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Medicines Regulation and TGA
QB24-000169**ISSUE: IV fluid shortages****QUESTION: How is the shortage of IV fluids being managed?**

Topline response: The TGA is working with states and territories, private hospitals, sponsors and stakeholders to monitor the situation, and has instigated management strategies to minimise patient impact.

- States and territories coordinate use and supply of IV fluids within their jurisdictions.
- Jurisdictions, the Commonwealth and other professional bodies have initiated (commencing Monday 12 August 2024) a National IV fluid Response Group consisting of state and territory Health representatives, private hospitals, the AMA and the Australian and New Zealand College of Anaesthetists (ANCPA) to work collaboratively on IV fluid supply issues and to coordinate a national response. The Response Group has taken immediate steps to address the shortages by agreeing to:
 - Broad understanding that coordination and management of the issues surrounding supply and demand of IV fluids is a responsibility of the jurisdictions, and not the Commonwealth.
 - Partnering across governments and private hospitals to work with manufacturers and distributors to help address supply issues.
 - Sharing demand and supply data to enable accurate modelling across jurisdictions. This includes ensuring that producers and suppliers of IV fluids in Australia are providing data on current supply and production forecasts, to better understand the severity and duration of the shortage.
 - Agreement to work together to create consistent messaging across all jurisdictions to support appropriate usage while supply remains constrained.
- Outcomes from IV fluid response group meeting held on Monday 19 August 2024 are:
 - Agreement to release regular communique after weekly meeting.
 - Creating a repository of clinical guidance for conservation strategies, in collaboration with the Australian Commission on Safety and Quality in Health Care (ACSQHC) and the ANZCA.
 - Major IV fluid sponsor will work with jurisdictions to collect and analyse demand data against supply data to optimise production and manage ordering of products.
- As an outcome of the Health Ministers Meeting (HMM) on Friday 16 August 2024, Health Ministers released a joint statement on IV fluid shortages. The

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statement outlines steps being taken to address supply in Australia by the National IV fluid Response Group, as well as reassurance to the Australian public that health services are continuing.

- The AMA issued a media statement on 20 August outlining the positive coordination efforts and action taken by the IV Fluid Response Group, as well as providing reassurance that patients will continue to be able to access care across the health sector (attachment A).
- The IV Fluid Response Group and the TGA are engaging directly with private hospitals to request data on their supply needs, provide support and share clinical guidance to ensure consistent messaging.
- The Australian Private Hospital Association support the actions that are being taken by the Commonwealth and the IV Fluid Response Group to manage the shortage.
- The Government cannot compel sponsors to increase manufacturing or supply medicines in Australia. However, the TGA monitors and mitigates medicine supply issues, and has approved several alternative supplies from overseas, under s19A of the *Therapeutic Goods Act 1989*, to supplement the local production and supply of other registered products.
- To ease demand, the Government has secured supply of over 22 million IV fluid bags over the next 6 months, both locally produced and imported. This supply volume exceeds the forecast demand over this period.
- The TGA is aware that jurisdictions are alerting staff of the shortages and instructing all staff to use IV stock judiciously.
 - Decisions on service prioritisation (elective vs emergency utilisation), rural vs urban distribution, and geographic distribution of available IV fluid stock are all matters managed at the state and territory level.
- The TGA is also asking IV fluid suppliers (Australian sponsors and s19A sponsors) if they need assistance in addressing any delays in shipping and unloading containers at docks and if needed will work with the Office of Supply Chain Resilience in the Department of Industry, Science and Resources to prioritise supplies at Australian docks.

Background on shortages and TGA actions

- IV fluids are critical hospital medicines used in routine and critical care settings, as fluid replacement, for resuscitation, and to administer other IV medicines.
- 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.

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- The TGA is aware that supply of some IV fluids is also constrained in other countries (e.g. USA and Canada).
- Supply is expected to be constrained throughout 2024.
- Update from TGA’s Medicines Availability Working Group (MAWG) on 20 August 2024:
 - Stock on hand has improved across jurisdictions over last two weeks, with some states and territories in a better position than others.
 - Jurisdictions experiencing lower stock levels include QLD and VIC. Both states noted the lack of centralised distribution methods were making the situation harder to identify the issues and manage, with both states actively developing a centralised system.
- In Australia, the shortage of saline products has been ongoing since April 2023. The TGA has been working closely with jurisdictions and sponsors over this time to mitigate impacts. However, the situation has recently worsened. This is in part due to:
 - Sponsor’s experiencing delays in procurement and shipments of overseas saline products.
 - In addition, sponsors have reported a further increase in demand in recent months as jurisdictions began experiencing low stock levels.
- The TGA has taken the following immediate actions:
 - Approval of multiple overseas-registered alternative saline fluids under s19A of the Act. The first approval was issued in April 2023, with a total of 13 approved applications covering multiple volumes. The TGA continues to prioritise the evaluation of additional applications. Current approvals and date of issue are as follows:

Dates for TGA’s section 19A approvals
April 2023 <ul style="list-style-type: none"> ● 20 April 2023 (this was the initial approval for Baxter overseas product, which lapsed as approvals are time limited. Replaced by another approval in April 2024).
April 2024 <ul style="list-style-type: none"> ● 29 April 2024
May 2024 <ul style="list-style-type: none"> ● 24 May 2024
July 2024 Please note some approvals cover multiple products (i.e. different volumes) <ul style="list-style-type: none"> ● 16 July ● 22 July

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- 23 July
- 26 July

August 2024

Please note some approvals cover multiple products (i.e. different volumes)

- 1 August (2 approvals)
- 2 August
- 6 August (yet to be published on public TGA database)
- 15 August (yet to be published on public TGA database)
- 20 August (yet to be published on public TGA database. Approval was requested by NSW)

- Asking IV fluid suppliers (Australian sponsors and s19A sponsors) if they need assistance in addressing any delays in shipping and unloading containers at docks. If assistance is requested, the TGA will work with the Office of Supply Chain Resilience in the Department of Industry, Science and Resources (DISR) to unlock existing IV fluid supplies at Australian docks.
- Asking sponsors of Australian registered IV fluid products if any regulatory actions could assist with increasing supply such as consideration of additional manufacturing sites for Australian sponsors. Sponsors have been notified that any submissions made to the TGA will be expedited.
- Increasing national coordination on monitoring of supply for this shortage through the Medicines Availability Working Group (MAWG).
- Publishing a web statement with information about the shortages and overseas registered alternatives approved under section 19A.
- The TGA is undertaking supply modelling using data obtained from suppliers and state and territory health departments, and one private hospital, to understand gaps in future supply and assist sponsors to forecast future supply appropriately, to meet required demand.
- Saline products are not 'reportable medicines' under the TGA's medicine shortages framework, and sponsors are not required to notify the TGA of supply issues. However, due to these products' criticality, the TGA has been working closely with stakeholders on issues relating to supply.
- Pharmaceutical companies are private entities that make their own commercial decisions regarding their products, and cannot be compelled by the Commonwealth to register, manufacture, or supply a product in Australia.
- Baxter is the major supplier of saline products in Australia and manufactures most of their supply in Australia. They have advised the TGA that they are

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working to expand domestic manufacture in 2024. Baxter are also supplying overseas registered products as an interim measure.

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Medicines Regulation and TGA
QB24-000169**MEDIA COVERAGE****Attachment A**

'AMA Media release – Call for calm on IV shortages'

Publication: AMA Media Release**Publication date:** 20 August 2024**Attachment B**

'IV crisis: morphine now low'

Publication: The Australian**Publication date:** 19 August 2024**Attachment C**

'Feds knew about IV fluid shortage a year ago: Ruston'

Publication: Medical Republic**Publication date:** 19 August 2024**Attachment D**

'Intravenous fluid shortage sparks 10-fold jump in costs'

Publication: The Australian**Publication date:** 16 August 2024**Attachment E**

'IV scandal: Excuses are fluid'

Publication: The Australian**Publication date:** 16 August 2024**Attachment F**

'2CC Breakfast Radio interview – Steve Robson on IV Fluid Shortages'

Publication: 2CC Radio transcript**Publication Date:** 19 August 2024**Attachment G**

'Health Minister Health Ministers Meeting (HMM): Joint Statement on IV Fluids 16 August 2024 – Sydney'

Publication: HMM Communiques**Publication date:** 16 August 2024

Date last updated by Dept:	20 August 2024	Cleared by Adviser/date:	20 August 2024
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MEDIA RELEASE

Tuesday, 20 Tuesday, 20 August 2024

AMA reassured by coordinated response to IV fluid shortages

The federal, state and territory government recent response and coordination efforts on IV fluid shortages provides growing reassurance that patients will continue to be able to access care across the health sector, the Australian Medical Association said today.

AMA President Professor Steve Robson said media reports on the issue had caused concerns among patients and providers, however coordination efforts by governments meant steps were being taken to address the issue.

"As a surgeon who works in both public and private hospitals, I know all too well how critical IV fluid is to providing high quality, timely care," Professor Robson said.

"The AMA was quick to engage with governments when this issue first came to light and has been reassured by how seriously our concerns have been taken.

"The cross-jurisdictional response group established by Minister for Health and Aged Care Mark Butler is meeting frequently to share data; co-ordinate action on IV fluid usage and supply; establish forecasts for future needs; discuss logistics and issue clinical guidance and updates to our front-line healthcare workers.

"This effort should be comforting for Australian patients, no matter where they live, or where they are being treated."

Professor Robson said most IV fluids used in Australia are produced locally and the AMA had been advised that the local producer was continuing to operate at full capacity — working to meet the regular demand in orders from public and private hospitals.

"Responsible and measured steps are being taken to conserve supply when necessary and we are now seeing real coordination of efforts to ensure that we not only have enough supply, but it also gets to where it is needed.

"We also recognise that some practices, including general practices, might be facing short term disruptions. I want to assure those practices that governments are working to address these disruptions quickly."

"The AMA will continue to monitor the situation closely and provide feedback through the cross jurisdictional working group that we are part of — ensuring that clinician feedback continues to inform decisions being taken at the highest levels."

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**HEALTH****EXCLUSIVE**

IV crisis as morphine supplies are now low

By STEPHEN RICE and NATASHA ROBINSON

19 minutes ago

 0 Comments

Supplies of several crucial medicines are running short around the nation, including morphine products vital to ease the suffering of palliative care patients, as some medical specialists reject claims by the nation's health ministers that the shortage of IV fluids – which has thrown hospitals into chaos – is easing.

The IV fluids crisis has exposed major supply shortages in other critical areas of medical practice, including palliative care, where a lack of oral liquid morphine is causing distress to some patients, particularly for children who cannot swallow tablets.

The Australian has obtained correspondence showing Health Minister Mark Butler was warned nine months ago that palliative care patients were in danger of losing access to vital opioid analgesic medicines, particularly liquid morphine, but it appears no effective action was taken.

Australian & New Zealand Society for Palliative Medicine CEO Joe Hooper says the shortage is a “government policy failure which has hit us hard in that patients at the end of their life cannot access vital liquid-based morphine medications to relieve pain”.

Mr Hooper said Mr Butler had “flicked it off to various departments and we got a response via the TGA (Therapeutic Goods Administration) which wasn't exactly a call to arms or an action list”.

Other countries such as the UK had no issues of supply of the drugs, Mr Hooper said. ^{Document 1}

“The current government is failing because, first, we have no manufacturing and second, you’re relying on sponsors – the drug companies – to apply for approvals,” he said. “The government is telling us it’s really at the behest of the commercial interests to decide which medicines are available to the Australian public. So there’s a flaw in the process.”

ANZSPM president Michelle Gold said: “Oral liquid morphine is such a basic medication for pain management in palliative care, especially for children and other people who can’t swallow tablets.

“It’s flexible, it’s safe, it’s basic pain relief and not to have access to it, in 2024, is just extraordinary.”

In October last year manufacturer Mundipharma announced it intended to remove its Ordine morphine oral liquid and other products from Australia, even though the company knew it was likely to discontinue the product up to three years before.

“Despite the company making us aware of it six months ago, there is not a reliable, consistent supply of a PBS-subsidised product currently available”, said Dr Gold, who is also director of palliative medicine at the Alfred Hospital in Melbourne.

“These are people who are frail or who are in pain and they don’t need to be going backwards and forwards to different pharmacies and different hospitals.

“Parents of a child who is dying are often giving these things through feeding tubes which you can’t do as easily with the tablets, and with the liquid version you can finetune a very tiny dose for a very tiny patient.”

The ANZSPM wrote to Mr Butler in November 2023, warning that discontinuation of vital opioid medicines – often with little notice – and sustained shortages would cause great distress to patients at the end of life.

“This is a serious risk for all Australians requiring quality pain management, including those receiving palliative care,” ANZSPM’s then-president Christine Mott wrote in a letter asking Mr Butler to take urgent action to ensure opioid supply and access.

“We now regard (the shortages) as a looming crisis for palliative care patients of all ages as well as those with chronic pain, cancer and other conditions requiring effective pain control.”

Morphine oral liquid is an extremely critical medicine in Australia for management of severe pain in adults and children, and a range of products is needed to take into account an individual patient’s ability to swallow, need to use feeding tubes, kidney or liver issues, and how they respond to one medicine over another.

“Some palliative care patients are already using the only opioid analgesic medicine they can tolerate,” Dr Mott said.

The present minimum reporting period for the pharmaceutical industry to inform the market of medication discontinuation is six months. That should be extended to at least 12 months for opioid analgesic medicines, Dr Mott recommended, and the process for TGA registration reviewed to ensure a fast-track pathway for critical medicines.

A TGA spokesman said it was working to manage and improve supply of the medicines as a priority. To facilitate ongoing access to oral morphine products, the TGA had approved access to several alternative overseas-registered medicines, some of which were included on the PBS.

“The TGA is also continuing to investigate the registration and/or supply of new Australian products,” the spokesman said.

“Medicine sponsors are private businesses and make their own decisions regarding if and how to market a product in Australia.”

Meanwhile, some anaesthetists and obstetricians have hit out at the claim made by federal and state health ministers after a joint meeting on Friday that shortages of IV fluid bags “while easing, are expected to continue through 2024”, saying they had seen no sign of improvement.

Australian Society of Anaesthetists president Mark Sinclair said: “We’re not seeing that yet at the coalface, all we’re hearing from our hospitals who supply this is: be judicious please, be careful please. We haven’t seen any change in that directive.

“We’re not hearing from the hospitals that it’s OK, we’re certainly not hearing that.”

IV fluids were particularly vital for anaesthetists in certain emergency situations, Dr Sinclair said, such as an anaphylactic reaction to anaesthesia drugs. “You might need a very large amount of IV fluids as part of the management of that sort of life-threatening scenario, so it’s a critical component that, until this year, we’ve never had to really think about.”

Some anaesthetists in private hospitals have already faced a choice between cancelling procedures because of lack of IV fluid or going ahead but knowing that patients will come out of the surgery “feeling like crap” because they didn’t get IV fluids.

Patients often go into surgery already dehydrated from fasting or because they’ve taken preparations, and rehydrating them during anaesthesia can help them feel better afterwards.

“It’s a difficult decision I have to make every day now when I go to work”, said one anaesthetist, who said he did 10 procedures in a private hospital last week but could not use IV fluids on any of them because of the need to quarantine supplies for bigger and more urgent cases.

“What is the point of having all these desk jockeys sitting in airconditioned offices in the various departments of health or TGA, when they can’t predict or prevent

something like this occurring?” he said. “The current federal Health Minister’s ^{Document 1} position is untenable, given he has let this occur on his watch. This is a public health policy failure on a much grander scale than anything that happened during the Covid-19 pandemic.”

The situation with the IV fluid shortage varies across the country. Some hospitals have sufficient supply, and patients who need IV fluids are being prioritised.

However, National Association of Specialist Obstetricians and Gynaecologists president Gino Pecoraro said on Monday that the situation in private maternity wards was still critical.

“An easing of the shortage is not at all what I am seeing,” said Dr Pecoraro, an obstetrician who works across private hospitals in Queensland. “The government’s representation that the shortage is easing is absolutely contrary to what I’m seeing and hearing.

“I’ve just finished a small operating list this morning, and the anaesthetist tells me it is far from over, that there are cases that are being cancelled, and I’ve heard around the country that there are people who have had their inductions of labour cancelled.”

Inductions were now being done according to prioritisation of need, but by delaying inductions the small amount of risk to the baby may increase depending on circumstances, Dr Pecoraro said.

“If something unexpected happens, which is the nature of obstetrics, then you can’t guarantee that there won’t be an adverse outcome,” he said.

“This IV fluid shortage is just a symptom of how bad our mismanagement of health is. They’re still trying to say that it’s a worldwide issue, and it isn’t a worldwide issue. It’s a lack of proper planning. It’s just horrific. I can tell you, the feeling and the morale in operating theatres today is just awful.”



19 AUGUST 2024

FEDS KNEW ABOUT IV FLUID SHORTAGE A YEAR AGO: RUSTON

3 MINUTE READ

POLITICAL SHORTAGES



By

CATE SWANNELL



But the health ministers' joint statement was all about monitoring and reassurance with not much detail on how the crisis is being addressed.

THE FEDERAL GOVERNMENT KNEW A YEAR AGO THAT A SHORTAGE OF IV FLUID WAS A POSSIBILITY, ACCORDING TO OPPOSITION HEALTH SPOKESPERSON SENATOR ANNE RUSTON, AS FRIDAY'S HEALTH MINISTERS' MEETING PROMISED CONTINUE MONITORING THE SITUATION.

Senator Ruston released a statement on Friday claiming that Finance Minister Katy Gallagher had admitted that the Albanese Government became aware of the impending shortage more than a year ago.

“There are serious and immediate questions to be answered by our health ministers, including why it has taken so long to act and how significant the impact is going to be for our hospitals,” said Senator Ruston.

According to The Australian, the country's only onshore IV fluid manufacturer, US firm Baxter Healthcare, has a factory in western Sydney, and is continuing to supply New Zealand with adequate stocks.

“It was outrageous to hear Minister Gallagher admit that the government has been aware of an impending shortage since May 2023,” Senator Ruston told the paper.

“We are now in August 2024 and a ‘monitoring group’ was only set up just over a week ago. We are beyond monitoring. We need action and leadership.”

Senator Ruston said Health Minister Mark Butler “must immediately stand up and assure Australians that their federal government is guaranteeing our supply of these critical fluids”.

“We need an urgent and nationally coordinated response to the shortage of IV fluids to ensure no Australian patient is harmed by this national crisis,” she said.

Friday’s Health Ministers’ meeting in Sydney referenced the formation of the “cross-jurisdictional response group” to deal with the ongoing shortage of IV fluids.

In a joint statement released late on Friday, the health ministers said the response group would “continue to meet on a weekly basis, or more frequently if required, while supply remains constrained in Australia”.

The group is made up of all states and territories, the Commonwealth and a broader representation from private hospitals and primary care.

Steps had already been taken, said the health ministers, to address supply and distribution issues, including:

- Sharing data across jurisdictions on usage and supply, and ensuring that producers and suppliers of IV fluids in Australia are providing data on their current supply and production forecasts, to better understand the severity and duration of the shortage;

- Ensuring there is a coordinated national approach to distribution across the jurisdictional supply chains;
- Partnering across government to work with manufacturers and distributors to help them address supply issues; and
- Agreeing consistent messaging across all jurisdictions to support appropriate usage while supply remains constrained.

“Ministers reiterated that the response group will continue to identify additional procurement opportunities while supply remains constrained,” said the joint statement.

“The response group was directed by Ministers to consider options to maintain supply of IV fluids within Australia.”

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PALLIATIVE CARE PATIENTS ‘DESERVE BETTER’ THAN SHORTAGES



ORAL MORPHINE S PAIN FOR PATIENTS

A spokesperson for DoHAC told the Australian that IV fluids were a state responsibility.

“States and territories coordinate use and supply of IV fluids within their jurisdictions,” she told the newspaper.

“The current supply of IV fluids in Australia is being affected by a global supply limitation, unexpected increases in demand and manufacturing issues.

“The Therapeutic Goods Administration actively monitors the supply of important medicines in Australia. While it is not the role of the TGA to coordinate the supply of medicines, the TGA works with pharmaceutical companies, peak bodies and other stakeholders to minimise the effects of shortages on consumers and health professionals.”

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HEALTH

EXCLUSIVE

Intravenous fluid shortage sparks 10-fold jump in costs

By STEPHEN RICE and NATASHA ROBINSON

8:22pm August 16, 2024

[307 Comments](#)

Healthcare providers are paying from five to 10 times as much for imported IV fluid bags as they were prior to the shortage that is now causing chaos in hospitals, as medicos call on the federal government to incentivise a local manufacturing industry for critical medical supplies.

On Friday, the nation's health ministers promised a recently formed emergency Response Group would bring "unprecedented collaboration" to the crisis, as the medicine regulator came under fire for failing to avert the catastrophic shortage of IV fluid bags. Health ministers meeting in Sydney on Friday said the shortages, "while easing, are expected to continue through the rest of this year".

The shortage is placing enormous stress on hospitals, as doctors are forced to severely ration intravenous fluid, reserving it for critically ill patients, postpone inductions of labour, and deliver medications by alternative injection methods.

Alarm over the shortage of IV fluids comes as a global shortage of crucial blood culture bottles in WA has forced authorities to approve use of the bottles up to two months past their expiry date.

"It might not be as profitable for a company to manufacture medical supplies in Australia but Australia does need to have a guaranteed access to a core set of supplies and that might mean incentivising manufacturing onshore," said chair of Royal Australian College of General Practitioners' expert committee for quality care, Mark Morgan.

. Document 1

“Australia needs the capacity to manufacture essentials onshore, even if this means using taxpayers’ money to build incentives. Australia should take a disaster planning approach to essential supplies.”

Professor Morgan, who is also professor of general practice at Bond University, added: “A planned, responsive, staged alerting system for supplies that might become shortages, and then do become shortages, I think a lot can be learnt from the disaster planning we have in this country and the same should happen for medical supplies.”

AMA president Steve Robson called for some form of national medical inventory, with a continuous monitoring of stocks of medical supplies.

“This is something previous governments should have done, and they’ve left the current government in a really bad spot – we need some form of national inventory of what really are critical medical supplies.

“We should know what our requirements are, where we’re getting them from and how secure those supply lines are. At the moment with IV fluids, there’s no national oversight.

“If there’s a good case for stockpiling or building greater sovereign manufacturing here I think that would be really good. It absolutely is time there needs to be an evaluation and this has been let slide by the previous government. The one thing I’d encourage the current government to do is to review that and make sure that we have mechanisms going forward to keep an eye on these critical things and have plans.”

The Therapeutic Goods Administration claims its role is around regulation and safety of products and not necessarily ensuring adequate supply, in the face of criticism that the crisis is “the ultimate example of poor procurement policy”.

But Nick Coatsworth, representing the Australian Patients Association, said the role of the TGA was “absolutely to monitor supply of essential medicines”, pointing out that the federal Health Minister oversees the TGA. The states contract individually with companies for saline supplies for the hospitals.

Document 1
“Australian patients expect both regulator and minister to be constantly vigilant to keep them safe, and in the case of the IV fluid shortage that is coming perilously close to not being the case,” Dr Coatsworth said.

One senior doctor who played a high-level role during the Covid-19 pandemic said: “The issue of our lack of local manufacturing was identified during the pandemic but appears to have been forgotten quickly. Pressure on the government to take more action to promote drug and medical device manufacturing industries (or even minimum stockpiles) in Australia would be helpful.”

A critical shortage of blood culture collection bottles that is expected to last until the end of September is affecting public and private healthcare providers.

In WA authorities have approved the use of blood culture bottles for up to two months after the expiry date in order to manage the reduced supply. The product is used to culture bacteria from a patient’s blood.

“While we are maintaining sufficient supplies to meet demand throughout WA, we are aware that some clinical teams, particularly in remote areas, may have blood culture bottles at or near their expiry date”, a notice from PathWest Laboratory Medicine CEO Narelle Hadlow said. “We are taking all necessary steps to address the issue.”

Australian Clinical Labs advised in July it had taken “steps to review and rationalise blood culture stock levels and mitigate wastage to ensure that we can continue to provide this critical service”.

Founder of chemotherapy at home service ViewHealth, Julie Adams, said that along with the devastating effect on patient care, there were cost issues that would severely impact the private health sector. “The cost of the imported saline is upwards of six times the previous cost,” said Ms Adams, who has worked in oncology and haematology for 25 years. “A bag which cost \$2.50 is now \$13-\$14. We use thousands of these bags. This is going to drive health to the wall. We haven’t recovered from all the additional costs of managing Covid ... now this.”

Two senior Queensland Health bureaucrats also confirmed prices for IV alternative products that are being hurriedly imported are between five and 10 times what

Australia was paying previously.

Local manufacturer Baxter Health Care had been ramping up production after importers struggled to deliver supplies due to shipping route interruptions but there was no certainty the company would be able to meet demand, Ms Adams said. “It’s a bloody mess,” she said.

State governments each have contracts for the supply of saline fluids, and Baxter Health Care manufactures about 75 per cent of the market’s products onshore, with overseas suppliers B. Braun and Fresenius Kabi supplying the rest. Baxter also exports to New Zealand, with product manufactured in its western Sydney plant. New Zealand’s medicines regulator, Pharmac, says it is not currently experiencing supply issues.

Queensland is faring better than some other states because it sources much of its supply of IV fluids from Baxter and because its Central Pharmacy agency plays a major role in co-ordinating supplies. It also keeps a contingency stockpile, which NSW does not.

Nevertheless, three major Brisbane teaching hospitals that perform the most critical surgery have been in the extraordinary situation of having between 24 and 48 hours’ of the vital IV fluids in their emergency stores in the past fortnight. The Australian understands that those hospitals are the Princess Alexandra, the Royal Brisbane and the Prince Charles.

NSW has also now centralised management of supply. NSW Health Minister Ryan Park said the shortages were not yet impacting surgery, but “we’re not out of the woods”.

The national cross-jurisdictional Response Group, convened by all states and territories and the commonwealth, will include representation from private hospitals and primary care, the health ministers said on Friday. The group will continue to meet on a weekly basis, or more frequently if required, while supply remains constrained in Australia. The Response Group has taken steps to address supply and distribution issues by sharing data; ensuring a co-ordinated national approach to distribution; and working with manufacturers and distributors to address supply issues.

MORE ON THIS STORY



Intravenous scandal escalates: the excuses are fluid

By NATASHA ROBINSON, JOANNA PANAGOPOULOS



The IV fluids crisis should not occur in a First World nation like ours

By EDITORIAL



16 AUG, 2024

IV scandal: excuses are fluid

The Australian, Australia

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■ TGA'S 'GLOBAL SHORTAGE' CLAIM REFUTED ■ BOTCHED PROCUREMENT ACCUSATION ■ SYDNEY FACTORY SUPPLYING NZ

IV scandal: excuses are fluid

EXCLUSIVE

NATASHA ROBINSON
JOANNA PANAGOPOULOS

A shortage of intravenous IV fluid bags that is causing chaos in Australian hospitals is being dubbed “the ultimate example of poor procurement policy”, as the medicine regulator’s claims of a widespread global shortage is contradicted by health authorities around the world.

Australia’s only onshore IV fluid manufacturer, which has a factory in western Sydney, is still

supplying adequate stock to New Zealand, as medics and pharma insiders say they are “mystified” as to why Australia appears to be the only country significantly impacted by what regulators say is a global shortage.

The pharmaceuticals director for New Zealand’s drug-purchasing agency Pharmac said there were “currently no issues with supply of IV fluids for New Zealand and stock is available at wholesalers” while the US Food and Drug Administration only records a shortage of a particular size of saline product.

The Therapeutic Goods Administration is insisting that there is a global shortage of IV fluids such as saline “due to glo-

bal supply limitations, unexpected increases in demand and manu-

facturing capacity constraints”.

Three major teaching hospitals that perform the most critical surgery have been in the extraordinary situation of having only

24 hours of the vital IV fluids in their emergency stores in the past fortnight, and a major Sydney hospital has warned staff that patients who had minimal IV fluid during

surgery should be monitored longer for hypotension and dehydration. There is also mass rationing by hospitals across Australia as disaster-mitigation strategies are implemented.

Amid growing questions over the transparency of the response to the crisis, it has emerged that Australia is the only country experiencing a major supply shortage of IV fluid, other than Taiwan, whose major manufacturer was forced to halt production over numerous violations.

The commonwealth now faces questions over why it apparently lacks contingencies to guarantee

patients are not at risk from supply

interruptions. The Therapeutic Goods Administration issued a national alert on July 25 when the supply crisis escalated to an emergency across virtually every hospital in the country as doctors were forced to scramble to retrieve half-used saline bags from ambulances. Queensland had established a critical response working group for the shortage on May 7.

The national medicines regulator has been managing the issue, which recently worsened, for the past 18 months but no shortages have been publicly reported in that time because saline fluids are not a

reportable medicine under commonwealth therapeutic goods legislation.

Pharmaceutical industry insiders say they are baffled by the TGA’s explanation of the crisis which they blamed on the lack of a functional national procurement policy. “There are no global shortages, only in Australia,” said one industry insider with high-level knowledge of saline fluid contracting in Australia.

State governments each have contracts for the supply of saline

Continued on Page 2



16 AUG, 2024

IV scandal: excuses are fluid

The Australian, Australia

Intravenous scandal: the excuses are fluid

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fluids, and Baxter Health Care manufactures about 75 per cent of the market's products onshore, with overseas suppliers B. Braun and Fresenius Kabi supplying the rest.

New Zealand has a virtual exclusive contract to supply the whole of its nation's saline fluids with Baxter, and the drip bags are all manufactured in Baxter's Sydney manufacturing plant.

Pharmac's director of pharmaceuticals, Geraldine MacGibbon, told The Australian it had no supply issues and stock was available at wholesalers.

"To make sure New Zealand does not experience similar issues we are meeting with Baxter and Health New Zealand regularly to monitor New Zealand's ongoing supply," Ms MacGibbon said. "If we expect a supply issue will have an impact on people, we will take steps to resolve the issue as quickly as possible and keep the health sector informed."

Pharmac said its contractual agreements required suppliers to keep a certain amount of stock in the country. It is understood stiff penalty clauses are also built into the NZ government's contracts with Baxter, which mitigate against the company failing to

supply saline products.

That is possible because of the exclusive bargaining – a situation that existed in Australia in the past but was changed after a court challenge by the competition regulator which successfully pursued Baxter for cartel behaviour.

The Food and Drug Administration in the US told The Australian it had no major supply issues in relation to IV fluids, apart from certain sizes of bags.

"The public should rest assured the FDA is working closely with numerous manufacturers and others in the supply chain to understand, mitigate and prevent

or reduce the impact of intermittent or reduced availability of certain products," an FDA spokesperson said.

Medics in the UK reported minor issues with supply of saline products in hospitals. A product manufactured domestically, Plasmalyte, is widely used and mitigates global supply shocks.

Insiders say that at the core of the saline crisis in Australia is the fact that global shipping interruptions – largely caused by the closure of the Red Sea shipping route – have hit imports and caused a spike in demand for Baxter products. Baxter has ramped up production by as much as 135 per cent but is unable to immediately meet

the sudden extra demand.

The TGA has pointed to higher demand within hospitals, but there is no immediate explanation for why demand would increase in such a manner. Elective surgery is proceeding as normal or has reduced in many states.

"The TGA has approved a number of alternative supplies from overseas to supplement the local production, which is managing to get us through this period of higher demand," the regulator said. "The government is working with states and territories, and with private hospitals, to minimise any impact on patient care."

Concern is growing however among doctors. They're calling for transparency. "I've spoken extensively to senior Health Department figures and ... have been told that Australia is experiencing a global supply problem," said Australian Medical Association president Steve Robson. "Yet when I've contacted colleagues in the US and the UK, they're mystified. There seem to be minor shortages but nothing like we're now experiencing here."

A Baxter spokesperson said last week its manufacturing plant was "operating at historical volumes and full capacity".

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

THERAPEUTIC GOODS ADMINISTRATION



“There are no global shortages, only in Australia”

INDUSTRY INSIDER



Breakfast at 07:37 a.m.

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It's 23 minutes to eight. We talked about this on Friday. This national shortage of IV fluids that are starting to affect, uh, not only medical procedures but, uh, elective surgeries. Um, and I imagine at some point, probably emergency surgeries as well. Uh, the nation's health ministers are trying to reassure that the shortage is easing, but they say it will continue for the rest of the year. Absolutely extraordinary. One of the people that, uh, warned them that this was going to be a problem was president of the Australian Medical Association, Professor Steve Robson. He joins us now. Steve good morning. Steven. Why is this happening? Because we're I know whenever anything happens here in Australia, we try to blame the rest of the world. But the rest of the world seems to have solved this problem.

It's a really good question, Steven. And I think people are still trying to get to the bottom of things. I think there are probably three factors at play at the moment. The first, and I think most important, has been transport issues because a substantial amount of the intravenous fluids that we use here in Australia are manufactured overseas and brought here on ships. And I think we all recognise there have been issues with terrorism around coasts and things like that have affected shipping. Yeah. Second thing is, for reasons nobody can quite get to the bottom of, this seems to have been an increase in demand. So countries are ordering more intravenous fluids. Um, again, it's not clear why that's happening, but we're told that's the case. And the third factor probably is some changes in manufacturing. And I think we see that in all sorts of things that we want to get, whether it's cars or whatever. For Australia, they've just been over the last few years, issues in manufacturing. So it seems like all three things are really coalesced at one point and had an effect on the supply available to us here in Australia.

Well, look, it seems extraordinary to me that something that and I don't want to simplify this, but effectively we're talking about high quality, uh, salt water basically. I know a very, very low, uh, um, concentration, but the fact that we can't produce this ourselves is, beyond me.

So, Steven, again, another incredibly good point. We do make intravenous fluids in Australia. There's a large



Health Ministers Meeting (HMM): *Joint Statement on IV Fluids* *16 August 2024 - Sydney*

Health Ministers met today in Sydney and discussed ongoing management of shortages of IV fluids.

Ministers noted the global supply limitations of IV fluids due to unexpected increases in demand and manufacturing capacity constraints. Shortages of IV fluids, while easing, are expected to continue through 2024.

Ministers outlined the steps being taken to address supply in Australia and sought to provide reassurance to all Australians that supply challenges are being addressed and that health services are continuing.

Jurisdictions are bringing unprecedented collaboration to the issue, with a cross-jurisdictional Response Group convened by all states and territories and the Commonwealth and including the views of the broader health system through representation from private hospitals and primary care.

This Response Group will continue to meet on a weekly basis, or more frequently if required, while supply remains constrained in Australia.

The Response Group has already taken immediate steps to address supply and distribution issues in jurisdictions agreeing to:

- **Data and Transparency:** Sharing data across jurisdictions on usage and supply, and ensuring that producers and suppliers of IV fluids in Australia are providing data on their current supply and production forecasts, to better understand the severity and duration of the shortage.
- **Distribution and Logistics:** Ensuring there is a coordinated national approach to distribution across the jurisdictional supply chains.
- **Coordination and partnership:** Partnering across government to work with manufacturers and distributors to help them address supply issues.
- **Clinical Guidance and Communications:** Agreeing consistent messaging across all jurisdictions to support appropriate usage while supply remains constrained.

Ministers reiterated that the Response Group will continue to identify additional procurement opportunities while supply remains constrained.

The Response Group was directed by Ministers to consider options to maintain supply of IV fluids within Australia.