitations, unexpected increases in demand and manufacturing capacity constraints.

s22



**Key Issues:**

- In Australia, the shortage of IV Sodium Chloride (saline) products has been ongoing since early 2023 but has recently worsened. s47G  
[Redacted]  
[Redacted]. A delayed shipment for another supplier, Fresenius Kabi, has also contributed to the worsening shortages. In addition, sponsors have reported a further increase in demand in recent months as jurisdictions began experiencing low stock levels.

s22







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**From:** s22 [redacted] <[redacted]@health.gov.au>  
**Sent:** Tuesday, August 6, 2024 11:58 AM  
**To:** s22 [redacted] <[redacted]@health.gov.au>; s22 [redacted] <[redacted]@health.gov.au>; s22 [redacted] <[redacted]@health.gov.au>; s22 [redacted] <[redacted]@Health.gov.au>  
**Cc:** s22 [redacted] <[redacted]@health.gov.au>  
**Subject:** ACTION BY COB Thursday 8 August - HMM 16 August - Backpocket Brief on Re-establishment of committee on Medicine Shortages [SEC=OFFICIAL]

Good afternoon

At the July HCEF, there was discussion regarding IV fluid shortages which was raised by South Australia. s22 [redacted]

s22 [redacted]



BACK POCKET BRIEFING, IF THE BELOW ISSUES ARE RAISED NOTE THESE ITEMS ARE NOT LISTED ON THE AGENDA	
POSSIBLE ITEM	CRITICAL BACKGROUND
IV fluids shortage - update on current situation and actions taken	<p>s22</p> <p>s22</p> <ul style="list-style-type: none"><li>Sponsors have noted global supply limitations, unexpected increases in demand, and manufacturing capacity constraints as the reasons for the shortages.</li></ul> <p>s22</p>

POSSIBLE ITEM	COMMONWEALTH VIEW	RISKS AND SENSITIVITIES	STATE / TERRITORY VIEWS	CRITICAL BACKGROUND
				s22





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Good afternoon

At the July HCEF, there was discussion regarding IV fluid shortages which was raised by South Australia. s22

s22









**From:** s22  
**To:** s22  
**Cc:** [KELLEHER, Brian](#); s22; [LAWLER, Tony](#); [LANGHAM, Robyn](#); s22; [LANCSAR, Emily](#)  
**Subject:** RE: Intravenous fluid shortages [SEC=OFFICIAL]  
**Date:** Friday, 2 August 2024 3:08:11 PM  
**Attachments:** [image002.png](#)  
[image003.png](#)  
**Importance:** High

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s22



Dear xx

As you may be aware, there is currently a critical national shortage of intravenous (IV) fluids, due to supply disruption and demand and utilisation issues.

s22





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**Talking points**

- The Government is aware of shortages of multiple intravenous (IV) fluid products from all three Australian suppliers (Baxter Healthcare, B.Braun, and Fresenius Kabi), and is acting decisively.
- The shortages are due to multiple factors including global supply limitations, unexpected increases in demand, and manufacturing issues. Specifically, these shortages have recently worsened due to:
  - sponsors experiencing delays in procurement of overseas products, including issues with transport and logistics.
  - sponsors reporting further increases in demand in recent months due to stockpiling of products, which is often experienced with medicine shortages.

















**Australian Government**  
**Department of Health and Aged Care**

**Secretary**

s22

s22

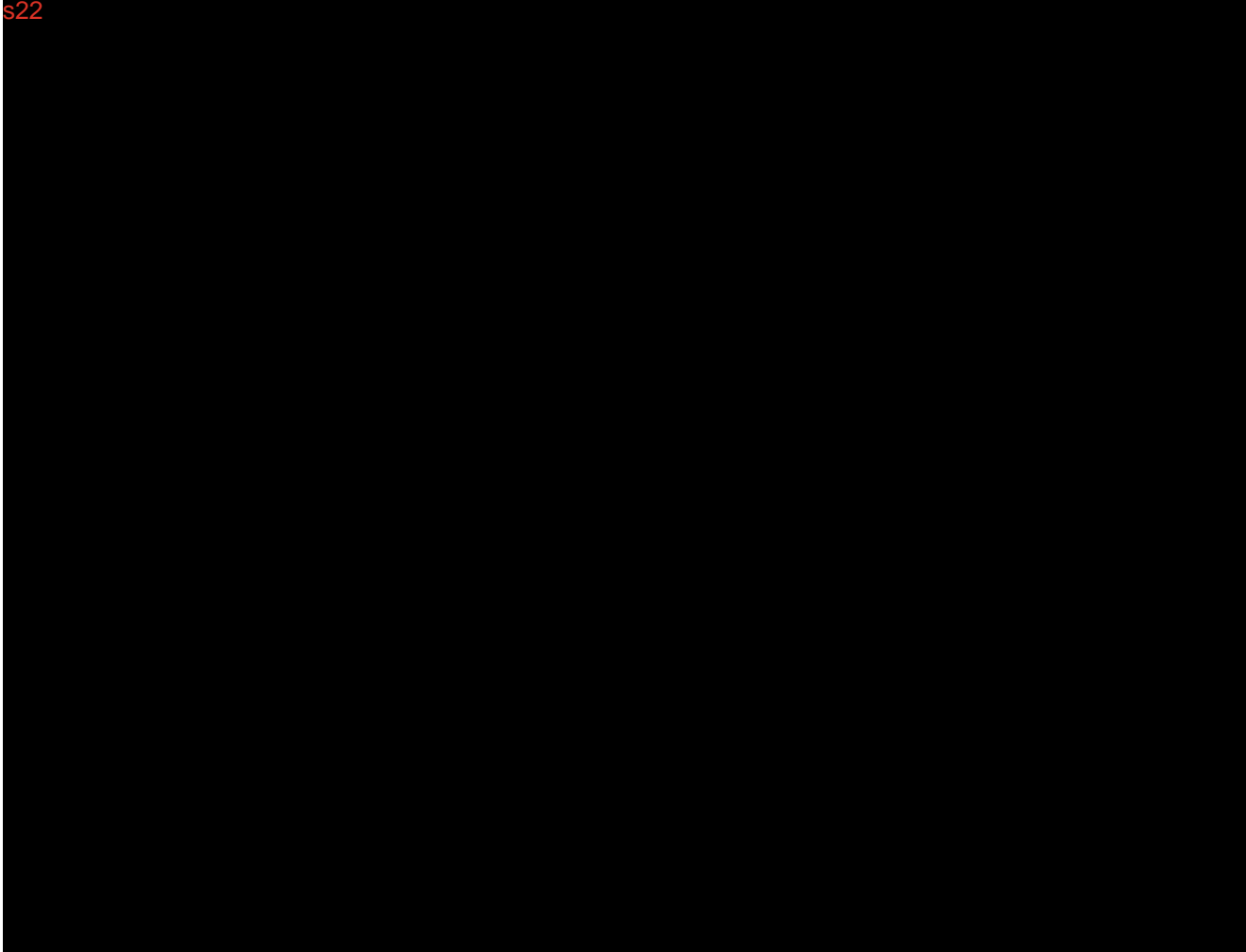
Health Chief Executives' Forum  
C/O NSW Ministry of Health Level 7, 1 Reserve Road  
ST LEONARDS NSW 2065

Dear s22

s22

It is also clear a significant component of the current issue is the management of demand and product utilisation. This includes the relative prioritisation of emergency over elective utilisation, the preservation of supply to rural and remote locations within jurisdictions, the use of IV fluids in private settings, and any relative maldistribution between jurisdictions.

s22



Yours sincerely

A handwritten signature in black ink, appearing to read 'Blair Comley', is written in a cursive style.

Blair Comley PSM

31 July 2024











**Australian Government**  
**Department of Health and Aged Care**

**Secretary**

s22

Health Chief Executives' Forum  
C/O NSW Ministry of Health Level 7, 1 Reserve Road  
ST LEONARDS NSW 2065

Dear s22

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Yours sincerely



Blair Comley PSM

31 July 2024

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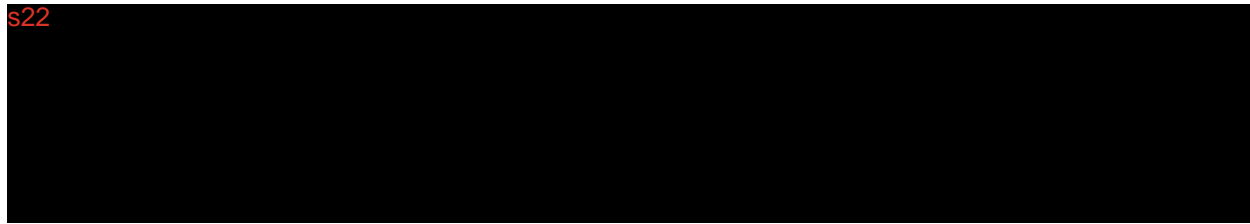








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**Shortage reasons and background**

- The shortages are multifactorial in nature
  - Spikes in demand and fluctuations between different products making it difficult for Baxter to predict supply across individual SKUs, partic where different products use the same line.
  - Baxter is reacting and changing manufacture based on the spikes in demand of different SKUs but Fresenius and s47G
  - <sensitive information internal info only s47G end sensitive information> s47G
  - Global shortages (because of global demand changes, manufacturing capacity constraints, and some suppliers withdrawing from other markets so fewer suppliers globally)
  - The delayed Fresenius shipment has had flow on effects
  - The Baxter s19A from the US becoming less available.
    - Shipping of IV fluids is expensive as they are heavy, and incredibly large quantities are needed, which also takes up a lot of shipping space.
  - Hospital contracts also cause complexity with an inability to easily switch between suppliers





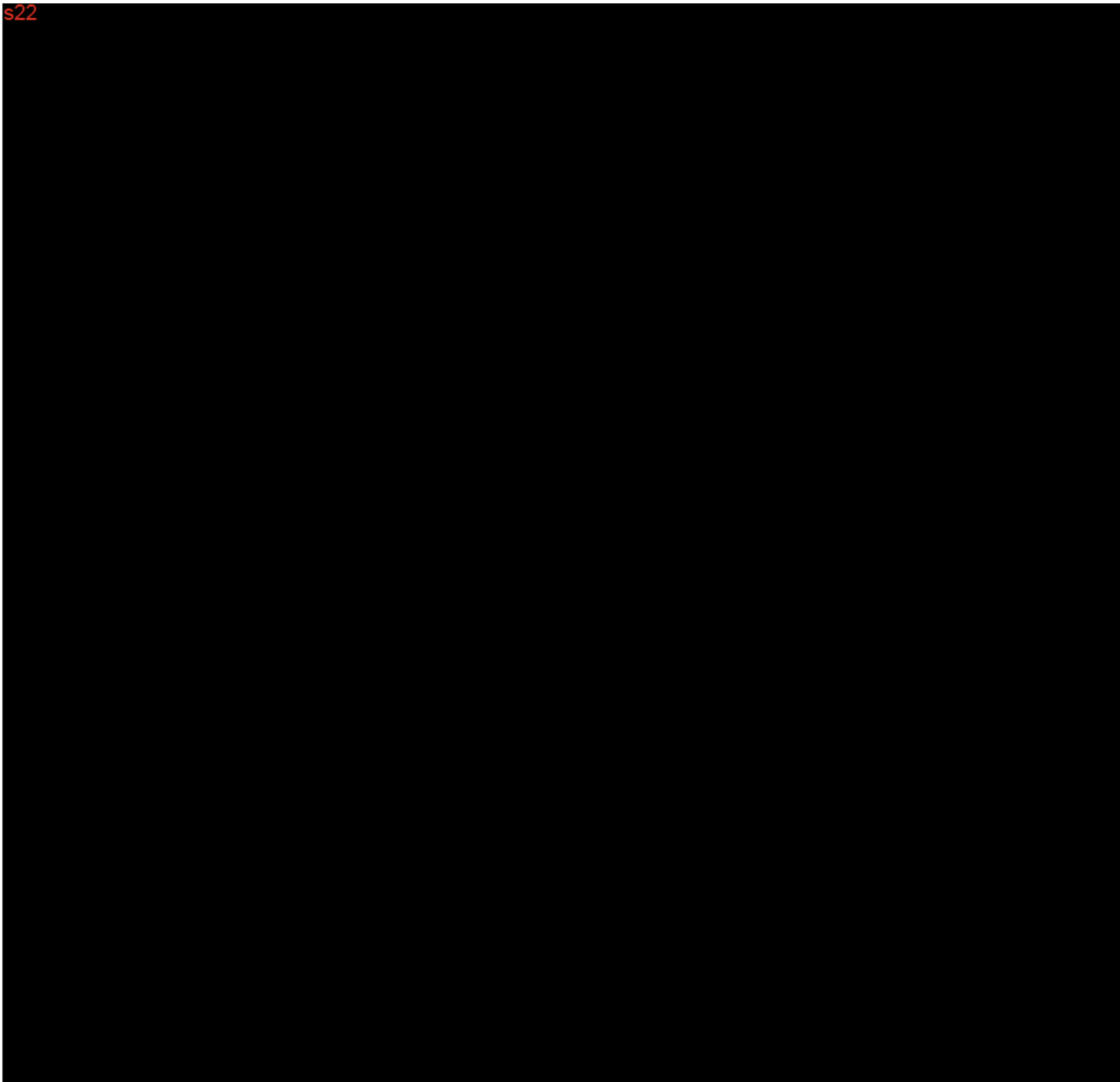






<b>TOPIC (if raised)</b>	<b>Intravenous fluids shortage</b>
<i>Responsible Deputy Secretary</i>	Professor Anthony Lawler

s22



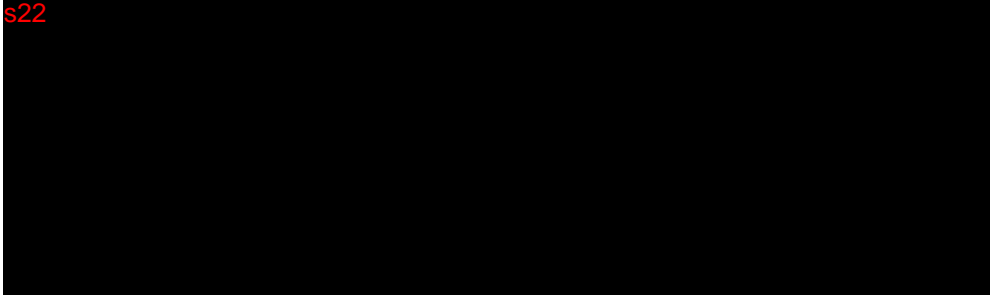
**Critical Background**

- s22
- [Redacted]
- The sponsors have noted global supply limitations, unexpected increases in demand, and manufacturing capacity constraints as the reasons for the shortages. Supply is expected to be constrained throughout 2024.
- s22
- [Redacted]





s22



**From:** Medical Device Supply Disruptions <MD.SupplyDisruptions@health.gov.au>

**Sent:** Friday, June 21, 2024 2:52 PM

**To:** s22 (Act.gov.au); s22 @act.gov.au; s22 @sa.gov.au; s22 @health.nsw.gov.au; s22 @act.gov.au; s22 @ths.tas.gov.au; s22 @act.gov.au; s22 @health.vic.gov.au; s22 @act.gov.au; s22 @health.tas.gov.au; s22 @act.gov.au; s22 @health.wa.gov.au; s22 @health.wa.gov.au; s22 @safetyandquality.gov.au; s22 @health.wa.gov.au; s22 @nt.gov.au; s22 @health.qld.gov.au; s22 @health.tas.gov.au; s22 @health.wa.gov.au; s22 @safercare.vic.gov.au; s22 @health.tas.gov.au; s22 @nt.gov.au; s22 @health.wa.gov.au; s22 @health.wa.gov.au; s22 @health.wa.gov.au; s22 @safetyandquality.gov.au; s22 @safetyandquality.gov.au; s22 @health.qld.gov.au; s22 @health.nsw.gov.au; s22 @health.tas.gov.au; s22 @healthsharevic.org.au; s22 @health.nsw.gov.au; s22 @health.wa.gov.au; s22 @health.qld.gov.au; s22 @health.nsw.gov.au; s22 @healthsharevic.org.au; s22 @act.gov.au; s22 @nt.gov.au; s22 @sa.gov.au; s22 @sa.gov.au; s22 @health.nsw.gov.au; s22 @health.qld.gov.au; s22 @ths.tas.gov.au; s22 @health.qld.gov.au

**Cc:** DUFFY, Tracey <Tracey.Duffy@health.gov.au>; NOJA, Marcelle <Marcelle.Noja@health.gov.au>; s22 @health.gov.au; s22 @Health.gov.au; s22 @health.gov.au; s22 @health.gov.au; s22 @Health.gov.au; s22 @Health.gov.au

**Subject:** Medical Device Supply Disruptions Update – 21 June 2024 [SEC=OFFICIAL]

Dear state and territory health representatives,  
 The TGA has received information in relation to supply disruptions of the 8 categories of products below. The TGA continues to actively monitor signals and information in relation to these products and provide the current situation report.  
 Pursuant to subsection 61(3) and 61(7) of the Therapeutic Goods Act 1989 (the Act):-

In relation to:

s22

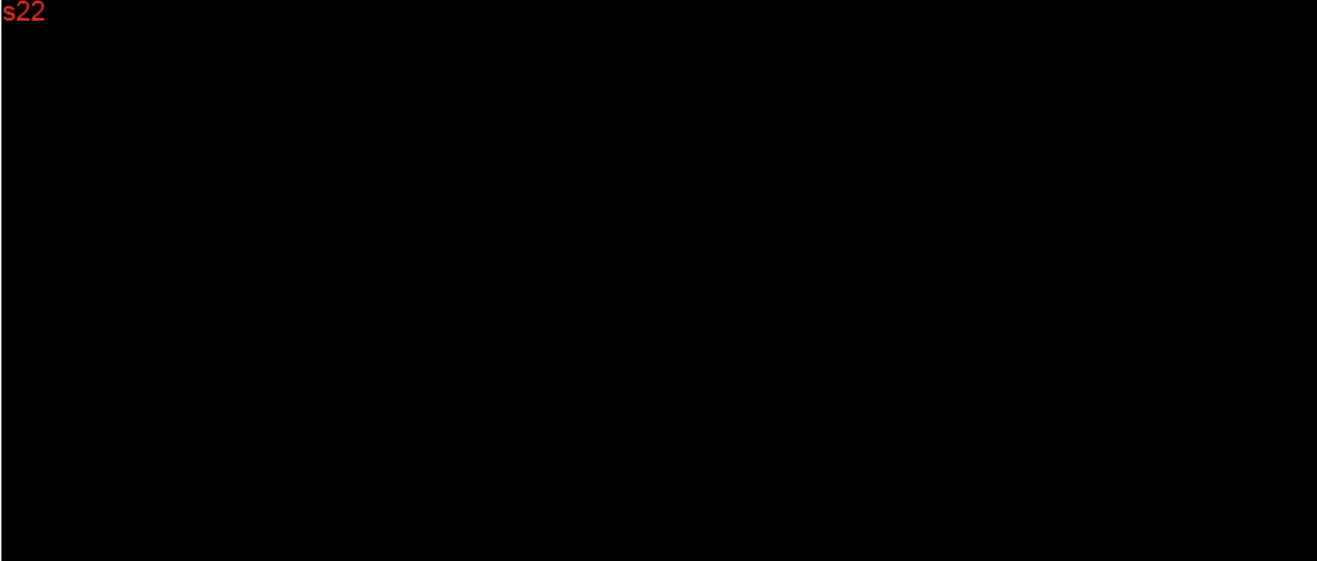
- Baxter Healthcare Pty Ltd IV Fluid Bag Shortage
- s22

s22





s22



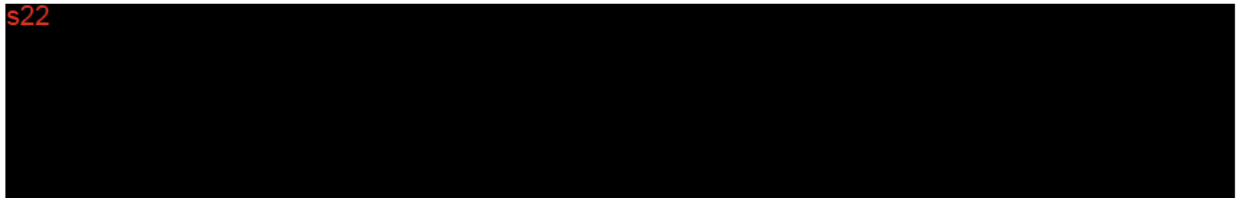
## Baxter Healthcare Pty Ltd IV Fluid Bag Shortage

s22

- s47G

s22

s22



Kind Regards,

s22

Medical Device Investigator

\_\_\_\_\_

Medical Device Supply Disruption Team | Device Post Market Monitoring | Medical Devices Surveillance Branch

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

Location: s22

Phone: s22

PO Box 100, Woden ACT 2606

[www.tga.gov.au](http://www.tga.gov.au)

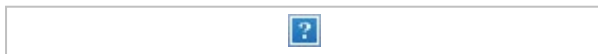
*The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.*

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*delete all copies of this transmission.*

Woden ACT 2606, Australia

[www.tga.gov.au](http://www.tga.gov.au)



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# Other Business | IV Fluid Shortage Update

16 August 2024

Document 12

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- Baxter reports their shortage has been attributed to a significant increase in demand over the last 18 months, with 70% of demand driven by hospitals. Baxter cannot cope with current demand – would need demand to return to 2022 level or have TGA approve manufacturing increase.

s22









## ISSUE: IV fluid shortages

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### Background on shortages and TGA actions


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- Sponsors of IV Sodium Chloride (saline) have noted global supply limitations, unexpected increases in demand, and manufacturing capacity constraints as the reasons for the shortages.

s22



- In Australia, the shortage of saline products has been ongoing since early 2023 but has recently worsened. This is in part due to:
  - s47G 
  - A delayed shipment for another supplier, Fresenius Kabi, has also contributed to the worsening shortages.
  - In addition, sponsors have reported a further increase in demand in recent months as jurisdictions began experiencing low stock levels.

s22









**MINUTE TO THE SECRETARY**

To: Blair Comley PSM

**SUBJECT****Purpose**

Provide advice on reported intravenous (IV) fluid shortages and the Department of Health and Aged Care's response to the issue.

s22

**Issues**


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2. Shortages of IV fluids from all 3 Australian suppliers (Baxter Healthcare, B.Braun, and Fresenius Kabi) have worsened and could interrupt selected hospital services in Australia. Supply is expected to be constrained throughout 2024.
3. Sponsors have noted global supply limitations, unexpected increases in demand, and manufacturing capacity constraints as the reasons for the shortages.

s22



6. In Australia, the shortage of IV Sodium Chloride (saline) products has been ongoing since early 2023 but has recently worsened. s47G
- 

s47G

The TGA issued approval for the US-registered products in May 2023 under section 19A of the *Therapeutic Goods Act 1989* (Act), and this stock has bolstered supply over the last 12 months. A delayed shipment for another supplier, Fresenius Kabi, has contributed to the worsening shortages. In addition, sponsors have reported a further increase in demand in recent months as jurisdictions began experiencing low stock levels.

s22







# s22

# s22



**From:** [KELLEHER, Brian](#)  
**To:** s22 [REDACTED]@toowongprivatehospital.com.au; s22 [REDACTED]; s22 [REDACTED]  
 s22 [REDACTED]@dayhospitalsaustralia.net.au  
**Cc:** [LANGHAM, Robyn](#)  
**Subject:** Advice from the Department of Health and Aged Care - Action to address shortage of intravenous (IV) fluids  
 [SEC=OFFICIAL]  
**Date:** Friday, 2 August 2024 4:05:16 PM  
**Attachments:** [image002.png](#)

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Good afternoon, s22 [REDACTED], s22 [REDACTED] and s22 [REDACTED]

Thanks for the opportunity to have a brief word earlier today.

As you are aware, there is currently a critical national shortage of intravenous (IV) fluids, due to supply disruption and demand and utilisation issues.

The Therapeutic Goods Administration (TGA), part of the Department of Health and Aged Care, is responding to mitigate the impact of this supply disruption through the application of its established processes in the management of medicines shortages. This includes through:

- the approval, under section 19A of the *Therapeutic Goods Act 1989*, of overseas-registered alternative saline products to increase current supply. Information on current section 19A approvals can be found [here](#).
- a prioritised and expedited approach to evaluating other section 19A applications, including those received from states and territories,
- convening and overseeing a Medicines Availability Working Group (MAWG), comprising senior state, territory and commonwealth representatives, that serves as a consultation and information sharing collaboration,
- regular interactions with sponsors to understand current or imminent developments with respect to product supply, and
- linkages with infrastructure to discuss and mitigate logistics impediments to supply, and

To support a coordinated approach to this issue, the Health Chief Executives Forum (HCEF) will establish a time-limited working group of clinical and operational leads in each state and territory, to:

- coordinate a national response to intravenous fluid utilisation,
- report to HCEF, and
- complement the TGA's supply mitigation activities.

Engagement with the private hospital sector will be undertaken through this group, to ensure that all sectors are informed and engaged as this situation evolves.

Further questions in relation to this issue should be directed to Professor Robyn Langham as the A/g Chief Medical Officer.

Yours sincerely

Brian

Brian Kelleher

Assistant Secretary

Private Hospitals Branch

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Australian Government Department of Health and Aged Care

T: s22 [REDACTED] | M: s22 [REDACTED] | E: [brian.kelleher@health.gov.au](mailto:brian.kelleher@health.gov.au)

Executive Assistant: s22 [REDACTED]

T: s22 [REDACTED] | E: s22 [REDACTED]@health.gov.au

**From:** [BEDFORD, Chris](#)  
**To:** [COMLEY, Blair](#); [LANGHAM, Robyn](#)  
**Cc:** [MARTIN, Nick](#); [EXELL, Blair](#); [s22](#); [HENDERSON, Nick](#)  
**Subject:** RE: IV URGENT [SEC=OFFICIAL]  
**Date:** Friday, 16 August 2024 3:02:02 PM  
**Attachments:** [image001.png](#)  
[image002.png](#)  
[image003.png](#)

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Hi Blair

We have discussed the number with [s22](#) [s22](#) said the figure is from Baxter and it is actually ordering volumes (up 50%) and used as a demand proxy. This does cover 85% of Australian supply, but is a single data point and not actual demand / use in Australia.

We have talked with Baxter. They are comfortable with the number 50% increase in demand for their IV fluid products since the middle of 2022. The data is derived from the top 8 products (bulk of supply).

[s22](#) (as [s22](#)) has advised the data is the first issue on the Response Groups agenda to address to support the understanding of the severity and duration of the shortage. Only the jurisdictions have access to the actual hospital demand data.

We pushed the supply data again...into double digits of requests. Nothing yet, but still committed for today.

Suggested TP for the Minister

- The current supply of intravenous (IV) fluids in Australia is being affected by a global supply limitations, unexpected increases in demand and manufacturing issues.
- I have been advised by our largest producer that demand for their 8 high volume products has increased 50% over a two year period.
- A cross-jurisdictional Response Group convened by all states and territories and the Commonwealth has been established to address the shortage.
- This Response Group will continue to meet on a weekly basis, or more frequently if required, while supply remains constrained in Australia.

Let us know if you need more.

Cheers, Chris

**Chris Bedford**

---

Acting Deputy Secretary

Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: [s22](#) | M: [s22](#) | E: [chris.bedford@health.gov.au](mailto:chris.bedford@health.gov.au)

Location: Gulgana Building, Fairbairn, Canberra

GPO Box 9848, Canberra ACT 2601, Australia

**Executive Assistant** | [s22](#)

T: [s22](#) | E: [s22](#)@health.gov.au

**Executive Officer** | [s22](#)

T: [s22](#) | E: [s22](#)@health.gov.au

*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.*









12<sup>th</sup> August 2024

Health Minister's Letter

Email:

Dear Minister,

I am writing to you today on behalf of Baxter Healthcare, to provide an update on our ongoing supply of intravenous (IV) and irrigation fluids in Australia and highlight the actions Baxter is taking to manage the current heightened demand for these critical products.

As the only medical manufacturer of Australian Made intravenous (IV) medical fluids, Baxter is experiencing heightened demand for sterile fluid products in Australia

Baxter is manufacturing these products above historical volumes and at full capacity at our advanced manufacturing plant in Old Toongabbie, New South Wales.

I would like to clarify that Baxter has not experienced any manufacturing issues in its supply of sterile medical fluids.

Patient care remains our top priority. We are acting expeditiously to support all customers, prioritising supply continuity for public and private hospitals based on urgent need.

We are also pursuing several actions to further increase supply volumes. These actions include securing additional units from our extensive global supply chain network and investing in additional local manufacturing capacity expansion efforts, some of which are in operation, and others anticipated to come online later this year.

Baxter is working with regulatory bodies, state procurement departments and private hospital groups to help facilitate their chosen priority and delivery matrix to ensure hospitals get the supply they need.

For 50 years, Baxter's locally manufactured products and services have supported hospitals and improved outcomes for patients across Australia

Our medical manufacturing facility in Toongabbie produces more than 250 types of intravenous medicines, as well as dialysis fluids for patients on peritoneal dialysis, and bottles of sterile fluids used in surgery and sterilisation.

Importantly, Baxter IV fluids are subject to the highest standards of quality and compliance checks as set out by the Therapeutic Goods Administration (TGA).

To see first-hand the work we do to support the Australian health system, I would like to personally invite you to visit our manufacturing facility in Toongabbie, New South Wales.

If this is something you would interested in, please contact **s22** and **s22** ([@Baxter.com](mailto:s22@Baxter.com)) and we would work with your schedule to find a suitable date.

We thank you for your support and for partnering with us to meet the needs of the national healthcare system.

Yours Sincerely

**s22**

**s22**

**s22**

Baxter Healthcare

M: **s22**

**s22** ([@baxter.com](mailto:s22@baxter.com))

1800 BAXTER (1800 229 837)

Confidential - template letter sent to health ministers