Medicines Environment Standardization Programme
BSI convening a multi-stakeholder, consensus-driven standards programme for defining and aligning terminology, methodologies, and measurement of environmental impact of medicines.

R&D, eco-design → Clinical Trials → Commercialized Medicines → Environmental footprint - measuring medicines impact

GHG Emissions (priority) → Pharmaceutical in the Environment (PIE) → Anti-Microbial Resistance → Waste / Circularty → Green Chemistry → Packaging / Plastics → Others?

Care Pathways → Patient → Others? (Inhalers, Cardio, etc.)
AMR is a top 10 global public health threat according to the WHO and is expected to get worse. It threatens to undermine the basis of modern medicine by rendering the antibiotics used to treat and prevent infections ineffective, making medical advances. In 2019, antimicrobial resistant bacteria accounted for 1.27m deaths and contributed to another nearly 5m deaths during the same year, according to IHME/The Lancet.

BSI Approach - Project

Industry Standard - following extended relationship building, the AMR Alliance engaged BSI facilitate development of a private standard by working with the Alliance and multiple industry stakeholders.

Certification Scheme- The Alliance and BSI will develop a certification scheme and serve a governance and program management role that will enable antibiotic manufacturers to demonstrate that the requirements of the Standard have been satisfied.

Benchmark / Data - Pharmaceutical environmental expertise from the consulting business has served as a critical role for the development of the standard and in supporting certification assessment model for the future scheme.
Ecosystem-wide approach to consensus – BSI convening community of practice

Consensus communities comprises:
- Typically 10 to 15 stakeholders
- Broad range of stakeholders e.g. patients, regulators, customers, associations, academics, etc.
- Signed up to a Steering Group protocol around consensus

Responsible for:
- Providing stakeholder group expertise
- Reviewing and commenting on technical drafts
- Attending Steering Group meetings
- Resolving comments, building consensus and approving drafts
- Identifying stakeholders for the Review Panel
Healthcare systems’ point of view
Defining environmental impact categories for benchmarking medicines in commercial tenders

Healthcare systems procurement are becoming more systematic in defining environmental criteria in tenders. They are keen to influence change around manufacturer product design processes, with initial priorities around GHG emissions. BSI ran a 8 geography healthcare systems workshop where we received feedback on the appetite of HCPs to collaborate with industry to co-define LCA methodologies and data mechanisms:

- 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.

Manufacturer’s point of view
Defining environmental impact categories and methodologies for consistent LCA data

The pharmaceutical industry has taken more seriously in recent years the approach to developing products that have focus environmental impact based on life cycle assessment (LCA) – focusing on “eco-design” R&D stage for new medicines, through towards the end of life purpose of medicines.

Manufacturers’ desires
- Integrate eco-design at each stage of medicine lifecycle.
- Better enable commercial and external affairs to relay 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.
  - "If we ask for data in a systematic way, we will be able to provide it in a way that can be understood by everyone, not just the experts."
Agreement to progress together as a healthcare ecosystem

“It varies by geography, and even by hospital procurement systems within geographies. We need to push forward together, rather than duplicate efforts, with all the extra workload that creates.”

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

“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.”

“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 industry – manufacturers and their customers.”

“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.”

“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.”
A unique combination of BSI statuses – role of a neutral convener

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<th>National Standards Body</th>
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<th>Consulting Body</th>
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<tr>
<td>Creation and sharing of standards</td>
<td>Assessment / Certification</td>
<td>Acting on behalf of regulator to approved medical device safety and quality at market entry</td>
<td>Sustainability, EHS, and supply chain practices</td>
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<td>Legacy of consensus building</td>
<td>Product Certification</td>
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<td>Convener of industry ecosystems</td>
<td>Training / Upskilling</td>
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<td>Global auditors, understand assessment methods</td>
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<td>Ability to link assessment with regulation</td>
<td>Deep SME for program governance &amp; vendor improvements</td>
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Not-for-profit distribution, Global, Royal Charter
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**Standard / Framework**

- R&D, eco-design
- Clinical Trials
- Care Pathways
- Patient

**Lifecycle of Medicine**

- **Commercialized Medicines**
  - Environmental footprint
    - Product category rules/standard
      - (Over-arching and by product platform – i.e.- small molecules, biologics, etc)

**Environmental Categories**

- GHG Emissions (priority)
- Pharmaceutical in the Environment (PIE)
- Anti-Microbial Resistance
- Waste / Circularity
- Green Chemistry
- Packaging / Plastics
- Others?

**Environmental footprint**

- Clinical trials Medicine carbon footprint standard
- Medicine carbon footprint standard
- AMR Industry Alliance / BSI standard
- American Chemical Society?

**Strategic Advisory Board**

- Standards development oversight

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Express interest in learning more or participating

Register interest in stay informed of progress in this workshop