All information regarding future IHI Call topics is indicative and subject to change. Final information about future IHI Calls will be communicated after approval by the IHI Governing Board.

Topic 5: Safe & sustainable by design (SSbD) packaging and single use device solutions for healthcare products

Expected impacts to be achieved by this topic

The project is expected to strengthen and make more competitive the European healthcare industry by positioning it at the forefront of the development of medical technologies, products, and services of the future - those that generate less waste, require less waste treatment, have reduced carbon footprints, increased circularity, and other approaches that reduce the environmental impact of healthcare.

It aims to promote the development of new health products by integrating the principles of the safe & sustainable by design (SSbD) framework[1], from the earliest design stages, and notably for packaging and device design including the end-of-life of a product. In the context of this call, packaging includes primary packaging in direct contact with products (e.g. drugs, medical devices, *in vitro* diagnostic reagents, etc.) and secondary packaging made of plastic polymer materials – excluding secondary and tertiary cardboard packaging. Medical devices refer to single-use plastic pharmaceutical and medical devices used for the administration of medicines such as pens used for insulin injection or devices used for surgeries such as trocars and staplers. They may contain additional components such as metals and electronic components as is the case of smart staplers, for example.

The project should as a minimum have all of the following impacts:

- Developers of health products (e.g. drugs, medical devices, *in vitro* diagnostic reagents, combination devices, etc.) are able to draw general lessons and best practices for their current research, and integrate research results on packaging and devices that generate less waste, make more efficient use of materials, and minimise the use of single-use components.

- Alignment with the European Green Deal objectives for healthcare systems, especially in the field of waste management and CO_2 reduction, as well as an improved competitive position for healthcare companies.

- Improving the recyclability of medical devices, independent of whether the material of construction (e.g. plastic, metals) is classified as non-hazardous or infectious waste.[2]

- Reduced carbon footprint of health products in alignment with the Paris Agreement on climate change and the European Green Deal (55 % by 2030, NetZero by 2050).

- Propose new solutions that are holistic in nature, and which do not create additional adverse ESG (environment, social & governance) issues.

- New solutions should facilitate circularity even if the end points are not a closed loop back into the healthcare sector and instead are used for other applications.

[1] https://publications.jrc.ec.europa.eu/repository/handle/JRC128591
[2] https://www.who.int/news-room/fact-sheets/detail/health-care-waste

- Identify a range of physical, mechanical, chemical and/or composting recycling infrastructures such that packaging materials and single-use medical devices (e.g. pens used for insulin injection, surgical trocars) can be recycled.

Expected outcomes

The project should contribute to the following outcomes:

1. Paradigm shifts in standard materials to shape products of the future (e.g. reduced material usage by pushing the boundaries on material specifications such as down gauging foils/films, blending virgin and recycled polymers, inclusion of more sustainable materials as newly proposed from material suppliers, etc.).

2. Development of new and effective technologies, products and innovations that generate minimal waste from packaging and enable the recycling of used devices (including devices which have been in contact with human tissues, i.e. infectious waste[3]) throughout their lifetime of use in healthcare systems, by applying the principles of the safe & sustainable by design (SSbD) framework.

3. Alignment with the European Packaging and Packaging Waste[4] and Ecodesign of Sustainable Products[5] Directive proposals.

4. Such innovations – i.e. packaging materials & single-use medical devices (e.g., pens used for insulin injection, surgical trocars) are easily accessible in sufficient quantities to healthcare providers (e.g., hospitals, medical analysis laboratories, caregivers, and patient associations/organisations).

5. Environmentally-friendly packaging and device materials are designed from sustainable raw components and manufacturing processes with minimal carbon footprint.

6. Selective sorting procedures, implementable by healthcare providers.

7. The creation of short circuits for recycling packaging and device waste from healthcare providers' locations.

Healthcare systems more widely adopt a lifecycle assessment approach, enabling healthcare to become a more sustainable industry with closer and more circular recycling loops for packaging as well as single-use devices, including those which may have been contaminated (i.e. infectious waste).

Solutions should include a holistic approach such as:

1. adoption of biomass balanced materials that reduce environmental impacts, and

2. inclusion of advanced recycling technologies such as various chemical recycling technologies (hydrolysis, pyrolysis, solvolysis, etc.) if improvements to environmental impacts can be properly documented.

[3] https://www.who.int/news-room/fact-sheets/detail/health-care-waste
[4] https://environment.ec.europa.eu/publications/proposal-packaging-and-packaging-waste_en
[5] https://environment.ec.europa.eu/publications/proposal-ecodesign-sustainable-products-regulation_en

Patient outcomes and the safety/performance of medical products should not be compromised by the environmentally-friendly packaging and device solutions to be developed by the project.

Notably, these packaging solutions should be compliant with existing standards (e.g. primary packaging with sterile barrier: ISO 11607) to guarantee the safe use of medical products, i.e. maintenance of the safety and performance levels that are claimed throughout their intended shelf life.

- Depending on the use cases selected by the project, they must provide a sterile barrier, maintain controlled humidity, protect against light, etc. throughout their shelf life, including shipment from manufacturing site to end users.

- When used as a sterile barrier, they should be compatible with common sterilisation processes (e.g. steam, gas sterilisation such as hydrogen peroxide; radiation treatments such as e-beam, gamma irradiation, X-rays, etc.).

- When used as medical products for use in humans, existing safety & biocompatibility standards are met such as European Pharmacopeia (EP) compendia, ISO 10993, etc. (e.g. not generating extractible and leachable harmful products during the full shelf life of the products).

- The chemical and physical properties of the new material formulations should also guarantee the intended shelf life of the medical products (e.g. up to 5 years).

- Work with regulators (e.g. European Chemicals Agency (ECHA), European Directorate for the Quality of. Medicines & HealthCare (EDQM), European Pharmacopeia (EP), US Pharmacopeia (USP), American Chemical Society (ACS), etc.) to create new or revised standards/monographs for new materials that are used in health products. By extension, this engagement should contribute to the generation of future product eco-design labels / green claims.

- For example, the use of packaging composed of biodegradable, recyclable and/or environmentally benign ingredients is favoured if the claimed performance and safety of the medical products are maintained.

- Improved and simplified protocols for the management, collection, and recycling of medical device waste (packaging and devices) to reduce waste management costs for healthcare providers and minimise the environmental impact of the medical waste generated by medical devices.

- Protocols for the collection of single-use devices and their packaging to drive circularity should be easily implementable by healthcare providers. Their adoption must be possible for the greatest number of healthcare providers, regardless of their location. They may potentially include the decontamination of products if they have been in contact with human tissues to allow their sorting and recycling under the safest conditions.

- Improved and simplified protocols for supply chains and logistics for sorting of packaging waste of health products for healthcare providers with a minimised carbon footprint.

The outcomes must be as cost-effective as possible so as not to burden health systems with prohibitive additional costs.

Overall, the project is expected to yield strong results from the use cases. The results should be taken as evidence to collaboratively shape European legislation on packaging and packaging waste and the eco-design of sustainable products for health technology industries.

Scope

Product development

The project should accelerate the implementation of alternative eco-packaging and device materials through collaborative work by including policy makers, regulators, and standards bodies. It should identify, characterise, and test new replacement materials according to specifications and in compliance with existing standards (e.g. primary packaging with sterile barrier: ISO 11607).

The project should examine the European landscape of materials, whether commercially available or under development, which may be acceptable as components of sustainable packaging and appliance solutions, from different perspectives, regulations, possibility to recycle with current and future waste management processes, and sustainability of industrial supply. Such a review can benefit from and partner with the European Partnership for the Assessment of Risks from Chemicals (PARC) and with the successor partnership of the M.ERA-NET III and the AMI2030 initiative. In addition, synergies with projects funded in the Horizon Europe Cluster 4 addressing SSbD could be envisaged (HORIZON-CL4-2023-RESILIENCE-01-21: Innovative methods for safety and sustainability assessments of chemicals and materials (RIA); HORIZON-CL4-2023-RESILIENCE-01-22: Integrated approach for impact assessment of safe and sustainable chemicals and materials (RIA); HORIZON-CL4-2023-RESILIENCE-01-23: Computational models for the development of safe and sustainable by design chemicals and materials (RIA)).

Health tech companies are expected to design and develop new packaging and devices (e.g. insulin pens, staplers) by starting from solutions that already exist or are at an advanced stage of development (e.g. available paper-based covers / packaging seals reinforced with polyolefins, or mixtures of virgin and chemically recycled polymers for the manufacture of blisters), and/or by selecting fully compostable or recyclable materials (for example, biomass balanced polymers as currently proposed and under development by chemical companies) to generate innovative packaging and device solutions. The polymers or materials to be selected must not only be recyclable/compostable, but also manufactured with a minimal environmental footprint.

The design and development of the new packaging and devices should apply and adapt circular economy principles and be guided by the SSbD framework. It should be done in close partnership with all players of the value chain from the manufacturers of the raw materials to the end users, the healthcare providers. The packaging and device use cases of the project are highly expected to improve and enrich the current SSbD framework, through concrete feedback to the European Commission and lessons learned. It is envisioned that this will necessitate regular interactions between the project and the developers of the SSbD framework at the European Commission.

Recycling

The project should promote the management of waste from packaging and single-use devices (including complex devices) by end users, the healthcare providers, considered as key partners of the project. This should lead to the effective implementation of the sorting and recycling of waste through collaborative work, including technical, organisational, and regulatory aspects (e.g. allowing the reuse of plastics etc. after industrial disinfection and/or decontamination of infectious waste, development of new recycling processes, setting up composting units etc.). Preferably, healthcare providers should include not only hospitals, but also other end users such as nursing homes. Healthcare providers should preferably be from several EU Member States or associated countries (e.g. minimum 3 EU Member States or associated countries), given the great disparity of practices from one country to another, in terms of legislation and implementation of waste sorting and recycling.

Importantly, the project should extend existing life cycle assessment (LCA) based metrics systems to packaging and devices, by considering the life cycle of the packaging materials, from their manufacturing to their recycling / composting. The LCA study must be carried out by an independent institution. Key

performance indicators are expected to come from comparing LCA metrics with the implementation of the SSbD framework, which should lead to better packaging and device recyclability and more favourable life cycle outcomes.

Another key element of the project is expected to come from an active partnership with European non-profit packaging associations, single-use plastic, and waste management associations and, possibly, standards bodies and approval bodies responsible for marketing authorisations. These institutions should work with European policy makers to support evidence-based policy making based on the findings of the different use cases of the project. The development and implementation of recyclable packaging and device solutions should also be articulated by the health tech trade associations, at the European (i.e. EFPIA, COCIR, MedTech Europe, EuropaBio and Vaccines Europe) or national levels, in particular with their working groups on sustainability and the circular economy.

General lessons / best practices and results will be shared as far as possible (e.g. peer-reviewed articles, white papers, press releases, web media, report deliverables, etc.). Communicating project results is essential to collaboratively shaping the acceptability, adoptability, and implementation of European legislation on packaging and packaging waste and the eco-design of sustainable products for health technology industries.

Besides this topic, another topic in this IHI call entitled “Sustainable circular development and manufacturing of healthcare products and their quantitative environmental impact assessment” will aim to improve the manufacturing efficiency of drug substances of chemical/biological origin (covering all chemical drug substances, proteins, oligonucleotides, vaccines or polypeptides etc.) by developing new manufacturing technologies, saving natural resources like water and fossil or fossil-based raw materials, and reducing waste in accordance with circularity principles (reduce, reuse, refine, recycle).

To jointly develop new strategies to ensure a greener healthcare industry along the whole value chain, and to avoid overlaps, a close collaboration between the two topics is essential and should be reflected by providing dedicated resources in both projects to align on common life cycle assessment (LCA) methodologies and LCA data.

Why the expected outcomes can only be achieved by an IHI project

To fully develop and foster the adoption of recyclable packaging and device recycling solutions to drive a circular economy for healthcare products, it is essential that different industry sectors come together and exchange knowledge and best practices to find optimal solutions. Combining expertise from various industrial and research sectors is critical to the success of this project.

It is essential that health tech industry partners from different sectors, e.g. the pharmaceutical industry, medical device manufacturers, *in vitro* diagnostic, biotech & vaccine companies, etc. exchange knowledge and experience and provide complementary use cases.

Healthcare providers (HCPs) are identified as key stakeholders as end users of healthcare products. Packaging and device management goes through HCPs with the implementation of selective sorting solutions to integrate them into appropriate recycling channels. HCPs should be from different European Union countries, preferably a minimum of three countries of different sizes.

This cross-sectorial collaboration is expected to include circular economy specialists, notably for life cycle assessment (LCA), European not-for-profit packaging, single use plastics and waste recycling associations, and, possibly, standardisation bodies. Such institutions and all partners of the project are committed to working with European policy makers to support evidence-based policy making.

Beyond classical health tech industries, the project may be even more impactful by including as partners other industry players of the value chain, notably from the materials and packaging industries.

This will ensure optimal implementation of the technical and scientific innovations expected to stem from this topic. IHI JU offers a unique opportunity to break down existing silos along the packaging and device value chain for a measurable impact on adopting recyclable packaging and device materials and reducing waste from packaging & device materials.

Pre-identified industry consortium

The pre-identified industry consortium that will contribute to this cross-sectoral IHI project is composed of the following pharmaceutical and medical technology industry partners:

- Boehringer Ingelheim
- Eli Lilly
- Fresenius Medical Care
- J&J
- Medtronic (Lead)
- Novo Nordisk
- Pfizer
- Takeda

In the spirit of partnership, and to reflect how IHI two-stage call topics are built upon identified scientific priorities agreed together with several proposing industrial beneficiaries, it is envisaged that IHI proposals and projects may allocate a leading role within the consortium to an industrial beneficiary. Within an applicant consortium discussing the full proposal to be submitted for the second stage, it is expected that one of the industrial beneficiaries may become the coordinator or the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries are encouraged to discuss the weighting of responsibilities and priorities regarding such leadership roles. Until such roles are formalised by execution of the Grant Agreement, one of the proposing industrial leaders shall facilitate as project leader an efficient drafting and negotiation of project content and required agreements.

Indicative budget

The maximum financial contribution from IHI is up to EUR 8 300 000.

The indicative in-kind and financial contribution from industry partners can go to EUR 8 300 000.

Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be in kind contributions to operational activities from those countries that are neither part of the EU nor associated to the Horizon Europe programme.

The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities (IKAA).

Indicative duration of the action

The indicative duration of the action is 48 months.

This duration is indicative only. At the second stage, the consortium selected at the first stage and the pre-identified industry consortium may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium

The industry consortium is not limited to health tech companies (i.e. pharmaceutical, medical devices, *in vitro* diagnostic & imaging companies, etc.).

The industry consortium expects to contribute to the IHI project by providing the following expertise and assets.

- Grant administration & project management
  - To provide legal support for project-related tasks.
  - To support project management.
- Packaging & single-use pharmaceutical and medical device use cases
  - To design and develop safe & sustainable packaging solutions and to apply the safe & sustainable by design (SSbD) framework. For example, such activities should consider from project start, i) recycling routes; and ii) if relevant, second life of packaging and devices.
  - To implement and execute flagship projects guided by the SSbD framework by including recyclable materials as components of sustainable packaging and appliance solutions.
  - To identify materials not yet marketed and/or under development, but compatible with the regulatory and normative requirements of the industrial manufacture of health products.
  - If the design and development stages are successful, industrialisation activities are expected to lead to the implementation of new pilot and/or industrial manufacturing lines.
  - To be inspired by and learn from other industries by possibly exploiting synergies, with the food industry for example.
  - To look for cost-effectiveness: new and innovative sustainable solutions should be reasonably cost-efficient compared to existing solutions.
  - To identify implementable sustainable solutions: New and innovative sustainable solutions should be still acceptable and adoptable by end-users (e.g. patients, nurses / caregivers, healthcare providers [HCPs], etc.), or even better compared to existing solutions.
  - To compare the performance of the sustainable packaging & device solutions with existing solutions and determine if they are suitable to be used with current products, according to specifications and standard requirements. It is essential that the sustainable packaging and device solutions do not compromise the safety and performance of the medical products.
- Recycling
  - To contribute to the definition of “recyclable” vs. “recycle-ready” with all partners of the project. Recycling activities may be preceded by decontamination procedures in case of contact with human tissues.
  - As a first intent, “recyclable” means that a product is likely to be recycled and the infrastructure exists such that the “recycle-ready” product can be recycled.

- Physical, mechanical, and chemical recycling and composting are recycling solutions that are considered in scope.
- Burning and landfill solutions should be avoided as much as possible.
- Recyclable “at all” is good enough, but it does not have to be a closed loop in the health tech industry. Raw materials can also be re-used in other industries. The primary goal is re-use of recycled packaging and device materials.
- To understand drug-product interactions and biological contamination as potential limitations to recycling and propose solutions to overcome them.
- From waste management audits of HCPs, the industry and the public consortia will work together to make recommendations to improve the sorting and recycling of packaging and single-use devices.

The allocation of the EUR 400 000 financial contribution will be decided by the full consortium at second stage, when preparing the full proposal.

Applicant consortium

The first-stage applicant consortium is expected, in the submitted short proposal, to address the scope and deliver on the expected outcomes of the topic, considering the expected contribution from the pre-identified industry consortium.

Beyond grant administration and project management, the applicant consortium is expected to address all the research objectives and make key contributions to the defined deliverables in synergy with the industry consortium. It should include any relevant public and private organisations.

Grant administration

- To provide financial administration, submission of deliverables, periodic reports etc.

Project management

- To coordinate internal communication and meetings, general oversight and management of communication, exploitation and dissemination activities, risk management.
- To provide and maintain an IT infrastructure, to develop and implement an efficient data governance and management strategy of the joint consortium according to adequate standards and deliver the “data management plan”.
- To coordinate networking, joint activities and synergies with other European initiatives, or other relevant groups (e.g. Horizon Europe and IHI projects, etc.).
- To develop a strategy for the exploitation and sustainability of project results and outcomes and deliver the “exploitation and sustainability plan”.
- To prepare relevant documents / reports of the results being generated by the project (e.g. briefing books, guidance documents, etc.) to be shared with any stakeholders committed to the development, evaluation and regulation of packaging and single-use solutions including European regulators, policymakers and standards organisations.

Project activities

- Consortium to review, evaluate and recommend materials (already existing or under development at the pilot scale) which can be selected as safe and sustainable packaging and single-use devices, according to the regulatory landscape and current specifications / standards for packaging and single-use devices.

- Consortium to review and evaluate the waste management process solutions of the recommended list of materials with a focus on existing recycling schemes, at the industrial level or at a pilot scale, which can be leveraged by healthcare providers. The review should provide a European landscape assessment and highlight any regional disparities. It should also integrate the national and European regulations and incentives of waste management and recycling.

- The consortium should be acquainted with planned activities under the European Partnership for the Assessment of Risks from Chemicals (PARC) and take advantage of the partnership as a facilitator for open data and methodology sharing with risk assessors and their scientific networks.

- Healthcare providers (HCP) including hospitals, medical analysis laboratories, caregivers, and patient associations to contribute to the identification, evaluation and implementation of sorting and waste management solutions of packaging and single use devices. HCPs are also expected to generate audit reports on the waste they generate by categories (non-hazardous & hazardous) and by materials (e.g. plastic, metal, paper). The report should also include quantitative data on waste volumes / costs per category, identification of waste minimisation, opportunities / potential cost savings, facility walk through / stream analysis of waste, application of waste reduction principles (e.g. 10 R's rule[6]), improvement plans for compliance with regulation and waste minimisation goals set at the national level (e.g. see the Dutch example of Green Deal Sustainable Care 2.0[7]) or European level.

- From the waste management audit reports, recommendations to optimise waste management should be made by all actors of the value chain, including HCPs and health tech industries.

- HCPs with their external waste management partners are expected to run pilot studies of waste management from the use cases provided by the healthcare industries.

- Policy makers, health tech trade associations, notified bodies (for medical devices and *in vitro* diagnostic products), European Medicines Agency (EMA) and/or organisations working with EMA, environmental health, and sustainability (EHS) institutions, advocacy groups, standards organisations as partners or members of the advisory board, to work in partnership with all partners of the project on the acceptability, applicability and implementation of regulations on safe and sustainable packaging and single use devices.

- European non-profit packaging, single-use plastics & waste recycling societies or associations as partners to work with the industry consortium, policy makers and standards organisations to support evidence-based policy making from the findings of the project. These societies or associations are also expected to provide data and insight on trends of eco-design and waste management of health tech products, but also of products from other industries when possibly benefiting the health tech industries.

- Small and medium-sized packaging companies will co-develop innovative, safe and sustainable solutions with the industry consortium.

- Small and medium-sized health tech companies including vaccines and biotech players are also invited to develop their own packaging and / or device solutions.

[6] https://www.sciencedirect.com/science/article/pii/S0921344919304598
[7] https://www.government.nl/topics/sustainable-healthcare/more-sustainability-in-the-care-sector

- Consortium – public and/or private entities – to assist the physical, chemical characterisation of new safe and sustainable solutions for packaging and single use devices, including compliance with the regulatory packaging and device requirements.

- Consortium – public and/or private entities – to evaluate the biocompatibility and toxicity of the new packaging and single-use devices according to regulatory and standard requirements (e.g. analysis of extractables and leachable compounds).

- To contribute to the regulatory landscape for life cycle assessment (LCA) standards in the EU and in other non-EU European countries.

- In conjunction with industry, to discuss with regulatory authorities, standards organisations, and advocacy groups the acceptability and implementation of the LCA metrics and in the EU and harmonisation with efforts in other non-EU European countries and the US.

- Evaluate the life-cycle assessment, including the costs in a comparative way (sustainable vs. current solutions).

- To evaluate the environmental impact of the new packaging and single-use device solutions with a holistic view, by including:
    - environmental toxicity of the end products;
    - environmental impact of the manufacturing process of the starting materials and their transformation into packaging and single-use devices.

- Standards bodies to adapt, revise, change current standards to accommodate the use of the sustainable solutions from the evidence generated by the use cases of the project and, possibly, other findings, notably captured by the different European non-profit packaging, single-use plastics and waste societies or associations.

- Subject to the rules of the IHI Horizon Europe Model Grant Agreement applicable to IHI, all major findings of the project – except for confidential information, notably pertaining to generated intellectual property – should be publicly disseminated and communicated. They should provide strong evidence to shape the acceptability, adoptability and the implementation of the future European regulations on packaging and single use devices.

- The project may include the question of certification or green claims of the materials used for the packaging and device solutions and also of the packaging and device solutions themselves.

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules under “Specific conditions on availability, accessibility and affordability” do not apply.