Can the lead poisoning of a 3 yr old in Australia help end lead poisoning from Ayurvedic medications globally?

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What’s the purpose of this article?

A three-year old child has a notifiable blood lead level in Australia after taking an imported Ayurveda medication from India, “prescribed” by an “Ayurveda doctor” in Australia’s largest population city, Sydney, who specialises in “treating” children. This article is aimed at leveraging this “index case” to finally bring about an end to lead poisoning from Ayurvedic medicines globally. Because over one billion people believe in the therapeutic value of Ayurvedic medicines, this article is NOT aimed at banning those Ayurvedic medicines which contain tiny trace or non-detectable amounts of lead and other heavy metals. Professor Venkatesh Thuppil wrote in an email to me on 22nd Sept 2020, that:

“AYURVEDA SYSTEM SHOULD NOT BE BLAMED. It is some self-declared Ayurvedic practitioners need to be blamed. IN GENERAL AYURVEDA IS A SAFE HMP [herbal medicine product]... With one case study it will be difficult to convince global leaders. We do have hundreds of cases across all age group where traditional and folk medicines have caused lead poisoning. Let us work together and make society and people better.”

My purpose is not to blame at all, but rather to figure out the actions needed to remove toxic Ayurvedic medications from the global market, actions triggered by one case but collating information from many other cases and taking it to the top – the World Health Organization. Surely the preventable intentional lead poisoning of a billion or so people is something WHO will take action on.

How did an Australian child come to be lead poisoned by a herbal remedy from India?

When the child’s paediatrician found out that the child had been taking the Ayurveda medication, he referred her for blood lead and blood mercury testing. When the child’s blood lead level was reported to the paediatrician on 24th August 2020 to be 7.1 ug/dL (micrograms per decilitre) after only 6-8 weeks on the Ayurvedic medication (one pill per day), the paediatrician phoned and advised the mother to immediately stop giving her child the Ayurveda medication. So the medication was started near the beginning of July 2020 and stopped by 24th August 2020.
By the time the state (New South Wales) Health Care Complaints Commission (HCCC 2020a and 2020b) and the Australian Therapeutic Goods Administration (TGA 2020) had responded to the case, my first sentence in this article would more correctly be written:

A three-year old child has a notifiable blood lead level in Australia after taking an imported Ayurveda medication from India which contained concerning levels of lead and other heavy metals and which was not registered by the importer Medcu re as a Therapeutic Good in Australia, but which was sold to the child’s mother by a man, Mr Rama Prasad, claiming to be an “Ayurveda doctor” but who was not actually registered as an Australian Health Practitioner, in Australia’s largest population city, Sydney.

Since I began writing this LEAD Action News article, other clients residing in NSW of Mr Prasad (who has clinics in Sydney and Melbourne and online) who are considered to have been placed at risk have now been contacted by NSW Health public health personnel, so more notifiable blood lead levels, including Mr Prasad who claims he took the medication himself, may eventuate.

**What advice does the Australian governments give regarding Ayurvedic medicines and practitioners who supply them?**

Here’s the advice from NSW Health Care Complaints Commission (HCCC 2020b):

The Commission strongly urges those individuals seeking alternative therapies to be vigilant in their research prior to proceeding with any natural therapy medications or medicines and to discuss any such proposed therapies with their treating registered health practitioner.

Individuals can check to see if a practitioner is registered in Australia through the Australian Health Practitioner Regulation Agency (AHPRA) website at [www.ahpra.gov.au](http://www.ahpra.gov.au)

Individuals can also check the website at [https://www.tga.gov.au/](https://www.tga.gov.au/) to see whether medications or medicines have been approved by the TGA.

And the Therapeutic Goods Administration (TGA 2020) adds:

If you, or someone you care for, has Manasmithra Vatika (Manasamitram Pills), do not use them. If you have already taken some of these pills, you should seek medical advice from your doctor or call the Poisons Information Centre on 13 11 26.

If you suspect you have had a side effect (also known as an adverse event) to this product, please report it to the TGA. In addition, if you have concerns about this or other products, you can make a report to the TGA on 1800 020 653 or through our website.

**What happens in Australia when a blood lead level exceeds 5 ug/dL?**

All pathology laboratories in Australia are legally required to notify the state health department when a blood lead level exceeds 5 ug/dL so, in this case, New South Wales (state) Health department was notified of the child’s blood lead level by the lab.
Before the Health Department contacted the parents to follow up on the case, the mother contacted The LEAD Group Inc (lead poisoning prevention and management health promotion charity) and I immediately organised for the pill the little girl had been taking (1 Gulika or pill per day) to be delivered that day (25th August 2020) for heavy metal analysis at the Australian government laboratory, National Measurement Institute (NMI).

**How much lead, mercury and arsenic was found in the Ayurvedic medication?**

I’ve compared the results of the heavy metal testing on the Ayurveda medication to the Australian Government (2013) soil Health Investigation Levels (HILs), as there are no specific limits in Australia for heavy metals in Ayurvedic medications or other complementary medicines. It is simply assumed there are no toxic heavy metals in medicines and it is mandatory that all products sold are safe when used as intended.

The results were:

- 10,800 mg/kg lead or **36 times or 3600%** of the Australian soil HIL for lead (300 mg/kg)
- 130 mg/kg mercury or **8.67 times or 867%** of the soil HIL for mercury (15 mg/kg), and
- 77 mg/kg arsenic or **77%** of the soil HIL for arsenic (100 mg/kg)

**How do we know the child’s lead didn’t come from multiple sources?**

At the same time as the 3 year old who took the Ayurveda medication was referred for blood lead testing, the younger sibling who did not take the medication was also tested. The 1 year old younger sibling’s blood lead result was “not detectable”. When NSW Health local Public Health Unit sent Public Health Officers to the home to collect all likely lead sources relevant to the 3 year old, they found that there were “none” apart from the Ayurvedic medication, and soil. NSW Health’s testing of the Ayurvedic medication confirmed the initial test result of high lead, and found that the soil lead content was below the “Investigation” level, thus NSW Health was satisfied that the Ayurvedic medication was responsible for the elevated blood lead level in the 3 year old.

**Do all Ayurvedic medications have the same amount of lead, mercury and arsenic?**

No. When reading journal articles on cases of lead poisoning from Ayurvedic medications, it quickly becomes apparent that a very wide range of concentrations of a very long list of
toxic heavy metals are found in various Ayurvedic medications, but typically lead is the most likely element to be found at alarming levels.

Tait et al (2002) found the following lead levels (and mercury levels in brackets) in four different Ayurvedic medications prescribed by a doctor in India and taken daily for 9 years prior to the 24 year old pregnant woman in Australia developing a blood lead level of 108 ug/dL, or nearly 11 times higher than the notifiable level at the time (10 ug/dL). When the child was born, the neonatal blood lead level (245 ug/dL or 49 times the notifiable level of today) was the highest recorded for a surviving infant:

The lead (and mercury) levels found in the Ayurvedic medications which caused the most severe congenital lead poisoning in a surviving infant (Tait et al 2002) were:

- Brown tablet, called “HSY-15” – 89,000 mg/kg or **8.9% lead** (0.003% mercury)
- Red tablet – 45,000 mg/kg or **4.5% lead** (mercury not analysed)
- Pink tablet – 2,000 mg/kg or **0.2% lead** (0.08% mercury)
- Green tablet – 30 mg/kg or **0.003% lead** (0.002% mercury)

That is, 100% of the four Ayurvedic medications contained lead in the range 30 mg/kg to 89,000 mg/kg and the median concentration of lead was 34,007.5 mg/kg.

Mikulski et al (2018) wrote:

Two hundred and fifty-two samples of Ayurvedic products and herbal supplements [purchased from one Indian clinic by the cluster of US lead poisoning cases in Breeher et al (2015)] were analysed.... Lead was the most common element found in 65% \( (N = 164) \) of all samples with maximum level of 43,200 mg/kg [**4.32% lead** and minimum level of 0.46 mg/kg].... Lead and arsenic in doses per pill exceeding those recommended by the [United States Pharmacopeia Convention] USP (0.005 and 0.015 mg/day, respectively) were found in over one-third of the products analyzed in this study... *Indukantham* tablets contained the highest levels of lead of all the samples with lead detected in the study.

Mikulski et al (2018) also found that the median lead content of the 252 Ayurvedic medications purchased by US residents from India, was 4.9 mg/kg which is lower than the lowest soil lead concentration I’ve ever seen (5mg/kg) because lead naturally occurs in soil.

Saper et al (2004) found that: a total of 14 (20%) of 70 Ayurvedic medications purchased at stores in Boston in 2003 contained heavy metals: The median lead concentration in 13 (18.6%) of the medications was 40 µg/g (40 mg/kg); and the range was 5-37,000 mg/kg or **3.7% lead**. Mercury was found in 6 of the medications with the median concentration being 20,225 mg/kg; and the range from 28 to a massive 104,000 mg/kg or **10.4% mercury**; and arsenic was also found in 6 of the medications; median concentration, 430 mg/kg; range, 37-8130 mg/kg or 0.8% arsenic.
So the meta-analysis for lead in Ayurvedic medications just from those three journal articles above is:

Lead was found in 18.6% to 100% of samples tested in the three studies, the minimum concentration of lead was 0.46 mg/kg and the maximum was 89,000 mg/kg, (8.9%) and the median lead concentration ranged from 4.9 mg/kg to 34,007.5 mg/kg (3.4%).

Why are lead and other heavy metals found in most Ayurvedic medications and at extremely high concentrations in some?

In an interview for The Health Report on ABC Radio National, broadcast on 24/1/2005, Dr Norman Swan asked Dr Robert Saper, Director of Integrative Medicine in the Department of Family Medicine at Boston University USA (Swan and Saper, 2005):

Why was the lead there [in the 13 leaded Ayurvedic medications out of 70 Ayurvedic medications purchased at stores in Boston in 2003 (Saper et al 2004)] in the first place, do you think?

Robert Saper: I think three possibilities emerged. One is that the products could have simply been contaminated during the process of manufacturing. Another possibility is that the raw materials for the products could have lead or other heavy metals in them because of being exposed to these heavy metals in the environment, such as from contaminated soil or groundwater. But perhaps most provocative is that if you study the text books of Ayurveda, both published thousands of years ago and in the modern era in the last 25 years, and speak with traditional Ayurvedic physicians, all these sources will describe a very clear role for metals such as mercury and lead in Ayurveda. Some of these metals are purported to carry certain therapeutic qualities and may be added to the medicine to for example, increase the potential of the medicine to give vitality or longevity. So it’s possible in particular, for example, that medicines where we found tens of thousands parts per million of some of these metals, the metals may have been intentionally added.”

Professor Venkatesh Thuppil referred me to a paper he co-wrote with Robert Saper and others (2008) which concludes:

One-fifth of both US-manufactured and Indian-manufactured Ayurvedic medicines purchased via the Internet contain detectable lead, mercury, or arsenic.

Saper et al (2008) also state:

Ayurvedic medicines are divided into 2 major types: herbal only and rasa shastra. Rasa shastra is an ancient practice of deliberately combining herbs with metals (eg, mercury, lead, iron, zinc), minerals (eg, mica), and gems (eg, pearl). Rasa Shastra experts claim that these medicines, if properly prepared and administered, are safe and therapeutic. [Satpute (2003), Shastri (1979)]

Saper et al (2008) go on to comment:
Metals identified in our sample of Ayurvedic medicines are likely a result of the practice of rasa shastra [(combining herbs with metals, minerals, and gems)] or contamination. Many rasa shastra medicines are made with bhasmas, which are elaborately prepared with various forms of metals including cinnabar (mercuric sulfide), galena (lead sulfide), realgar (arsenic sulfide), and white arsenic (arsenic trioxide). [Satpute (2003), Shastri (1979)] Ekangvir Ras is an example of a rasa shastra medicine made with naga (lead) bhasma and parada (mercury). Ayurveda experts in India believe that if bhasmas are properly prepared according to ancient protocols, the metals undergo shodhana (“purification”), rendering them nontoxic and therapeutic. Case reports in the literature, however, have documented significant toxicity with the use of some of these products. [Ernst (2002), CDC (2004)] The prevalence of metals in non–rasa Shastra medicines was still substantial (17% [heavy metals were found in 27 medicines out of a total of 158 non-rasa Shastra medicines]) and could be a consequence of environmental contamination of the herbs or incidental contamination during manufacturing.

By the time Robert Saper was a co-author with Koch et al (in 2011), the hypothesis of the “Ayurveda experts in India” that in making bhasmas, the heavy metals undergo purification rendering them non-toxic, was firmly disproven and the opposite, increased toxicity, found for the most common Ayurvedic medicine in lead poisoning cases, Mahayograj Guggulu:

Lead bioaccessibility was high (close to 100%) in a medicine (Mahayograj Guggulu) that had been compounded with bhasmas (calcined minerals), including naga (lead) bhasma...

In the current study, sample 11 (Mahayograj Guggulu) contains a high concentration of lead, around 5% by weight (50,000 mg/kg), which was likely added as naga bhasma (lead ash) (Raza, 1975). Bhasmas are calcined or ashed minerals or gems; in chemical terms, the bhasma process is mainly oxidative roasting. The lead species in the sample could not be detected by X-ray diffraction analysis, likely because only amorphous forms were present, but the lead form was nearly 100% bioaccessible in the final product. This suggests that the bhasma process may actually increase the bioaccessibility of the lead starting material, most likely elemental lead, which is insoluble in water. Of note, Mahayograj Guggulu is the traditional Indian medicine most frequently associated with reported lead poisoning cases (Ernst, 2002; Centers for Disease Control and Prevention, 2004; Saper et al., 2008).

Is it in any way possible that lead, mercury, arsenic and other toxic heavy metals from any source are actually therapeutic?

In my view the answer is no. Devesh Thakur and Thuppil Venkatesh (better known as Venkatesh Thuppil) concur and have stated as much categorically, in Ubiquity of Lead in Our Lives - Lead in Food (2015):

Researchers and the entire medical profession are now convinced that this toxic heavy metal and its salts have no known beneficiary biological function. Hence everyone is convinced that lead and its salts have deleterious effects.

Could low life expectancy in India compared to in Australia make claims of Ayurvedic physicians more likely to be believed?
Nearly 40 years ago when I was studying Epidemiology in my post-graduate Health Education course, I distinctly remember being shocked when the lecturer told us that the life expectancy at birth of females in India was 46, and that of males, 54. In Australia, the figures were something like 75 (women) and 68 (men) respectively. The internet didn’t exist back then but Wikipedia (2020a) confirms that in the past, life expectancy at birth in the years 1970-1975 for both genders in India was 49.39 and in Australia was 71.75 years.

More recently, according to Wikipedia (2020b), the Human Development Report 2019 by the United Nations Development Programme, (based on 2018 data), ranks India as country number 130 (out of 186 countries) in terms of life expectancy at birth, compared to Australia at number 7, (number 1-ranked Hong Kong females had the highest life expectancy at birth, at 87.6).

Within that context of relatively low life expectancy at birth, I guess people in India are more open to believing traditional Ayurvedic physicians who purport that metals such as mercury and lead carry therapeutic qualities and increase the potential of the medicine to give vitality or longevity – they want to believe that something they can afford to buy can help make them live a healthier and longer life. The only belief change that’s needed for Ayurveda medicines to continue to be used safely, is to now know that whilst the bhasmas of metals are toxic, the herbs and other non-bhasmas in Ayurvedic medications can indeed be therapeutic.

**Research showing lead poisoning causes the opposite of vitality and longevity – lead causes life-long health impacts and early death**

The LEAD Group has created two lists citing dozens of research articles which demonstrate that lead poisoning - whether from Ayurvedic medicines or any other source – once in the blood, has life-long impacts including early death, and a fact sheet made up of quotes from media articles regarding the Lanphear et al (2018) article in The Lancet, which concludes that lead poisoning causes almost as many deaths annually in the US as cigarette smoking – another hugely popular behaviour in India, and one which, coincidentally raises the blood lead level of the smoker and those around them. See web addresses in the Reference list below for The LEAD Group’s three fact sheets:

*Health Impacts of Lead Poisoning* (Vella et al 2020);

*Health effects of a blood lead level below 10 µg/dL in both adults and children and even below 1 µg/dL in pregnancy* (Roberts et al 2020);


**What is the name of the Ayurvedic medication which lead poisoned an Australian 3 year old child in 2020?**
The particular Ayurvedic medication in this index case in Australia in 2020, has been found under 5 different spellings for the name of the medication, just between the prescribing doctor, the importer and the manufacturer:

Manasamitram Pills - in the prescription written by the man calling himself an “Ayurveda doctor” in Sydney

Manasamitravatakam Pills - in the prescription written by the unregistered Ayurveda health practitioner calling himself a “doctor” in Sydney

Manasmithra Vatika 100 Capsules – on the label of the plastic bottle that the “Senior Ayurveda doctor” in Sydney sold to the mother, and in the photo of the same bottle on the website of the Australian-based importer www.medcure.com.au (before the website info was removed while the site was “under maintenance” as at 27th September 2020).

Manasamithra vatika – on the Australian importer’s website www.medcure.com.au (previously); and on the online store VVMart of the manufacturer named on the Medcure capsule bottle label as: Manufactured by Vasudeva Vilasam Herbal Remedies P. Ltd. Made in India - https://vvmart.in/products/manasamitra-vatika-100-nos?_pos=1&_sid=5b94294d4&_ss=r - where it is still for sale as at 28th September 2020.

Manasamitra vatika – for sale online globally (and exported to 20 countries), at VVMart, the online store of Vasudeva Vilasam, https://vvmart.in/products/manasamitra-vatika-100-nos?_pos=1&_sid=5b94294d4&_ss=r

Just one other website (AyurMedInfo 2020) revealed sixteen more names/spellings for this medication:

Which of the Ingredients of Medcure Manasamithra vatika are most likely the source of the heavy metals?

The Ingredients of Manasamithra vatika appear on the Medcure capsule bottle purchased from the Sydney-based Ayurveda doctor, but are so small as to be illegible, but fortunately the Ingredients were listed (before “site maintenance”) on the Australian importer’s website: https://www.medcure.com.au/collections/capsules/products/manasamithra-vatika; though are not listed on either the manufacturer’s website: www.Vasudeva.com or the manufacturer’s online store website: www.VVMart.in

As at 27th September 2020, the only text at www.medcure.com.au is:

MEDCURE - SITE UNDER MAINTENANCE. WE’LL BE BACK SOON. You can write to us at connect@medcure.com.au

But of the Ingredients previously listed for Manasamithra vatika on the Medcure website (accessed on the 8th September 2020), the first 58 ingredients are listed as being present in the same amount (6.3mg), presumably per pill or per batch. The “amount per pill or per batch” for the remaining 9 ingredients is listed as Q.S.
According to The Free Dictionary online (2020), the acronym QS has 43 definitions, but among the 12 Science & Medicine uses of the acronym QS, the following two seem most likely to be what is meant in the Ingredients lists for Ayurvedic medications:

Q.S. = Quantum Sufficit (Latin: as much as suffices)

Q.S. = Quantum Sufficiat (Latin: sufficient quantity; on a prescription, indicates quantity is left to the dispenser's discretion)

One ingredient of Medcure Manasamithra vatika, *Sida cordifolia* is listed twice for the amount 6.3mg, and once for the amount Q.S., so in effect there are 65 different ingredients listed.

Four of the 65 ingredients in Medcure Manasamithra vatika are Ashes of metals. Six of the 65 ingredients are other non-plant ingredients and the remaining 56 ingredients are from 56 different plants.

According to Prpic-Majic et al (1996), “The metal and mineral contents in some Ayurvedic remedies are in a powdered ash form produced by the repetitive, temperature controlled burning of metals such as gold, silver, copper, zinc, iron, lead, tin, mercury, etc. and precious stones.”

The Medcure website lists the following Ingredients-of-concern in Manasamithra vatika, with the translation of Swarna bhasma being “sacred ash of gold”:

Bhasmas or Ashes of Metals:

Swarna bhasma(6.3mg),

Ash of silver(6.3mg),

Ash of Iron(6.3mg).

Professor Venkatesh Thuppil advises that if Manasamithra vatika were to contain ash of lead, then the lead content could be even higher than the 1.08% found in the Medcure Manasamithra vatika.

He advised in an email dated 15th September 2020: “Medicines containing heavy metals and pure lead bhasma called Naga Bhasma which is 100% lead, is also sold in India at Ayurvedic pharmacies.”

My guess is that the second most likely group of heavy-metal containing ingredients in Manasamithra vatika are the Other non-plant ingredients, but especially the mineral (iron pyrite) and bhasma (ash of deer horn) ingredients:

Iron pyrite(6.3mg),
Bhasma of deer horn (6.3mg),
Coral (6.3mg),
Pearl (6.3mg),
Musk (6.3mg),
Cow’s milk (Q.S).

Which of the Ingredients of Manasamitra Vatakam (listed by AyurMedInfo.com) most likely add heaps of heavy metals to the product?

Adjunct Professor Brian Priestly referred me to the AyurMedInfo.com website (2012) list of 71 ingredients of Manasamitra Vatakam, 60 ingredients at 10 g of each (perhaps per batch?), and 11 ingredients at Quantity Sufficient.

The following five bhasmas (ashes of four metals and ash of deer horn) are ingredients for Manasamitra Vatakam listed on the AyurMedInfo.com website (2012):

Swarna Bhasma;
Tapya – Makshika Bhasma – Bhasma of Copper-Iron Pyrite
Loha Bhasma – Bhasma prepared from Iron
Rajata Bhasma – Bhasma of silver
Mrigashringa Bhasma – Bhasma made of deer horn.

Indiaabundance.com (2020) in New Delhi, India, sells Manasamitra Vatakam Gulika – I could not find the name of the manufacturer – listing 72 ingredients including four metal bhasmas and deer horn bhasma. These five ingredients are exactly the same as the ingredients for Manasamitra Vatakam listed on the AyurMedInfo.com website (2012):

Swarna Bhasma
Tapya – Makshika Bhasma – Bhasma of Copper-Iron Pyrite
Loha Bhasma – Bhasma prepared from Iron
Rajata Bhasma – Bhasma of silver
Mrigashringa Bhasma - Bhasma made of deer horn.
Aside from Vasudeva Vilasam, which other companies make Manasamitra Vatakam in India and does the product always contain bhasmas?

The answer to this question could involve months of research but over a few days I have found that The AyurMedInfo site (2012) page about Manasamitra Vatakam reveals four manufacturers of that medication to be:

Kottakkal – Arya Vaidya Sala

Amruta Drugs, Vaidyaratnam

IMIS

Nagarjuna – Maanasamithra vatakam

Arya Vaidya Sala (AVS 2020), in Kottakkal does not list bhasmas amongst the 70 Ingredients for its Manasamithra Vatakam, but it does list the following metals:

- Gold (Sanskrit name: Hema),
- Iron Pyrite (Tapya),
- Iron (Kalaloha) and
- Silver (Rajata), as well as

Buffalo's Horn (Mrigasringa).

Which organisation is best placed to start purchasing Manasamitra vatika and Mahayograj Guggulu and other bhasma-containing Ayurvedic medicines and analysing them for heavy metals?

The LEAD Group would love to do it but could not do so without substantial financial backing. InSLAR may be in the same situation. Robert Saper and his colleagues could be asked. The World Health Organization (WHO) could have a role to play. A ground-swell of citizens who have already purchased such products could perhaps be convinced to pay for laboratory analysis, especially if they have already had blood testing for heavy metals and found elevated levels. Health departments that follow-up notifiable blood lead levels could be asked to ask every case whether Ayurvedic medications were a possible source of the lead, and if so, test them at a certified lab for at least lead, mercury and arsenic, recording results, the practitioner, medication supplier, manufacturer, ingredients if provided, and identifying if possible whether bhasmas were among the ingredients. National health departments could then draw together the data from local health departments, and WHO could draw it all together to create a global picture, allowing national governments to recall unsafe Ayurvedic medications, and ban ingredients which result in unsafe Ayurvedic medications.
If not all Ayurvedic medications include Metals or Bhasmas, why are so many contaminated with heavy metals?

I believe it’s possible that the reason so many Ayurvedic medications contain much smaller amounts of heavy metals than Medcure Manasamithra vatika made by Vasudeva Vilasam in India (which contains 1.08% lead), is that the same equipment is used (without thorough cleaning) to make a batch of a different medication, following the making of the high heavy-metal medications, despite the Vasudeva Vilasam factory where the Medcure Manasamithra vatika is made, in Kerala, India, being certified as GMP (Good Manufacturing Practice) and ISO 9001 (which sadly allows companies to set their own quality goals, in this case, clearly Vasudeva Vilasam’s goals do not include providing safe heavy-metal-free products).

What does ISO 9001 Certification and GMP mean in relation to products like Ayurvedic medications?

Regarding ISO (International Organization for Standardization) 9001, The 9000 Store (2020) states:

The standard is used by organizations to demonstrate their ability to consistently provide products and services that meet customer and regulatory requirements and to demonstrate continuous improvement...

- It is NOT a standard for products. It does not define product quality. This is a process-based standard: you use it to control your processes, then your end product should meet the desired results.

At least one manufacturer of Ayurveda products in India believes that Good Manufacturing Practices entail creating safe products. On the MAPI (Maharishi Ayurveda Products International) website (2017) vpk by Maharishi Ayurveda demonstrate that they’ve combined the “science of life” which is the Sanskrit meaning of Ayurveda, with the western science of product safety testing:

- ISO-9001 Certification - The ISO (International Organization for Standardization) - ISO is the world's largest developer and publisher of International Standards. Maharishi Ayurveda Products International meets the ISO’s stringent requirements for quality in the design, production, and export of herbal products.
- Good Manufacturing Practices (GMP & cGMP) Certification - Conducted by an independent panel of experts; certifies that Maharishi Ayurveda Products International products are “fault-free, safe and have consistent quality.”
And in their article Tested and Safe: Our Commitment to Purity - Maharishi Ayurveda Products International specifically state that:

...tests include examination for: Heavy metals (lead, arsenic, cadmium and mercury).

Can anything be done to force Vasudeva Vilasam and other ISO 9001 Certified Ayurveda medicine manufacturers to remove unsafe ingredients like metal bhasmas from their formulations?

Apparently the answer is yes. Email your complaints to info@vasudeva.com or md@vasudeva.com or phone on +91 471 409 1000.

According to Yehuda Dror (1995), one of the Common Myths about “the ISO 9000 (namely 9001, 9002 and 9003)” is that:

It doesn’t foster continuous improvement or improve product quality. One common criticism of the standard is all that a company needs to receive and maintain compliance is paperwork and a bureaucracy to guard it, while the product quality remains unimportant.

In defence of the ISO 9000 series of international standards, Dror goes on to respond to this myth:

This is far from correct. Though the standard does not explicitely require continuous improvement, it does require a system for review and correction, and implementation of corrective and preventive actions, which in essence form the Deming plan-do-check-act continuous-improvement loop. Thus, companies making bad product will undoubtedly hear about it either from their customers (customer complaints), or their own process (nonconformities and corrective actions) or from problems related to suppliers through the purchasing system. A company should be able to use its review-and-correction system, consisting of corrective actions, internal audits and management reviews, to ensure that its system weeds out the problems and can assure consistency in producing those products or services it deemed of good quality.

My reading of what Dror has said is that both customer complaints (eg that a product is unsafe) and problems identified by suppliers (eg that employees at manufacturing operations where bhasmas or metals of ashes ingredients are made are being poisoned by the heavy metals in these raw ingredients of Ayurvedic medications) should lead to Vasudeva Vilasam and other ISO 9001 certified Ayurvedic medications manufacturers changing their formulations to remove toxic ingredients.

What are the names and manufacturers of other Ayurvedic medications that have been found to contain lead, mercury and arsenic?

Saper et al (2004) compiled the following data (first presented here as a screenshot and then as searchable text, minus the data on % of stores selling HMP):
Could researchers supply the World Health Organization (WHO) with the company names of manufacturers of toxic Ayurvedic medications?

Theoretically, yes. The WHO could request this information from researchers such as Robert Saper and Marek Mikulski and the research teams of, for starters, the 96 journal articles about heavy metal poisoning from Ayurvedic medicines on the PubMed website (2020), and put it together with the known Vasudeva Vilasam manufacturer from this index case in Australia, and the four manufacturers of Manasamitra vatakam listed on the AyurMedInfo site (2012), to generate a list of manufacturers of likely-to-be-toxic Ayurvedic medications, which could then be analysed as to which of the manufacturers are, as Professor Thuppil suggests “back yard traditional and folk medicine producers that are difficult to track”, and which manufacturers have ISO 9001 certification, like Vasudeva...
Vilasam. Complaints could then be made to each manufacturer that has ISO 9001:2015 certification.

**What could get the ball rolling to remove toxic ingredients from Ayurvedic medications?**

If ISO 9001 certification is worth the paper it is written on, then complaints by WHO to every ISO 9001 certified Ayurvedic medicine manufacturer which has products identified by researchers as containing heavy metal-containing ingredients, could be the beginning of re-formulation of Ayurvedic medications without toxic ingredients. With the toxic ingredients no longer being added, based on my hypothesis that non-bhasma-containing Ayurvedic medications are likely mixed in the same vats following the mixing of bhasma-containing medications, without proper cleaning of the vat in between, I predict that the percentage of Ayurvedic medications containing heavy metals will fall drastically.

**Why aren’t there millions of cases of lead poisoning from Ayurvedic medications documented in India?**

There probably are hundreds of millions of lead poisoned people in India, but as in Australia, blood lead testing is extremely rare so how would anyone know? And without elevated blood lead levels being notifiable, no one in India is going to be lucky enough to have a Public Health Officer come to their home to check out whether they’re taking Ayurvedic medications which contain heavy metals or whether they have a myriad of other possible lead sources. Because Ayurvedic medicine has been an accepted therapeutic part of Indian traditional medicine for so long, it is very likely to be overlooked – it has become part of the fabric of life. People probably read ingredients lists which include metals and deer horn and pearl and milk etc and then read:

100% Herbal Product - Made with the Wisdom of Ayurveda - Safe and Effective

at the bottom of the page, such as on the indiaabundance.com website (2020) *Manasamitra Vatakam Gulika* page, and don’t even think “False advertising?” let alone, think: “is this product going to poison me?”
A woman prepares bhasma ingredients for an Ayurvedic treatment in India. Ayurveda is also used in the United States. *Photo: Luca Tettoni/Corbis, from Chen (2015)*

For those who’ve been working tirelessly in India and the United States for years on this issue, frustration and a sense of urgency are evident, as Angus Chen writes (2015):

In his own practice, [Professor Venkatesh Thuppil] says he sees people suffering from heavy metal toxicity because of Ayurvedic bhasma medicines almost every day. "Children have died. People have lost their lives," he says. Others have suffered permanent brain damage. "It must be stopped."

So far, stabs at effective policies in India and the United States to stop the production or distribution of contaminated Ayurvedics have fallen flat, according to Nancy Clark, the assistant commissioner for the New York Bureau of Environmental Hazards and Health.

For years, health departments like hers have routinely issued cease-and-desist orders to shops from selling specific Ayurvedic or other traditional remedies, but only once a laboratory test confirms the product is dangerous. "And believe me, we also notify the Indian government," Clark says. "There are attempts on the Indian side to regulate products. Obviously, it’s not working."

**Is it possible some ingredients in Ayurvedic medications naturally chelate heavy metals?**
Yes it is. As noted in *Treating Lead Toxicity: Possibilities beyond Synthetic Chelation* by Thuppil and Tannir (2013) there are numerous natural chelators (chelating agents remove lead and other heavy metals from the body), including Vitamin C, Alpha-lipoic acid (ALA), coriander or cilantro (*Coriandrum sativum*), tea, garlic (*Allium sativum*), turmeric (*Curcuma longa*), ginger (*Zingiber officinale*), Indian gooseberry or amla (*Emblica officinalis* Gaertn or *Phyllanthus emblica* Linn), ascorbic acid, allicin, flavonoids and catechins.

Many of these naturally occurring plant-based chelators are ingredients in Ayurvedic cooking and in numerous Ayurvedic medicines, even including Medcure Manasamithra vatika which contains turmeric (*Curcuma longa*) and Indian gooseberry (*Emblica officinalis*).

As Professor Thuppil was quoted as saying in Chen (2015):

"Every Indian kitchen is like an Ayurvedic pharmacy. We have pepper, ginger, turmeric," says Venkatesh. "It’s a great medicine, but one has to be very cautious."

**Are there any relevant regulations or litigation over lead poisoning from Ayurvedic medicines in India?**

If this metal bhasma-containing medication was being produced in Australia, the manufacturing workers would be required to wear Personal Protective Equipment to reduce their exposure to the heavy metals, and to have bio-monitoring (blood tests for heavy metals) before they started their employment and then within one month of starting employment, and then regularly, depending on the levels of heavy metals found in their blood (SafeWork Australia 2018).

Mikulski et al (2018) have described the heavy metal-related belief of Ayurveda practitioners and users as follows:

Ayurvedic formulations are based on herbal products but often include toxic metals and other elements as part of the *Rasa Shastra* practice. These elements are used intentionally, as Ayurvedic tradition holds that lead, mercury, copper, gold, iron, silver, tin, and zinc may help restore good health and normal function to the human body. Arsenic, aluminum, cadmium, chromium, and nickel may be found in Ayurvedic products as well. It is estimated that over 20% of the Ayurvedic medications manufactured and distributed by U.S. and Indian companies contain toxic metals such as lead, mercury, and/or arsenic.

I asked Professor Venkatesh Thuppil:

Does India have any similar Occupational Health & Safety regulation? Do you know whether any workers at Ayurvedic medication manufacturing plants have ever actually had their blood tested for heavy metals? Or, given the tradition of intentionally adding heavy metals to Ayurvedic medications (see above paragraph by Mikulski et al 2018), is it legal to sell medications containing heavy metals in India? Has any heavy-metal containing Ayurvedic medication ever been recalled in
India? Can you send me any documents about any Indian regulations, legal action or litigation in relation to Ayurvedic medication please?

Professor Thuppil replied:

To date there are no mandatory regulations in India in spite of the AYUSH [Ayurveda, Yoga & Naturopathy, Unani, Siddha & Sowa Rigpa and Homeopathy] Ministry - recently formed – which is looking at the safety of various alternative medicines including Ayurveda and Unani. However there were a couple of litigations. With regard to good manufacturing practices I am unable to comment as old traditional methods are adopted for the preparation of Ayurvedic medicines and varies from manufacturer to manufacturer. Testing of blood lead level (BLL) of the workers at the manufacturing unit is not in practice or not known as there is no mandatory regulation. Any person can sell medications containing heavy metals in India and there is no legal requirement. Most of the time the Ayurvedic practitioner will prepare and sell or advocate to his patients. The entire process is based on mere trust and faith. Kindly log on to the AYUSH web site for the regulations and safety aspects and with reference to the documents about any Indian regulations, legal action or litigation in relation to Ayurvedic medication.

I did spend an hour searching the AYUSH Ministry website www.ayush.gov.in but found nothing relating to litigation against Ayurveda medications manufacturers for heavy metals in products; or blood testing of customers or workers; or regulation or even analysis of Ayurvedic medications for heavy metals. I concluded that the “Ministry of AYUSH, Government of India was established to ensure the development and propagation of AYUSH systems of medicine” - apparently not to regulate them or protect the health and safety of workers exposed to heavy metals during manufacture of bhasmas of metals etc, though some concern was evident for the treatment of experimental animals used in drug trials, and guidance given on keeping heavy metals out of their diet, then feeding them Ayurvedic medications and testing their blood for heavy metals. All this within the seemingly unshakeable paradigm of heavy metals being therapeutic if properly processed, as demonstrated by the following (Ministry of AYUSH 2018):

It was known to ancient Ayurvedic scholars that metals, minerals and some plants are toxic and harmful to the body and therefore, it was advocated to process them properly so as to render them therapeutically safe. Ayurveda pharmaceutics strongly recommend various other safety aspects, which are known for their contemporary relevance, like Good Agricultural Practices (GAP), Good Field Collection Practices (GFCP) of medicinal plants and Good Manufacturing Practices (GMP) for preparation of quality assured drugs.

It doesn’t matter how you process it or how much you describe it as safe, it is illegal in Australia to supply unsafe products, although there is no particular lead level or mercury level or arsenic level etc that is deemed safe or unsafe, so an argument has to be made on a case-by-case basis that the product is unsafe. And to demonstrate that a workplace where heavy metals are used is safe, you have to present the blood lead and other blood heavy
metal results of the workers. It is not the same in India and the Ministry of AYUSH is clearly not going to accept the science on this anytime soon.

Breeher et al (2015) described a cluster of lead and mercury toxicity cases in 2011 among a community of adherents of traditional medical practice of Ayurveda [who all purchased their medications from one clinic in India – sadly, the clinic is not named].... Adherents of Ayurveda were offered heavy metals screening following the identification of the index case. Forty-six of 115 participants (40%) had elevated blood lead levels (BLLs) of 10 ug/dl or above, with 9.6% of BLLs at or above 50 ug/dl.

**How many people in India have likely been lead poisoned by Ayurvedic medicines?**

In 2005 on The Health Report, Dr Robert Saper told Dr Norman Swan that:

In India, it is estimated that up to 80% of their population of 1-billion uses Ayurvedic medicine, and in fact there are over one-half-million registered Ayurvedic physicians in India, as well as over 2500 hospitals, and 22,000 clinics that are solely dedicated to Ayurvedic medicine.

The following Results and Conclusions come from the Abstract of Mikulski et al (2018) in which the researchers analysed Ayurvedic medications that US residents purchased from one clinic in India:

**Results:** Lead was found in 65% of 252 Ayurvedic medicine samples with mercury and arsenic found in 38 and 32% of samples, respectively. Almost half of samples containing mercury, 36% of samples containing lead and 39% of samples containing arsenic had concentrations of those metals per pill that exceeded, up to several thousand times, the recommended daily intake values for pharmaceutical impurities.

**Conclusions:** Lack of regulations regarding manufacturing and content or purity of Ayurvedic and other herbal formulations poses a significant global public health problem.

Whilst Mikulski et al (2018) also found that the median lead content of the Ayurvedic pills purchased from India was 4.9 mg/kg and thus half the products had a lead content below 4.9 mg/kg, until someone does a survey of the heavy metal content and sales figures for each Ayurvedic medication sold in India, to find out whether Ayurvedic doctors generally favour prescribing the heavy metal-containing Ayurvedic medications (because they believe the heavy metals are therapeutic) or users of Ayurvedic medications prefer to purchase the heavy metal-containing Ayurvedic medications (because they believe the Ayurvedic doctors when they say the heavy metals-based ingredients – the ashes of metals and other Bhasmas - are therapeutic) it’s not possible to estimate how many people in India have been lead poisoned by Ayurvedic medications, but the figure is surely in the order of hundreds of millions.
When I asked Professor Thuppil any actions InSLAR (or National Referral Centre for Lead Poisoning in India (NRCLPI) before it) have taken regarding lead poisoning related to Ayurvedic medications which would potentially bring an end to the practice of intentionally adding toxic heavy metals to Ayurvedic medications globally, he answered:

We at InSLAR during the recently concluded International Lead Conference discussed the presence of toxic heavy metals in Ayurvedic preparations. We had some of the top Ayurvedic experts and we are moving in the right direction and due to COVID the progress is hindered. We will arrive at some mutually agreed recommendations to the Government of India. Hopefully we in India should be able to tackle this issue in a diplomatic way. My recommendation is to stop using all medicines containing toxic heavy metals including lead to all age groups till regulatory authorities come out with legislation in any part of the globe in the interest of the health of people.

**What actions initially need to be taken to ensure this case leads to massive change?**

The customers of Ayurveda “doctor” Rama Prasad (including the mother of the 3-yr-old girl) need to write to him to ask what he tested for and to request a copy of the test results he claims to have had done on Manasamithra vatika before taking it himself and prescribing it (or more correctly, as this is a case of a person who is not actually registered to practice as a Health Practitioner in Australia, selling it) and if he provides test results demonstrating that lead was in the product, to then complain that he knowingly sold an unsafe product. If he didn’t have the product tested for lead prior to selling it, then the complaint is that he recommended an unsafe untested product and the request should be made that he should make a complaint to his supplier, Medcure.

If Mr Rama Prasad did have the product tested for lead (and other heavy metals) before selling it in Australia, and therefore recommended the product knowing that it contained over 1% lead, then the complaint from the parents should be that he not be allowed to practice until he is registered with AHPRA and that AHPRA be advised that Mr Prasad as at May 2020 believed that lead (and other heavy metals like mercury and arsenic) were therapeutic, and that unless he recants, he never be allowed to register and practice in Australia.

Until more blood lead testing is done in people taking bhasma-containing Ayurvedic medications as a priority, and more credible laboratory analysis results are obtained on both bhasma-containing Ayurvedic medications AND the metal bhasma ingredients themselves, this will remain an isolated case, but the difference is: we now know the name of one manufacturer of one toxic medication and we know the names of the ingredients (the bhasmas) that are the likely source of the heavy metal concentrations, and the manufacturer has ISO 9001 certification. A complaint to Vasudeva Vilasam requesting that the metal bhasmas are analysed for lead and other heavy metals, should, according to the ISO 9001 quality assurance system, lead to a change in the ingredients so that heavy
metals are not found in the end product - or a cessation of manufacturing Manasamithra Vatika by this one company.

Next step – ask purchasers of this and other known metal bhasma-containing Ayurvedic medicines to have them tested for heavy metals at an accredited lab. If heavy metals are found, purchasers should undergo blood lead and other heavy metal testing and complain to the supplier/importer/manufacturer, especially those with ISO 9001 Certification... and so on... one case at a time... building to critical mass... and ending with only heavy-metal-free Ayurvedic medications on the market.

Who needs to take which steps to make Ayurvedic medications safe globally?

1. Anyone who has tested and found heavy metals in Ayurvedic medications should make a complaint to the supplier and manufacturer demanding that the manufacturer (or an independent auditor) analyse each of the ingredients of the medication, to determine which ingredients provided the heavy metals in the final product, and to also test other products they make containing those ingredients;
2. WHO should coordinate this complaint process (so complaints cannot be ignored by the manufacturers) and build a database of toxic ingredients and names of suppliers and manufacturers’ names of formulations which include those toxic ingredients;
3. Anyone who has taken those Ayurvedic medications which have been identified as containing heavy metals, should ask their doctor for blood testing for lead, mercury, arsenic and antimony;
4. If blood lead testing occurs in countries where blood lead notification by the pathology lab to the health department is mandatory, these countries would then be motivated to analyse the particular Ayurvedic medications taken and identify more manufacturers, and feed more data into Step 1 and Step 2 in this list;
5. Anyone working in bhasma-manufacturing should ask their doctor for blood testing for lead, mercury, arsenic and antimony (to begin with, more heavy metals could be tested if any of the first 4 heavy metal results are elevated);
6. Anyone working in bhasma-utilising Ayurvedic medicine manufacturing should ask their doctor for blood testing for lead, mercury, arsenic and antimony (to begin, more heavy metals could be tested if the first results are high);
7. If blood lead testing of bhasma-manufacturing workers and bhasma-utilising Ayurvedic medicine manufacturing workers occurs in countries where blood lead notification by the pathology lab to the occupational health and safety department is mandatory, these countries would then be motivated to analyse the particular Ayurvedic ingredients or medications manufactured where workers are lead poisoned, and identify more manufacturers, and feed more data into Step 1 and 2 in this list;
8. If a respected body such as InSLAR (Indian Society for Lead Awareness and Research) were to raise awareness of the need for blood heavy metal testing and
laboratory analysis of the heavy metal contents of both Ayurvedic ingredients like bhasmas and the final products, then critical mass could be reached in India;
9. When a critical mass of poisoning cases and data about particular heavy metal-containing Ayurvedic ingredients, medications and manufacturers has been reached, manufacturers, firstly those with ISO 9001 certification, and then those without it, will be forced to reformulate Ayurvedic medications leaving out lead and other heavy metal-containing ingredients;
10. As lead is associated with early death, life expectancy in India and other countries where Ayurvedic medications are taken by a majority of the population should rise and this rise may even show up in the next United Nations Development Programme Human Development Report.

**Why is this Australian 3 year old’s lead poisoning from an Ayurvedic medicine so special?**

What gives me so much hope that this case can improve the lives of perhaps a billion or more people? What’s special about this case, is that Vasudeva Vilasam has made one (that we know of until further testing is done) Ayurvedic medicine – Manasamithra vatika – that contains 1.08% lead (plus mercury and arsenic) and the company claims on their website that with nearly 140 years experience in manufacturing Ayurvedic medicines, and with ISO 9001 Certification, they are truly Ayurvedic – quality assured.

Vasudeva Vilasam is not just some unscrupulous backyard Ayurvedic medicine manufacturer.

I’ve identified the Customer Complaint process of ISO 9001 Certification as the key ingredient which has not been tried by any other proponents of heavy-metal-free Ayurvedic medications.

If you had tested an Ayurvedic medicine because a little girl with no other lead sources had been lead poisoned by it, wouldn’t you also be willing to try this novel approach? Sure, it may only go as far as this one medicine being reformulated without the toxic metals or just removed from the Vasudeva Vilasam VVMart online shop, but the approach has the potential to go much further... to acceptance by Indian manufacturers wishing to maintain their ISO 9001 certification, of Western science that says heavy metals in medications are toxic no matter how they’re prepared, and they don’t belong in medications.
I am happy to recommend Ayurvedic medicines - those that contain no heavy metals but do contain the natural chelating plants (like coriander) identified by Thuppil and Tannir (2013) - for detoxing lead and other heavy metals. Once more Ayurveda medicine manufacturers aim to keep heavy metals out of their products, wouldn’t that fuel a resurgence of Ayurveda and an acceptance in Western countries of the safety of Ayurvedic medications, and their therapeutic value, that would potentially benefit billions of people both outside and inside India?

References:


Choong, Emily (2018) Lead is an issue beyond childhood: A fact sheet by LEAD Group volunteer Emily Choong, using extracts of media articles about the landmark Lancet lead article by


https://www.ayush.gov.in/docs/guideline_safety_toxicity.pdf


PubMed (2020) 96 PubMed articles on lead & other heavy metal poisoning from Ayurvedic medicines, accessed 27th September 2020
https://pubmed.ncbi.nlm.nih.gov/?linkname=pubmed_pubmed&from_uid=11936709

Roberts, Anne; O’Brien, Elizabeth; Taylor, Robert; and JustOne Lead Soldier (2020) Health effects of a blood lead level below 10 µg/dL in both adults and children and even below 1 µg/dL in pregnancy, The LEAD Group Inc, 22nd September 2020.

SafeWork Australia (2018) Safe Work Australia, Safety by Topic: Lead - Managing risks associated with lead; Change to allowable blood lead levels; Lead processes and lead risk work; Health monitoring; Biological monitoring; Monitoring for airborne contaminants; Recent changes, April 2018, https://www.safeworkaustralia.gov.au/topic/lead

http://jama.ama-assn.org/cgi/content/abstract/292/23/2868

https://jamanetwork.com/journals/jama/fullarticle/182460?alert=article#_=_;
http://jama.ama-assn.org/cgi/content/short/300/8/915


Swan, Dr Norman, interview of Dr Robert Saper, Director, Integrative Medicine, Dept Family Med., Boston University, USA (2005), Heavy Metal Content of Ayurvedic Herbal Medicine Products, on The Health Report on ABC Radio

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Wikipedia (2020b) *List of countries by life expectancy*: The article documents lists of countries by average life expectancy at birth by various sources of estimates.  