Sustainable design and assessment of medicines

How do we define together?

BSI medicines environment standardization programme

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By Royal Charter

BSI Product environment categories rules – design and assessment

Introduction – Journey thus far

Whilst we understand the role that critical medicines serve in protecting populations and treating diseases and illnesses, it is also paramount that the patient safety and medicine efficacy is balanced and linked with the environmental impact of medicines during the production, use, and end of life uses of its lifecycle.

BSI, a National Standards Body, member of CEN, CENELEC General Assemblies, and founding member of ISO, has convened a series of working groups of pharmaceutical companies, healthcare systems, procurement and government agencies, and the financial investment community. The working groups have focused on better understanding current product environmental categories being used to inform the research and design (R&D) stages of new product design, the methodologies and considerations for lifecycle assessment/analysis (LCA) calculations and subsequently, in the procurement of sustainable medicines by pharmaceutical manufacturers' customers (healthcare systems, private hospitals, others).

Challenge outlined

There is an enhanced focus in the pharmaceutical manufacturers to report externally to customers (hospital systems, procurement agencies, and government buyers), shareholders, financial investors, and communities about sustainability. This has caused a lot of wasted time on reporting taking away resources from driving real environmental impact. Unfortunately, there's no consistent methodology for manufacturers to consider eco-design when producing medicines nor a way to assess environmental footprint of medicines consistently, leading to misaligned outputs and accusations of greenwashing or not doing "enough" by ecosystem stakeholders.

Additionally, it's preventing healthcare systems – who are starting to incorporate environmental criteria into their procurement commercial tendering process for medicines – from being able to benchmark or compare medicines' greenhouse gas (GHG) emission factors, impact on polluting environment, green chemistry composition, or even recyclability of packaging and plastics.

Finally, it is acknowledged that there's a need to link the environmental impact of medicines with the care pathway and impact on the patient in prescribing decisions.

BSI Product environment categories rules – design and assessment

Appetite for collaboration across healthcare ecosystem

Through a series of BSI convened industry engagement workshops, it was confirmed there is appetite for the healthcare ecosystem (regulators, government, procurers, manufacturers, and supply chain actors) to collaborate by co-defining what best practice looks like in this important area.

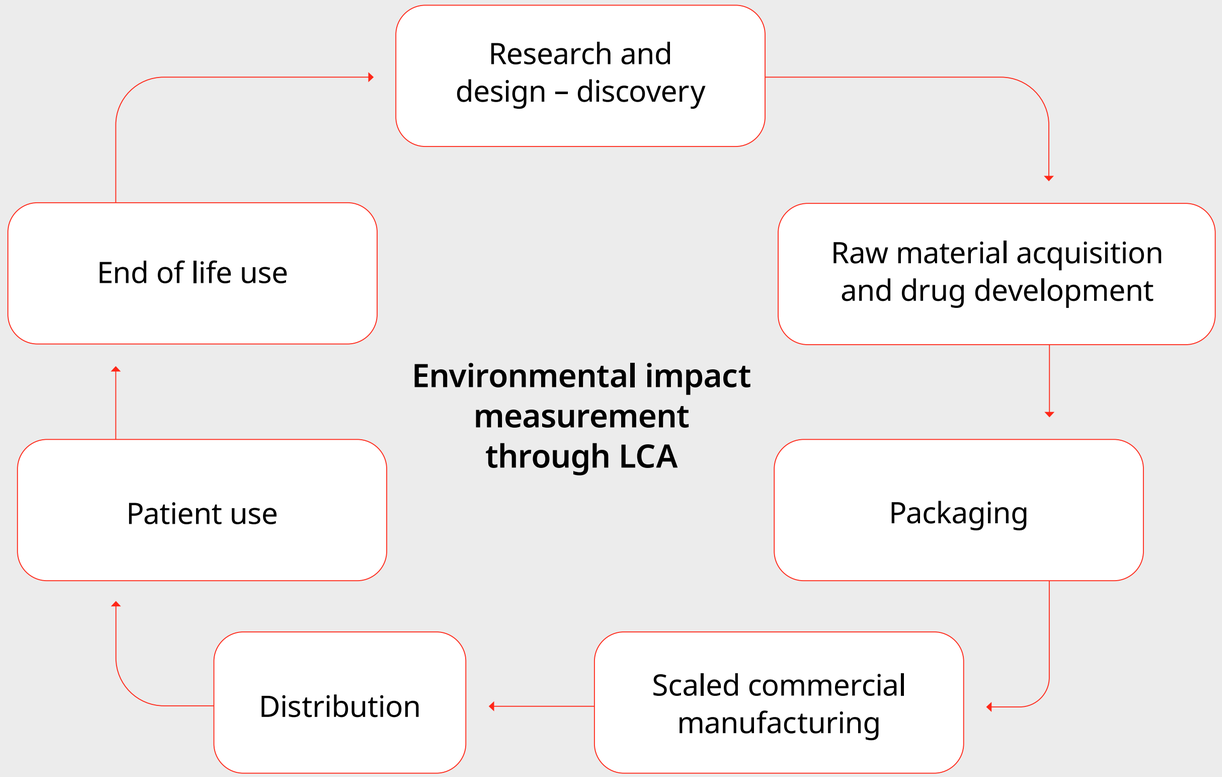
The BSI medicines environment standardization programme brings together the expertise and knowledge from across the healthcare ecosystem to achieve consensus around technical considerations for designing, assessing, and measuring the environmental impact of medicines – through product environment footprint categories, system boundaries, and LCA methodologies.

The concept would be to leverage the EU Product Environmental Footprint (PEF) measurement methodology and other international standards such as ISO 14067 but expanding upon it to create a medicine-specific environment footprinting measurement methodology. This definition and measurement methodology would be done through landscaping, prioritizing, and finally consensus-building through formal standards creation mechanism with BSI.

Drivers by stakeholder group – manufacturers

Manufacturers' desires – Product Environmental Footprint

- Integrate eco-design at each stage of medicine lifecycle.
- Better enable commercial and external affairs to trelay correct message, not greenwashing.
- Consistent methodology for measuring different product platforms.
- Desire to better capture data related to product environmental impact (existing and future drugs).
- LCA as an assessment technique to quantify the environmental impacts of medicines or processes throughout their life.

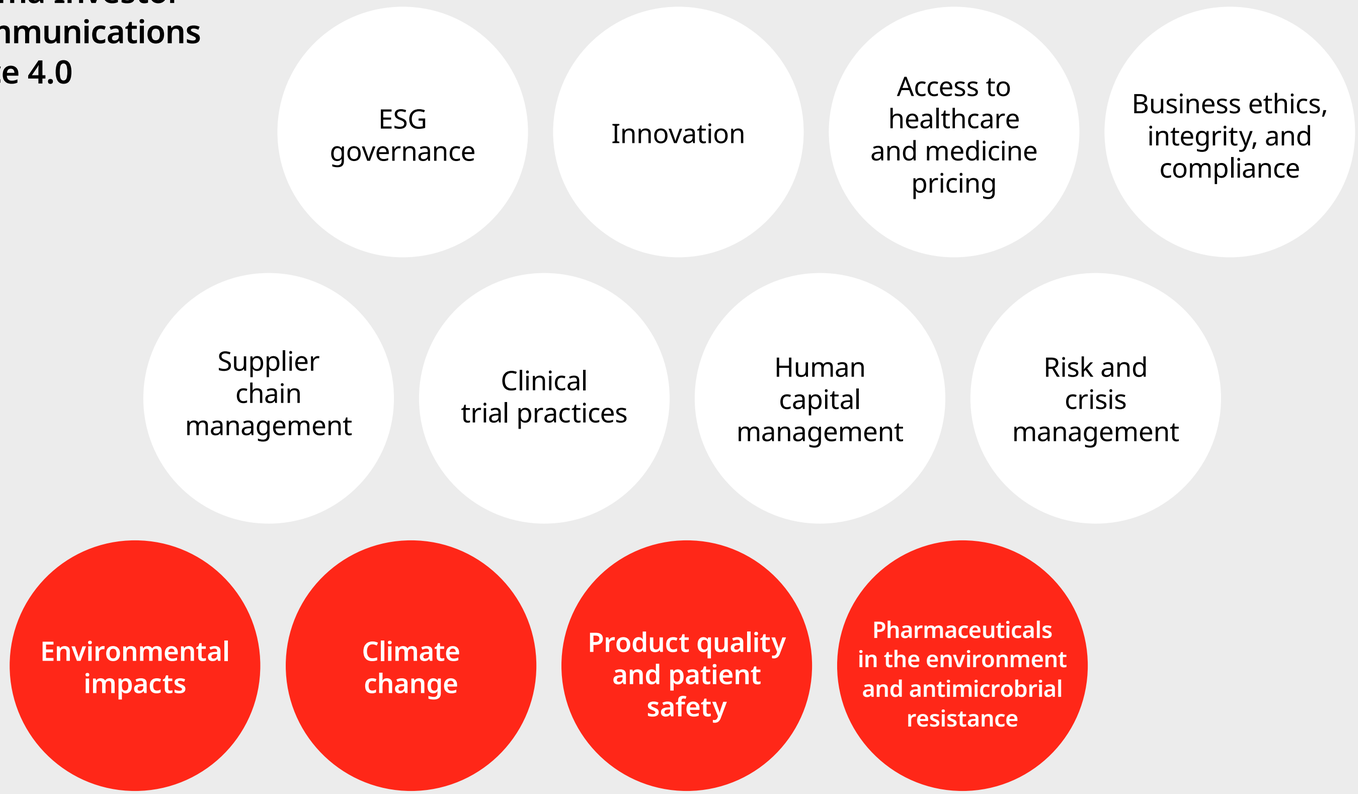


Drivers by stakeholder group – financial investment industry

Financial investment industry guidance on ESG to industry

- The financial investment community has produced a guidance to the biopharmaceutical sector with the request to communicate and report on key sustainability and environment, social, governance (ESG) initiatives externally. One of the key pillars of this ESG communication requirement is focused on climate change, environmental impacts, product quality, patient safety, and antimicrobial resistance (AMR).
- Used as evidence for green bonds from financial investment community towards the pharmaceutical sustainability program activity.

Biopharma Investor ESG Communications Guidance 4.0



Drivers by stakeholder group – healthcare systems

Healthcare systems – product footprinting and environment criteria setting

- Own the ability to drive pharmaceutical manufacturers to achieve and strive for greater environmental impact.
- Link data from LCAs with care pathways and treatment decisions.
- Have appetite to collaborate with manufacturers to define categories of environmental impact, with emphasis on GHG emissions as priority.
- Early stages of understanding what key environmental criteria are to systematically put into tenders.
- LCA data can be used for procurement but also for prescribing decisions.
- Should be applicable to all medicines, old, new, sold as sustainable or not.

Net Zero Supplier Roadmap, NHS England – Example of healthcare systems incorporating environmental requirements into commercial tenders

From April 2022:

All NHS procurements will include a minimum 10% net zero and social value weighting. The net zero and social value guidance for NHS procurement teams will help unlock health-specific outcomes (building on PPN 06/20).

From April 2023:

For all contracts above £5 million per annum, the NHS will require suppliers to publish a carbon reduction plan for their UK Scope 1 and 2 emissions and a subset of scope 3 emissions as a minimum (aligning with PPN 06/21). Carbon reduction plan (CRP) requirements for the procurement of NHS goods, services and works guidance outlines what will be required of suppliers and how it will be implemented.

From April 2024:

The NHS will extend the requirement for a carbon CRP to cover all procurements.

From April 2027:

All suppliers will be required to publicly report targets, emissions and publish a carbon reduction plan for global emissions aligned to the NHS net zero target, for all of their Scope 1, 2 and 3 emissions.

From April 2028:

New requirements will be introduced overseeing the provision of carbon foot printing for individual products supplied to the NHS. The NHS will work with suppliers and regulators to determine the scope and methodology.

From 2030:

Suppliers will only be able to qualify for NHS contracts if they can demonstrate their progress through published progress reports and continued carbon emissions reporting through the Evergreen sustainable supplier assessment.

NHS England

Drivers by stakeholder group – government and regulators

Future government policy and regulatory frameworks

- Health and social care government agencies and medicines regulatory agencies are in early stages of their journey of landscaping what the important environmental considerations are to embed in government policy.
- Regulators are starting to understand the conflicts between current regulations for medicines quality and safety control and environmental aspirations of the manufacturers.
- Stakeholder mapping and key environmental considerations are starting, and collaboration with national healthcare systems to align in progress on sustainability considerations for medicines.
- One of the main blocks of EU Green Deal – focuses on the design and production, and end-of-life use for a circular economy for almost all products on the EU market, including medicines.

Key considerations: Environmental criteria and categories – define, align, and measure

Healthcare systems

Some of the more mature healthcare systems' procurement, including the UK NHS and the Nordics, are becoming more systematic in defining environmental criteria in commercial tenders for medicines. The Greener NHS team has placed strong emphasis and priority on GHG emissions footprinting, and Nordics y are keen to influence change around manufacturer product design processes, with initial priorities around plastics, pollution, waste, and GHG emissions. Participants in in North America noted that their hospital systems are less advanced than their counterparts in Europe when it comes to environmentally preferable purchasing – or EPP as it is known. Crucially, a key obstacle is weak EPP standards and data. Measurement is currently either high level or qualitative (typically surveys), with no standardized or consistent cross-industry metrics.

"I can envisage a time when the environmental footprint of products will influence procurement decisions in the same way price does."

"The standard criteria must be challenging enough to drive the change we're trying to achieve. The fear is of industrial 'greenwashing' because it is difficult to validate manufacturers' claims. We can incentivize them to adopt it – there seems to be widespread eagerness to move in that direction."

Manufacturers

The manufacturers themselves are at different levels of maturity in areas of environment design and therefore, have differing product capabilities and data related to different environmental impact areas – i.e. some are very mature in green chemistry, but haven't had as much progress on Scope 3 emissions or vice versa. Manufacturers' R&D groups are conducting a lot of upfront work to ensure sustainable product design is done systematically and data-driven through LCAs, with focus on environmental impact. There isn't a consistent way to carry out the environment footprint on different medicines between manufacturers – including where the system boundary of the medicine's lifecycle starts and stops. Legacy product data can be difficult, so manufacturers want to shift to being more proactive in new R&D efforts to create a sustainable medicine. Finally, there's a trend identified by the manufacturers that the majority of healthcare systems are focussing organization-wide net zero as the primary objective. There's an acknowledgement that net zero should be the goal, but GHG emission reduction is only one area where environmental impact can be made, especially with medicines.

"I know we and other manufacturers are looking at this, and if they've made progress, there's a real need in the industry to share and align on them – please share it."

"We're forward-thinking, but many of our products are long established. Making these more sustainable retrospectively is a very different challenge to building in sustainability on an innovative platform."

"A lot of attention is put on the sustainable sourcing of packaging materials. Also, the extent to which packaging can be recycled. In the pharmaceutical industry's LCAs, we've identified that packaging relates to less than 1% of environmental impact, compared with, say, the impact of Pharmaceuticals in the Environmment (PiE)."

Key Considerations: Data and Benchmarking

There's no denying that tensions between manufacturers and healthcare systems exist over data related to product environmental footprints. Healthcare systems are capturing significant amounts of data from tender requests relating to environmental attributes of medicines, but manufacturers have no understanding of what happens with that data or how it is used to inform purchasing decisions – how are medicines compared or weighted for being "sustainable?" Sustainable product design is being used by some organizations overtly as a competitive differentiator, but comparisons are often impossible, making it difficult to make it relevant in commercial tenders.

Similarly, manufacturers are publishing external sustainable product goals as an investment differentiator to attract investors and equity analysts – but such goals are not easily compared, nor their achievement easily verified. There's also a need to ensure that patented medicines/products and generic medicines are both considered in this process, so we can determine a way to benchmark organizations, in commercial tenders – but also in terms of driving improvement and impact for the environment.

> "There's a lot of data collection, but we wonder what's happening with it all – is it actually used in purchasing decisions or just going into some sort of data lake!"

> "The data may not exist for legacy products. How do we accommodate that?"

Healthcare systems

It remains difficult for hospital systems to compare data in tender submissions. The key challenge for them is how to define a clear and consistent set of environmental criteria and award acceptance mechanism in tenders. Without collaboration between hospital systems and manufacturers to create more standardized criteria, the likelihood is that hospital systems will end up with vast, increasing volumes of data and evidence, with no mechanism for comparing 'apples with apples'. The expertise within healthcare systems procurement doesn't enable deep subject matter knowledge on each area of environmental impact of medicines – such as Pharmaceuticals in the Environment, or even Green Chemistry – there should instead be a simple way for healthcare systems to compare data outputs from such environmental analysis on a product level.

> "We need to agree with manufacturers and other industry stakeholders what the key environmental attributes should be – along with consistent measures for them."

> "If we ask for data in a systematic way, they will be able to provide it in a systematic way."

> "We may not be able to require the same level of environmental reporting for legacy medicines as we expect for new ones, but we will still want some assurance on the environmental impact of a legacy medicine."

Manufacturers

Manufacturers have said that healthcare systems continually require them to reach back into their R&D divisions to meet many and varied data collection demands – which is an expensive, time-consuming process. Manufacturers' R&D groups are conducting a lot of upfront work to ensure sustainable product design is done systematically and data-driven, with focus on environmental impact. Now, manufacturers' commercial functions are having to go back to operations and or the R&D groups to find additional data points requested in market entry/commercial tenders from hospital systems, which weren't originally included in product design plans. There is a risk that manufacturers begin to just submit tender responses to "tick a box" rather than accurate and comparable data, against an aligned methodology.

> "Right now, we haven't even agreed what those data points are. A good starting point would be to list, say, 12 key categories – from emissions to process mass intensity to waste-water discharge where we know manufacturers can provide data – so at least when HCPs are starting to gather data, it's at least around those 12 points. After that, we can start to weight them in importance."

Key considerations: Collaboration

One conclusion from the various workshops was an agreement that the development of a framework or standard would be the best starting point to drive long-term environmental impact with hospital systems and manufacturers. Participants acknowledged that there are likely to be many steps on the way to creating a mature system for ensuring sustainable product design and LCA measurement. The consensus and engagement of the ecosystem of manufacturers and hospital systems is critical – and the initiative should not be done with a bias to one view or the other, thus facilitated by a neutral and impartial body. There is an inherent need to establish more trust between parties around what is really environmental impact vs. what is perceived “greenwashing.”

Currently, the lack of alignment on methodology and data outputs is causing tension and lack of real environmental progress or impact. When setting out the different environmental product categories criteria, there needs to be a thought of how it would be measured or reported for data; however, the “how” to collect data should not prevent us from first agreeing on the categories and methodology to measure together. Finally, the initiative should seek to have a global view, rather than a single geography.

> “Clearly, what we can achieve today may not be where we want to end up with. We need objectivity and technical expertise to understand what is possible and practical, recognizing that this will be a continuous improvement process.”

Healthcare systems

Hospital systems would support a cross-industry initiative to accelerate the creation and adoption of a universally recognized standard for environmental footprint of medicines. Whilst each healthcare system recognizes their independent, national or local need to create environmental criteria, there was an agreement that a global approach was required. Without collaboration between hospital systems and manufacturers to create more standardized criteria, the likelihood is that hospital systems will end up with vast, increasing volumes of data and evidence, with no mechanism for comparing ‘apples with apples’. That is the key challenge they face.

> “We need to agree with manufacturers and other industry stakeholders what the key environmental attributes should be – along with consistent methodology for measuring.”

> All we want is a meaningful standard and assurance that the standard has been met. We don’t really need to know all the technical details. We just need to be able to trust that there’s a framework that the manufacturer is adhering to and that it’s been independently verified.”

Manufacturers

Pharmaceuticall manufacturers signalled their strong support for an impartial, trusted convener and consensus-building organization to take the lead in facilitating the process to define a sustainable medicine. When setting out the different environmental product categories/criteria, there needs to be a thought of how it would be measured or reported for data; however, the “how” to collect data should not prevent us from first agreeing on the categories together.

> “There are many people working on this in silos and coalitions – and some of them think they’re in the lead. My own view is that no-one is in the lead! We’re really keen to achieve some consensus and influence a standard approach. That would be way better for everyone in the inustry – manufacturers and their customers.”

> “It’s great that BSI has brought us together. BSI is the independent and impartial body that we can all feel comfortable to be involved with.”

> “As manufacturers, we should work together to inform hospital systems about where sustainable product design can lead to better environmental impact and improved LCA development.”

Taking a lead – BSI’s convening role

BSI can be a trusted agent of change, for organizations and businesses, helping to establish trust across the healthcare industry in a more holistic ecosystem approach.

When industry leaders recognize the importance of working together to agree on standards and best practice frameworks, BSI, with more than 100 years’ experience, convenes people and expertise to lead this effort.

We understand how organizations use national and international rules-based standards, systems of frameworks, and regulation. This enables us to act as a neutral convenor of industry, government, and societal stakeholders, bringing an independent view to the development and implementation of trusted market frameworks, standards, or policy.

Our duty to convene industry is supported by our impartiality, backed by our status as a National Standards body, our trusted role as a Notified Body on behalf of regulators, and our non-profit distributing company status. In the healthcare industry, this means providing expert independent advice and creating stakeholder consensus in the most effective way for industry to build trust and deliver desired outcomes in terms of sustainability ambitions, government policy and patient trust.

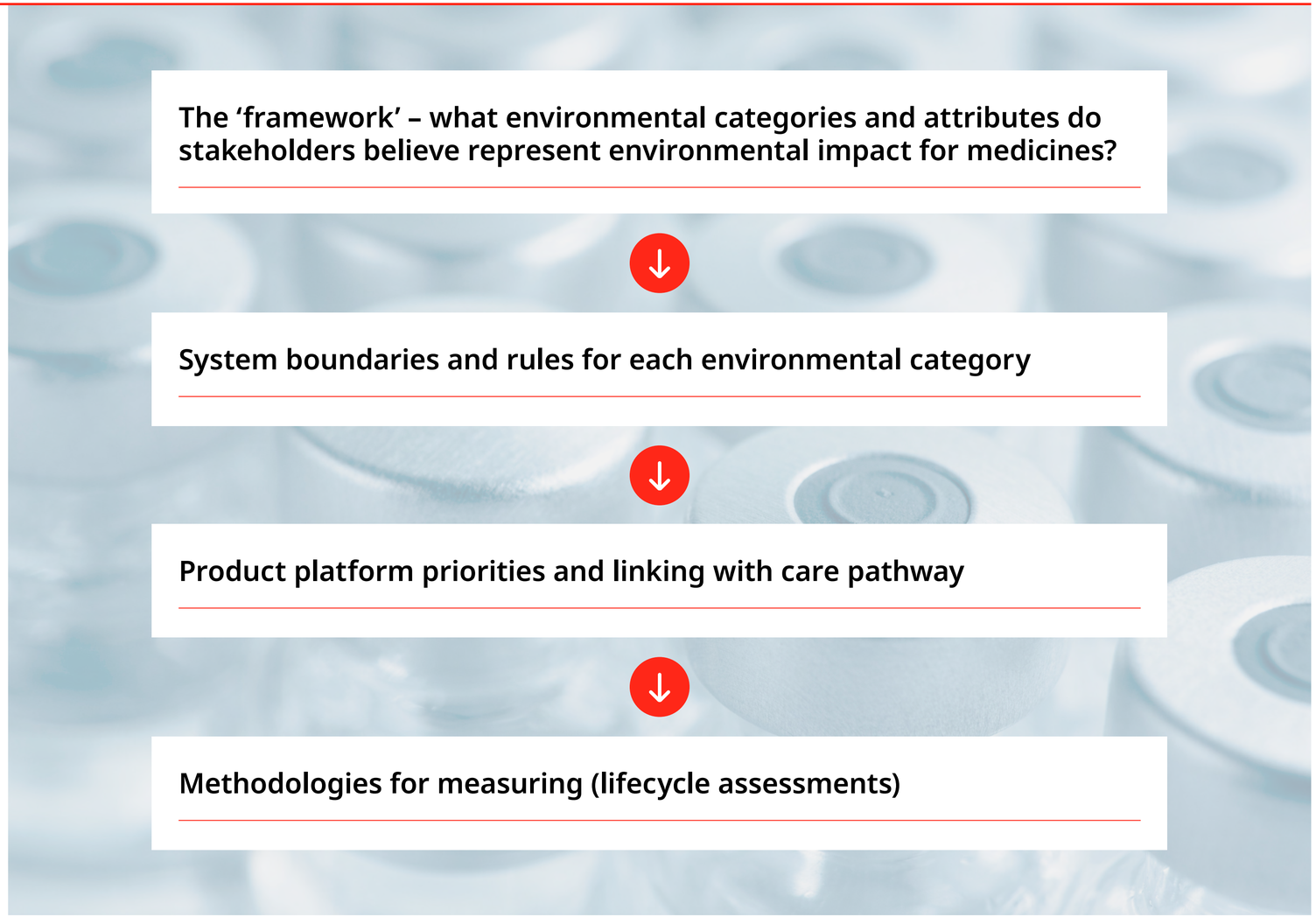
The experience BSI has in convening industry enables us to maintain an independent, non-competitive position, and to support collaboration aimed at solving challenges of today and the future.

Next steps – driving action

BSI proposes to engage further with hospital systems, manufacturers, trade bodies, policymakers, regulators, academia and others across the healthcare ecosystem. Given the consensus from our roundtable workshops and market research that there would be value in having a programme of standards for product environmental footprint – we now want to get all stakeholders together to build on this common ground and drive action.

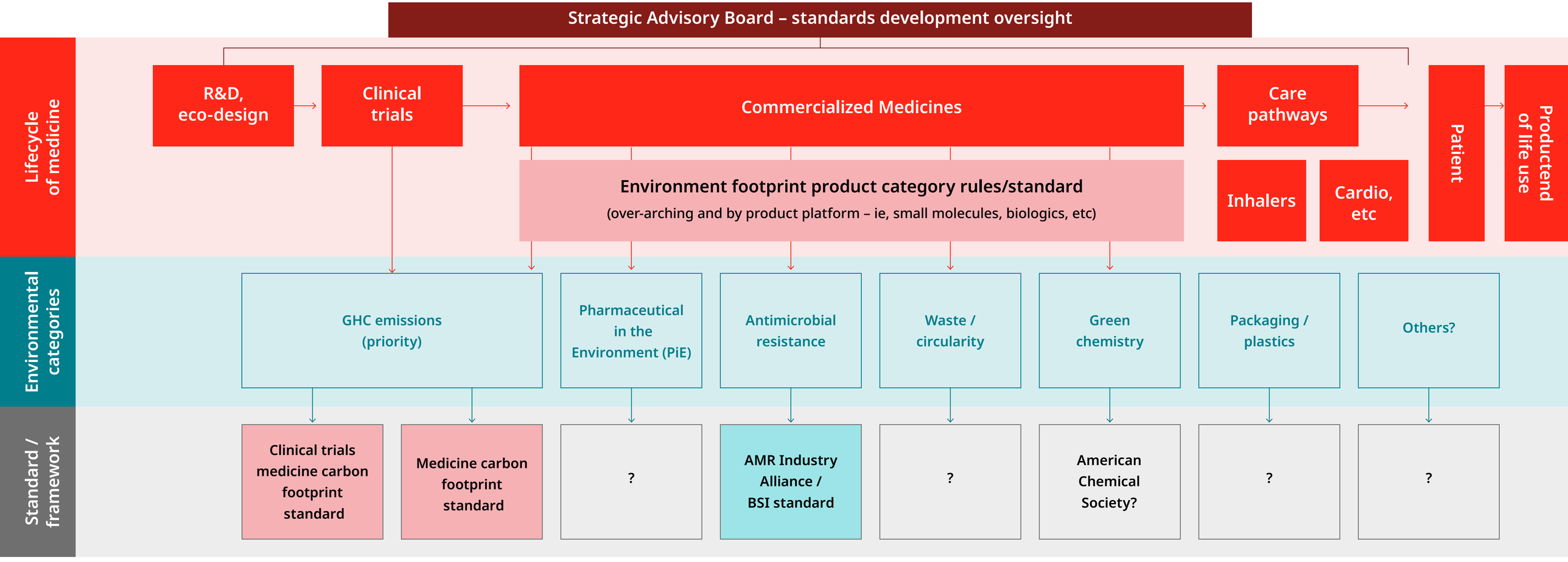
The next steps (opposite) would involve further collaboration, drafting, wider consultation and review. The starting point would be the formation of a steering group to establish.

> “What will help here, is the history of BSI, which gives credibility across all the different parties – manufacturers, HCPs, governments – everyone.”



Healthcare ecosystem – medicines environment standardization programme

Healthcare systems would support an initiative across the ecosystem, including manufacturers, healthcare systems, academia and government, to accelerate the creation and adoption of a universally recognized standard for environmental footprint of medicines.



Where we have come from and where we are going?

	Awareness / Manufacturing workshops	Wider ecosystem – workshops	Launch – landscape and prioritization / roadmap	Standards Development	Metrics and assurance
Activity	Through prospectus document and workshops – **Engage** industry ecosystem to raise awareness, validate and hear perspectives. Focus initially on manufacturers community.	**Engage** wider industry ecosystem to raise awareness, validate and hear perspectives – trade bodies, regulators, financial investment community, and healthcare systems.	**Launch** formal program of work. First steps – review landscape, prioritization of activities, finalize road map program of work including milestones though forming Strategic Advisory Group and awareness communities for input and engagement.	Form standards committees, nominate technical author, define industry committee members, **develop** an industry standard to define environmental footprint measurement methodology for “sustainable product medicines”.	Develop a metrics / assurance mechanism for verifying compliance and best practices against the created standard.
Timeline	Q3/Q4 2023	Q1 2023	Q2/Q3	Q4 2023 – Q4 2024	Parallel or subsequent

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