GOVERNING PANDEMICS SNAPSHOT

A SERIES OF PERIODIC BRIEFINGS ON THE STATE OF GLOBAL REFORMS FOR PANDEMIC PREPAREDNESS AND RESPONSE (PPR) | JULY 2024

Welcome to the fourth issue of the Governing Pandemics Snapshot. Following the 77th World Health Assembly (WHA)'s endorsement of a delay of up to one-year for finalizing a Pandemic Agreement, the Intergovernmental Negotiating Body (INB) is set to resume its work with a two-day session on 16-17 July 2024.

INB member states will be facing two potentially contentious procedural issues, as well as thorny debates over the resolution of substantive matters including: a system for Pathogen Access and Benefit Sharing (PABS); references to One Health; and a formula assuring more equitable access to pandemic health products, where wide gaps remain. Debate around these outstanding issues is a focus of this latest issue of the Governing Pandemics Snapshot. The issue, produced by the Global Health Centre at the Geneva Graduate Institute, also unpacks the WHA-approved amendments to the International Health Regulations and their meaning.

More frequent updates are available on our timeline at governingpandemics.org. Feedback is welcome at globalhealth@graduateinstitute.ch.

Authors: Daniela Morich, Ava Greenup, Gian Luca Burci, Suerie Moon
Editorial team: Elaine Fletcher, Ava Greenup, Bétina Zago

PANDEMIC AGREEMENT TALKS EXTENDED: ONE MORE YEAR TO RESOLVE CRITICAL ISSUES

By Daniela morich and Ava Greenup

The INB is set to resume its work with a two-day session on 16-17 July 2024. At the 10th INB session, members face two potentially contentious procedural issues and resume discussions on how to tackle key unresolved substantive matters.

Contentious procedural issues

The May WHA decision to continue the pandemic talks for up to one more year, also allows for the INB to decide on rotation of the INB's leadership. Known as 'The Bureau', this consists of six regional country representatives including two co-chairs from The Netherlands and South Africa.

Over the past few months, there was widespread grumbling amongst INB members regarding the Bureau's management of the process involving both technical issues as well as perceptions of missed opportunities for bridging gaps in diverse country positions. At the same time, delegates also have acknowledged the difficult challenges the Bureau faces in forging consensus on hotly debated issues such as PABS.

While there are unconfirmed reports that the Dutch co-chair, Roland Driece, may be stepping down, the Africa Group is supporting its co-chair, Precious Matsoso, to continue in her position. Meanwhile, the status of the other Bureau members remains unclear. Maintaining the same members would ensure continuity, institutional knowledge, and established working relationships.

Conversely, a change in the leadership structure could introduce fresh ideas and new approaches, and a more gender-balanced leadership team, given that the current structure is predominantly male (5 out of 6 members).

The composition of the Bureau is closely linked to the second matter of interest for member states: methods of work. How the Bureau has run the INB has frequently been mentioned as another source of frustration for member states. The wording of the WHA decision suggests that member states

wish to retain the possibility of revising both the leadership structure as well as the organization of the INB's work going forward.

Closely linked to this is the question of how the group will handle the work completed during the first phase of negotiations? Will the 'convergence' already achieved on 143 paragraphs out of 177 be preserved? Or will they reopen the entire text for further negotiations?

PABS remains the key unresolved issue

One of the most challenging, unresolved issues is certainly the establishment of a *PABS system*, currently included in Article 12 of the draft agreement. Given its technical complexity and the deep disagreement signified by the almost complete lack of convergence text in the INB outcome report, it is likely to continue being the make-or-break article of the talks.

Negotiators have so far reached agreement only on the fact that such a system should exist. They agree the system should enable the rapid and timely sharing of pathogen materials and sequence information with pandemic potential alongside the "fair and equitable" sharing of benefits that derive from them.

But the precise architecture for pathogen sharing remains unresolved and will be central to the next phase of negotiations. Disagreements persist over the modalities, terms and conditions for sharing relevant materials - with pharma and high-income countries pressing for modalities that ensure the preservation of free access, while low- and middle-income countries aim for a closer linkage between sharing of pathogens and access to benefits.

Related to this, the use of standardized, legally binding contracts, user registration requirements, intellectual property rights, remain open. And finally, there is the question of whether any sharing mechanism set out in the Pandemic Agreement would effectively supersede similar provisions of other international instruments, notably the Nagoya Protocol of the Convention on Biological Diversity - a key demand of pharma and high-income countries.

In relation to the sharing of benefits, another key disagreement regards the actual percentage, or proportion, of vaccine and medicines set-asides to be offered for free or at concessionary prices in the event of public health emergencies of international concern and pandemics.

Some factions, notably LMICs are pushing for higher, fixed percentages, while higher income countries say that the proportions need to remain flexible and responsive to the context and geo-location of any pandemic emergency.

PABS as a separate technical instrument?

Given the obvious complexities, it also remains unclear whether the final details of the PABS system will be delineated in the framework of the Pandemic Agreement, or if they might possibly be moved into a separate protocol or other legal instrument.

Pre-WHA, proposals on the INB table included the possibility of having the WHA launch an open-ended intergovernmental process to negotiate the details of the PABS system in a separate instrument. Notably, this option is not included in the most recent version of the draft INB text, as it was "frozen" before the Assembly. But the idea was being informally circulated by the INB co-chairs as part of a draft WHA resolution in the last INB negotiations (INB 9) just prior to the Assembly.

Given the substantial amount of technical and operational complexity required to create an effective PABS system, it is very possible that INB negotiators may ultimately reconsider this approach.

It is noteworthy that several countries have emphasized the necessity of broadening the discussion to include experts from beyond governmental spheres in the PABS debate, full of technical nuance. Engaging expert participation will be crucial for developing a robust and effective PABS system that will significantly impact scientists, universities, researchers, and industries.

One Health

Negotiators have also extensively debated the inclusion of the One Health approach in the agreement, which acknowledges the interconnection between the health of people, animals, and ecosystems. Developed countries mainly support a strong One Health article in the pandemic text. But a number of developing countries, backed by CSOs, have raised concerns about the regulatory burden, costs, and potential barriers to agricultural trade that such provisions could imply.

While the draft agreement suggests an initial convergence on a One Health approach, the current text is very general and there remains divergence on developing an additional instrument after the adoption of the agreement to further define its modalities, terms, conditions, and operational dimensions.

Developing country negotiators are aware of the importance attached to this approach by developed nations and may leverage it tactically in future negotiations.

At the same time, a number of other prominent CSOs have protested this becoming a geopolitical football. Those One Health advocates point to the fact that high income countries, as well as LMICs, need to adopt stronger measures to prevent the spread of pathogens such as H5N1. And at the same time, LMICs that are on the front lines of pathogen spillover from the wild can reap huge benefits from greater integration of One Health approaches into pandemic prevention.

Access to health products

Intense discussions are also to be expected on substantive issues related to access to health products, as highlighted by our colleague Suerie Moon, in a separate article in this edition of the Governing Pandemics Snapshot.

Considering these deep divides as outlined above, and a fading political momentum, experts have warned that one additional year of work still might not be enough to bring these discussions to a close.

Strong leadership, political commitment, and good-faith international cooperation, such as that which facilitated the successful amendment of the International Health Regulations, will be essential to bring the Pandemic Agreement to a final agreement in time for the May 2025 WHA.

Dragging deadlines

Concerns about meeting the latest deadline for WHA 2025 are all the more pertinent in light of the fact that the past six months of negotiations have seen member states repeatedly add to, and prolong, working sessions well beyond their original time frames.

As of January 2023, negotiations had already been underway for almost two years, when the INB faced a crunch to complete the agreement by May 2024. That, as per its original WHA mandate received in December 2021, at the height of the COVID pandemic.

Since the beginning of the year, four sessions of the Intergovernmental Negotiating Body (INB) have taken place.

The eighth meeting of the INB, held from February 19 to March 1, 2024, advanced discussions through the work of the drafting group and thematic subgroups, focusing on a proposal tabled by the Bureau in October 2023. However, this marathon, two-week negotiation session did not achieve a significant breakthrough.

In early March, following member states' request, the Bureau circulated a Revised Draft of the negotiating text of the WHO Pandemic Agreement. The INB9, which convened from 18-28 March 2024, considered that draft.

Member states proposed numerous amendments and textual edits, resulting, at the end of the session, in a 110-page document with no clear strategy for bridging differing views. The gaps were all the more glaring in light of the Bureau's stated intention of convening INB9 as the final meeting before WHA77. But delegates were so far divided on key topics at the close, that a new INB session was scheduled to continue negotiations.

'Consensus-ready' text did not bridge gaps

A new Proposal for the WHO Pandemic Agreement was released on April 22 ahead of the 'resumed' INB9 (29 April to 10 May). This draft text, according to the Bureau, featured a streamlined, 'consensus-ready' text.

It included ample use of qualifiers such as 'voluntary' and 'as appropriate'. It also deferred the resolution of more contentious issues like PABS and One Health to two additional, separate instruments to be negotiated at a later stage.

The "consensus-ready text," unfortunately, did not bridge divided opinions, as member states remained deadlocked in opposing blocs - including the "Equity Bloc" of primarily LMICs; a bloc of European Union, North American and other high income nations, as well as the African Group and other geopolitical alliances.

Unwilling to concede turf, member states agreed to continue working in yet another resumed INB9 session from May 20-24, concluding only on the Friday just before Monday's start of WHA77.

The net result was nearly a month of non-stop negotiations for member states under the auspices of the INB, as well as the separately constituted Working Group on International Health Regulations.

By 24 May at 6 pm, it became clear that no agreement on the pandemic agreement would be reached, with convergence achieved for only 13 out of 34 articles - and the ball was punted to the WHA.

More successful IHR Working Group

By that same Friday, the IHR Working Group managed to arrive at a more successful conclusion, and the few outstanding issues remaining were resolved during WHA, leading to final approval of the amended IHR, on June 1, 2024. Unlike the Pandemic Agreement, the amendments don't require member state ratification - although nations may opt-out from the amendments if they wish.

Buoyed by the successful completion of the negotiations on the IHR, the hope is that the coming months will also put the INB over the goal post in time for the 78th WHA in 2025, at the latest, or if ready earlier, at a special session of the WHA in 2024.

IS THE GLASS HALF FULL? THE HEALTH ASSEMBLY AMENDS THE INTERNATIONAL HEALTH REGULATIONS (2005)

By Gian Luca Burci

The 77th World Health Assembly (WHA) adopted by consensus on 1 June a package of amendments to the International Health Regulations (2005) (IHR), marking a successful culmination of a process jump-started by the United States in January 2022. This achievement stands in contrast with the decision by the WHA to continue negotiations on the Pandemic Agreement until the 78th WHA in May 2025 unless a breakthrough occurs before the end of 2024. I have discussed in previous snapshots various aspects of the negotiations and the politics surrounding them which will not be repeated here. In this snapshot, I will briefly discuss some aspects of the negotiation process that have not been included in previous snapshots, summarize the most significant amendments and assess the possible way forward.

The process

Observers have been comparing favorably the IHR negotiation process with the parallel one for the Pandemic Agreement. Amending an existing instrument is obviously a different and potentially easier task than creating a new and unprecedented instrument from scratch, even though the quantity and diversity of proposed amendments to the IHR created much uncertainty initially.

Besides that consideration, however, other factors may have contributed to the outcome. Firstly, what may have made a difference in the IHR negotiations was paradoxically their lack of transparency: unlike the frequent issuance of new drafts by the INB's Bureau, the first publicly available draft was only proposed by the WGIHR's Bureau in April 2024. This may have given negotiators some flexibility by not being publicly associated with specific proposals during the process. Secondly, the Bureau constantly strived to reduce, consolidate and rationalize the proposals in a way that made further amendments easier to manage, while motivating its proposals at every step unlike the INB Bureau. Thirdly, the WGIHR had at its disposal a thorough analysis of the amendments performed by an expert Review Committee that was used tactically by the Bureau to steer the discussions.

The outcome of the process was uncertain until literally the end of the WHA, mostly with regard to provisions on access to health products and to financing (the "equity proposals"), the establishment of a new Implementation Committee, and to whether negotiators would insist in maintaining linkages with the Pandemic Agreement process until the latter would be ready for adoption. It is unclear what explains the breakthrough: maybe the transaction costs of continuing with two parallel processes, a successful framing of the IHR as a technical and operational instrument justifying more "targeted" amendments, and possibly the consideration that the "equity" language could be used as a precedent in the Pandemic Agreement negotiations.

The amendments

At the outset, it should be recalled that the WHA adopted a first set of amendments in 2022 for the purpose of shortening the entry into force of future amendments from 24 to 12 months; those amendments entered into force on 31 May, thus the amendments adopted on 1 June will fall under the "new regime" and will enter into force 12 months after their notification by the Director-General except for states that choose to "opt out".

Secondly, whatever our assessment about the appropriateness of the amendments, the quantitative difference between the initial proposals and what was adopted is striking and probably more responsive to the directions by the 2022 WHA to negotiate a package of "targeted amendments" rather than a wholesale revision of the IHR. This outcome may be seen as validating the fundamental approach of the IHR despite the criticism leveled against it during the COVID-19 pandemic.

The adopted amendments fall roughly into two groups. The first group is more "technical", remains within the existing framework of the IHR and aims at strengthening or clarifying it. The main instances include the following:

- The concept of "pandemic emergency" (Article 1) as a particularly disruptive and geographically diffuse form of public health emergency of international concern (PHEIC). A pandemic emergency is declared by the Director-General through the same process as a PHEIC (Article 12). It does not carry specific consequences under the IHR but it may trigger special measures under the

Pandemic Agreement, hence the importance of ensuring complementarity and synergy between the two. Member states rejected the proposal to introduce an "early action alert" for events not constituting a PHEIC but requiring WHO's recommendations. This omission is unfortunate and perpetuates the binary approach (either a PHEIC or nothing) criticized by many actors as unrealistic and unhelpful;

- The requirement for States Parties to establish or designate a "National IHR Authority" (Article 4) with the responsibility of coordinating national IHR implementation. This obligation fills a gap in many countries and reflects the need for a "whole-of-government" approach in responding to health emergencies;

- Harmonization of health documents (e.g vaccine certificates) requirements to improve mutual recognition and proof of authenticity in particular for digital documents (Article 35 and Annex 6). This responds to the confusion prevailing during the COVID-19 pandemic and the proliferation of uncoordinated certificates.

The second set of amendments is more political and mostly reflects the demands by developing countries to inject equity into pandemic prevention, preparedness and response (PPPR) as the main priority, with particular regard to guaranteed access to health products, promotion of local R&D and manufacturing, technology transfer and access to financial and other benefits. These issues have stalled progress in the INB but were eventually solved in the IHR negotiations through a number of compromises:

- Article 13 deals with facilitating equitable access to health products during a PHEIC or pandemic emergency. Unlike the draft Pandemic Agreement, where obligations are mostly borne by Parties, WHO is the main actor in Article 13 and has to carry out a broad range of functions including assessing availability and accessibility of health products and supporting States Parties in diversifying their production. States Parties play a supporting role and their obligations are heavily qualified by subjecting them to national law and available resources. Placing emphasis on WHO may have been tactically useful for reaching consensus and may be complementary to the Pandemic Agreement, but it has already been criticized for not adding anything new to what the Secretariat is already doing in its technical cooperation programmes. The scope of the amendments is also open to interpretation since the chapeau of paragraph 8 talks about facilitating access to health products only during a PHEIC or pandemic emergency, but the subsequent sub-paragraphs formulate activities functional to that purpose in a more general and unqualified manner, i.e. to be carried out at all times. Agreement on the scope will be essential because lack of consensus could hamper WHO's mandate and activities;

- The delicate issue of financing is dealt with in Articles 44 and 44bis, that do not establish a new fund as requested by developing countries but rather a "coordinating financial mechanism" under the authority of the WHA. The mechanism should promote and harmonize access to existing financing sources and mobilize new financial resources. Once again, the language is heavily qualified, does not raise new obligations and much will depend on the process to establish the mechanism and on the commitment of donors;

- On a different note but as importantly, Article 54bis fills a major institutional gap by establishing a "States Parties Committee for the Implementation" of the IHR that should provide a more robust engagement by States Parties than the WHA. The Committee is not a compliance mechanism but rather a facilitative and consultative tool to improve cooperation and mutual learning. This article is a compromise among three initial proposals and may be disappointing for the USA and the EU that aimed at a more pointed compliance mechanism. Still, the importance of discussing challenges and improvement within WHO's governance – rather than through external initiatives such as the Global Health Security Agenda – should not be underestimated.

Way forward

What are the next steps and how do we assess the outcome of the negotiations? The first formal step is the Director-General's notification of the amendments, which may be delayed by the request in the adopting resolution to ensure conformity among the six official languages of WHO since the working draft has only been discussed in English. The notification activates the deadlines for entry into force but also for rejecting the amendments or filing reservations. Some countries have already stated during the WHA that they reserve the right to do so, and the more "political" amendments may require internal consultations and parliamentary approval. 12 months may not be enough for many countries to go through those processes, or their outcome may not be positive for political reasons. A substantial number of rejections or reservations would considerably complicate the implementation of the amendments, in particular the institutional ones such as Articles 44bis and 54bis. They would

also compromise the universality of the IHR, often presented as the main appeal of WHO regulations as opposed to treaties.

Finally, how do we assess the outcome of the amendment process? As noted above, the amendments have been sharply reduced and in good part watered down from the initial proposals. An equity component has been retained in Articles 13, 44 and 44bis, but again in a qualified form and without strong obligations for developed countries. This is often the price to pay in multilateral diplomacy to achieve a result that at least satisfies a shared bottom line. However, whether the final compromise is satisfactory depends in good part on what we consider as the essential function of the IHR. In my view, unlike the Pandemic Agreement, the IHR are and should remain an operational instrument focusing on preparedness, detection and containment with a strong role for the WHO secretariat. While most of the amendments fit within that perspective, will the equity elements strengthen it and make the IHR more acceptable, or risk politicizing implementation and WHO's role? Is the proverbial glass half empty or half full?

WHITHER ACCESS TO HEALTH PRODUCTS IN THE AMENDED IHR AND DRAFT PANDEMIC AGREEMENT?

By Suerie Moon

If there's one word that could capture what the Pandemic Agreement negotiations have sought to achieve, it is equity. While equity can refer to many issues, from protections for health workers to the rights of vulnerable groups in pandemics, most often it has been shorthand in the past 3 years of negotiations for broader, faster, fairer access to health products such as vaccines, drugs and diagnostics. A number of provisions in the IHR and draft Pandemic Agreement would influence access to health products for pandemics, including those on research & development, technology transfer, intellectual property, PABS, supply chain, procurement and financing – and it is these articles that tend to face the deepest disagreements. Now that the IHR amendment has closed, what are the implications for access to health products?

What does the amended IHR offer on health products?

It was not an easy negotiation to gain acceptance of new language on health products into the IHR. While a number of developing countries submitted wide-ranging proposed amendments on equitable access and PABS, some stakeholders considered expanding the IHR to address health products to fall beyond the agreed mandate to make only 'targeted' amendments to the regulations. It is also worth recalling that the historical roots of the IHR were to protect trade and travel in 1890s Europe, not population health and not equity.

It is therefore notable that consensus was reached to amend the IHR to include the promotion of equity and solidarity – alongside respect for dignity, human rights and fundamental freedom of persons – as core principles.

However, principles remain just principles unless tied to specific actions. The substantive amendments on health products were made in the IHR's Article 13. As also flagged by my colleague Gian Luca Burci in his article on the amended IHR above, Article 13(8) mandates WHO to facilitate and remove barriers to access to health products "after the determination of and during a" PHEIC or pandemic emergency. Yet addressing access barriers, in practice, needs to be done before an emergency as part of preparedness. Measures such as building local production capacity, facilitating technology transfer, conducting R&D or assessing health product supply takes years of focused effort; it cannot be turned on and off like a water tap responding to an emergency declaration. Governments should clarify their intention that this work should take place before emergencies arise.

Furthermore, WHO has already been engaged for years in initiatives that would fall under this umbrella, including the mRNA technology transfer programme, Technology Access Pool, and conducting clinical trials for an Ebola vaccine, and managing emergency international stockpiles of certain products for outbreaks. Nevertheless, strengthening its mandate in this area would support potential expansion to a wider range of health products, more financing, and regular monitoring of this work.

However, when it comes to medicines, much lies beyond the control — and budget – of WHO. Rather, it is private industry and a few governments that often hold the strings, as during the Covid-19 crisis. During the height of the pandemic, industry had a strong incentive to supply vaccines first to the highest bidder and governments were all scrambling to secure scarce vaccine supply. The end result was the richest countries securing more vaccines than they could use and vaccinating their populations first, which continues to deeply shape negotiations today. The IHR amendments would do little to change this next time. "Subject to applicable law and available resources" governments commit to support WHO in addressing access barriers, to engage with and encourage companies in their jurisdictions

to facilitate equitable access to products, and to "making available" terms of R&D agreements "as appropriate" – the latter clause a small but important step towards transparency.

It is an important step forward. But it will not be enough to ensure more equitable access to health products in future health crises. Most of the concrete provisions seeking to do so lie in the draft Pandemic Agreement.

Pandemic Agreement

Before delving into what the most recent Pandemic Agreement draft says on health products, it is worth recalling that it is the first meaningful effort to build equitable access to health technologies into a treaty. There is no other pre-existing treaty that seeks to improve access to health products. Under the World Trade Organization 1994 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), access to medicines is treated as an objective to be achieved through the use of flexibilities – that is, it is the exception to the rule, not the main purpose.

The closest we come to binding international rules on access is the Pandemic Influenza Preparedness Framework, through which governments commit to share samples of influenza virus of pandemic potential quickly and openly, and in exchange, vaccine manufacturers that rely on those samples to develop vaccines commit to provide a number of benefits which may include to supply WHO with 10% of their pandemic influenza vaccine production, and make annual financial contributions. The PIP Framework was adopted in the form of a non-binding World Health Assembly resolution, but is given legal teeth through binding contracts between various parties. It is limited to influenza viruses with pandemic potential and to physical samples; it does not address other pathogens, nor the crucial issue of genomic sequencing data (GSD), which was critical for product development and surveillance during Covid-19. Despite its limitations, PIP has demonstrated the political feasibility of a pathogen access and benefit-sharing system, although its effectiveness for improving health product access has not yet been tested in an actual flu pandemic.

Recognizing the unprecedented nature of crafting concrete treaty provisions to ensure access to medicines puts the magnitude of the challenge and the stakes into perspective. The latest draft of the Pandemic Agreement reflects convergence on many issues, hammered out over many painstaking hours and late nights of negotiations. There is much agreed and valuable text on technology transfer, R&D, regulatory cooperation, and procurement – and perhaps surprisingly – on the contentious issues of IP, transparency and financing. On IP, governments have agreed to reaffirm the TRIPS flexibilities, reiterating the norm also contained in many multilateral texts agreed since the 2001 WTO Doha Declaration on TRIPS and Public Health. Importantly, they also commit to 'respect' the use of such flexibilities, which is an important step forward given that political pressure has been exerted on countries in the past when they have tried to set aside patent monopolies for public health purposes. But whether these areas of agreement hold, or whether they are re-opened for negotiation, is up in the air.

There remains disagreement on whether governments will commit to place equitable access conditions on public financing of R&D, which is important because governments pay for or subsidize much of pandemic product R&D, which is often too risky for the private sector to take on alone. There also remains divergence on the breadth and depth of technology transfer commitments, what the successor to the Access to Covid-19 Tools Accelerator (ACT-A) should look like, and PABS.

PABS is the lynchpin of the agreement, as my colleagues Daniela Morich and Ava Greenup highlighted above. But it is a difficult issue to resolve, politically and technically. Nevertheless, it is the most important issue keeping parties at the negotiating table, since a wide range of countries recognize that reliable rules for PABS would be a step change for keeping everyone safer.

It will not be easy to achieve consensus on health products, as this is one of the most contentious issues in global public health, with life-or-death implications for many countries and billions in profits at stake for industry. But after nearly three years of negotiations, diplomats have a solid understanding of the issues, the interests of various parties and their positions – agreement should be within grasp.

Finally, strong, clear obligations should remain the goal. But if only vague or weak obligations are what is politically possible, as suggested by the IHR, then complementary mechanisms for monitoring and accountability will be critical. Negotiators had little time to give governance arrangements serious consideration in previous rounds of talks, but there is space to do so in the year ahead. Accountability could include reporting obligations on governments, shadow reporting by civil society, strong transparency obligations, and enabling the participation of civil society and journalists in the Conference of Parties that often follows treaty adoption.

With the fast-spreading H5N1 epidemic in dairy cattle in the US and persistent cases of mpox in Africa, among other outbreaks, there is no shortage of reminders of why we urgently need a Pandemic Agreement with concrete, meaningful measures on access to health products.