

An integrated strategy for Life Sciences in Europe - towards more resilient health systems

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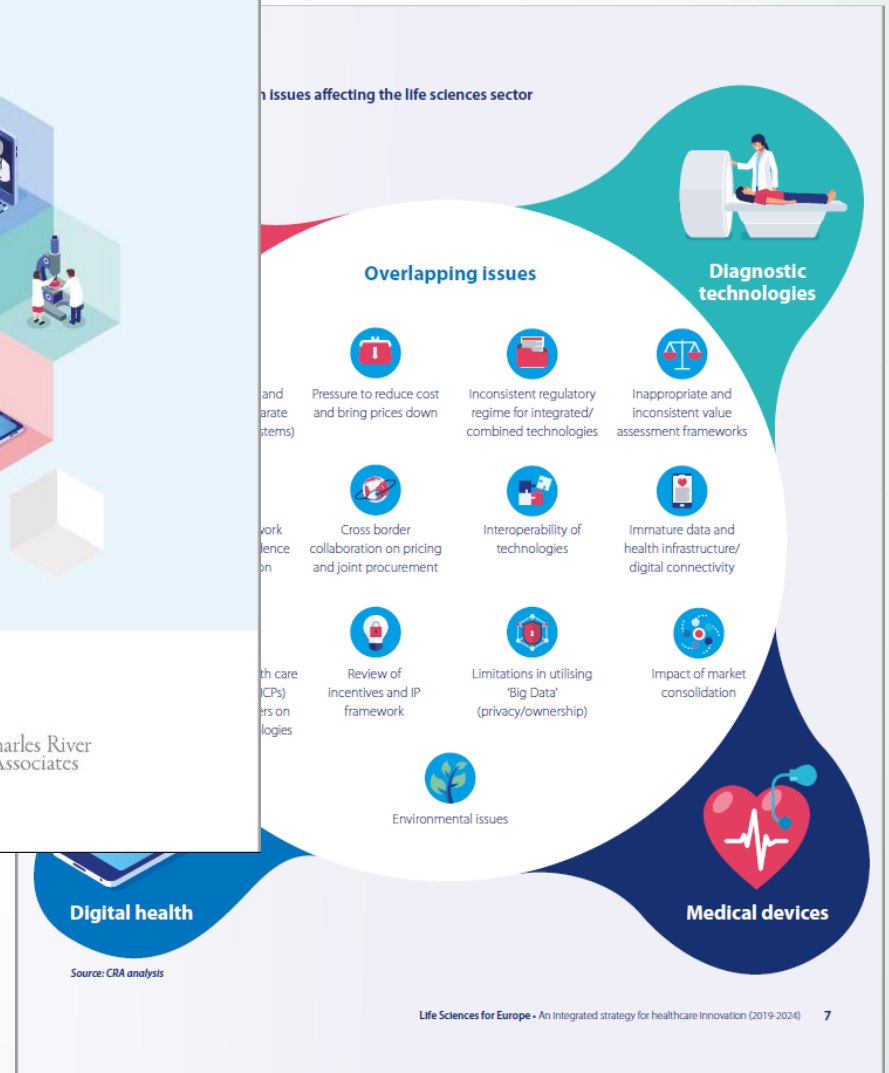
An integrated strategy for Life Sciences in Europe

- towards more resilient healthcare systems

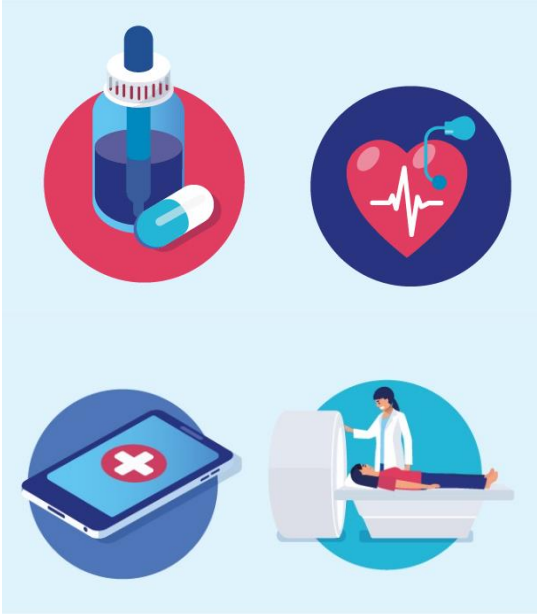
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4 June 2020

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An integrated strategy for healthcare innovation (2019-2024)



Background and objectives of this report



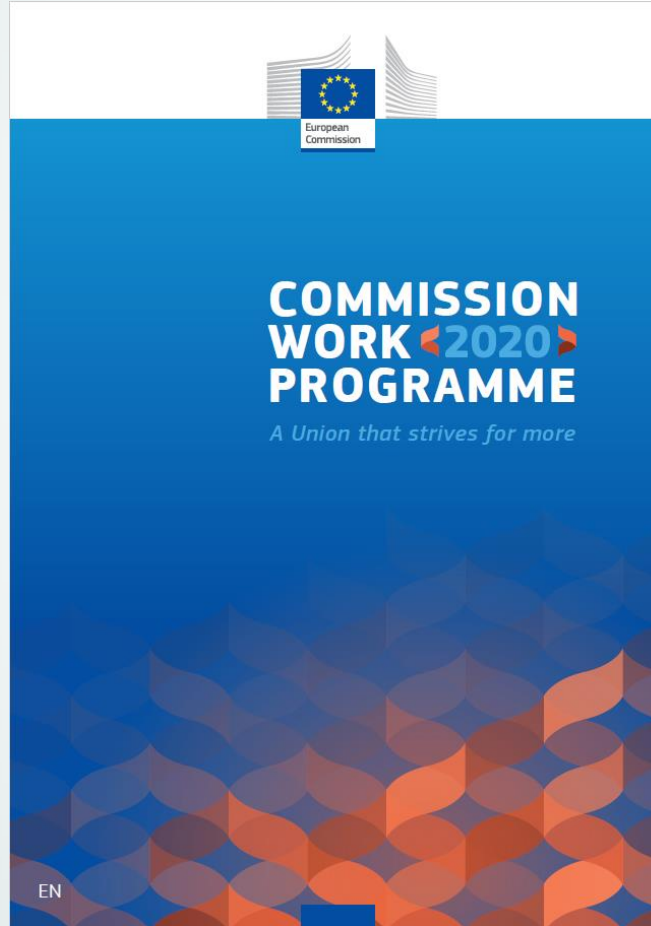
There are increasingly common challenges due to the integrated, combined use of healthcare technologies

This report focuses on:

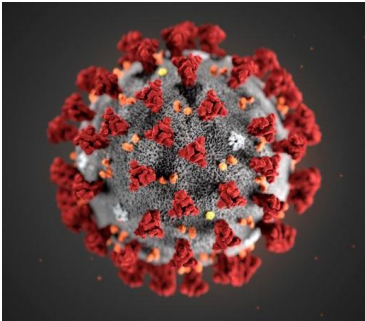
1. Distinctive policy solutions focused on the shared challenges across HC technologies
2. The need for distinct regulatory landscapes appropriate for individual health technologies.
3. Proposes novel policy solutions to help address these common issues

Last week, the European Commission has released its updated **Work Programme for 2020**

Later this year the Commission will launch a ***Pharmaceutical Strategy for Europe*** to “continue ensuring the quality and safety of medicines and consolidating the sector’s global competitiveness.”



Since then, the world has changed somewhat...



- COVID-19, officially a global pandemic as classified by the World Health Organization (WHO)
- The virus has prompted massive disruptions to major economies around the world, and the full economic impact remains to be seen.
- This is likely to lead to changes significant changes in healthcare policy and possible long-term impact of this crisis on the Life Science sector

Acceleration of on-going trends	Step-change in activity in response to crisis	Response to behavioural changes
Overall budget pressures on healthcare	Shift in resources within clinical care to focus on COVID-19	Trend toward greater digitalisation of healthcare (e.g. telemedicine)
Increased cost and pressure on drug prices	Increased focused on disease prevention and diagnosis	More emphasis on environmental concerns & EU Green Deal policies
Increased trend toward CCC & joint procurement	Stockpiling measures and pandemic preparedness	Increased protectionisms and possible trade war
Increased pressure on IP and incentives	Relocation of industrial activity back in Europe	Greater recognition of the value of science and research

We first reviewed key trends stemming from the use of combined health technologies and looked out for corresponding future policy challenges



Socio-economic

Trends that are exogenous to industry actions.

This includes demographic (changing epidemiology, consumer behaviour) and economic trends (overall health of public finances, etc.)

Budgetary pressures and the use of new mechanisms to fund and support the introduction of new therapies

Trend exacerbated by COVID crisis



Technology trends

Trends that originates from the evolution or emergence of new technology.

This also includes technologies which could provide opportunities to improve the healthcare infrastructure (e.g. eHealth solutions)

Significant scientific advances in innovative technologies that require specialized healthcare and testing

Trend exacerbated by COVID crisis



Policy landscape

Implementation of new policies that will negatively or positively affect the industry with respects to approval, access, P&R or market diffusion perspective

(e.g. harmonisation across countries/sectors, joint procurement, new regulatory rules, etc.)

Protocols and infrastructure for collecting digital health data is insufficient and often not interoperable

Trend exacerbated by COVID crisis

Each segment of health technology shares some common challenges

Medicines

- New pricing models: indication, combination
- Access and P&R of non-traditional products
- Developing awareness around personalised medicine
- Biosimilar regulation
- Antimicrobial resistance
- Inconsistent HTA
- Review of incentives and IP framework



Overlapping issues



Limited funding and budget silos (separate reimbursement systems)



Pressure to reduce cost and bring prices down



Inconsistent regulatory regime for integrated/combined technologies



Inappropriate and inconsistent value assessment frameworks



Need for framework for RWE collection



Cross border collaboration on pricing and joint procurement



Interoperability of technologies



Immature data and health infrastructure/digital connectivity



Education of HCPs and policy-makers on emerging technologies



Review of incentives and IP framework



Limitations in utilising 'Big Data' (privacy/ownership)



Impact of market consolidation



Environmental issues

Digital health

- Outdated IT infrastructure
- Digital literacy of HCPs
- Access and P&R of digital health
- Data security, ownership and management
- Different approval and reimbursement pathways across countries
- Uptake of electronic health (eHealth) solutions amongst HCPs
- Lack of international interoperability/ data sharing across countries



Diagnostic technologies

- New IVDR
- New MDR – high-risk classification for in vivo diagnostics
- Limited provision of biomarkers
- Lack of resources to manage diagnosis
- Interpretation of diagnostics results

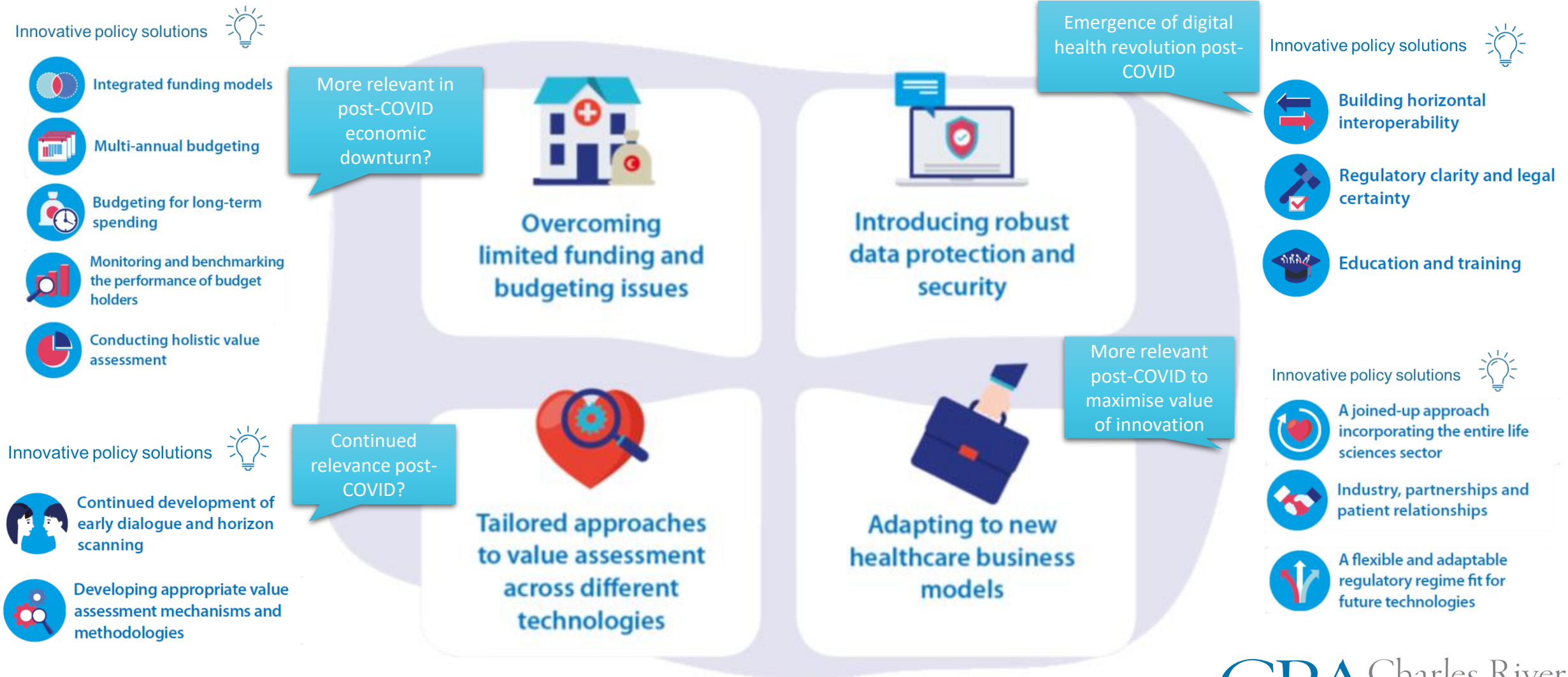


Medical devices

- Diagnostic classification within medical devices
- New set of EU regulations for medical devices
- Separate systems for reimbursement for hospital and community care sectors
- Innovative contracting mechanisms
- Clear approval/P&R pathways across medical device categories



We short-listed four novel policy area of importance to the entire LS sector that are not addressed by existing policy initiatives



We set out some concrete policy proposals in areas where evolving technologies are introducing new challenges



Overcoming limited funding and budgeting issues

1. Share best practices on bundled payment schemes or 'pooled' budgets to avoid silo-based decision-making.
2. Continue to foster long-term planning around the adoption of innovation (e.g. horizon scanning), and for identifying solutions of value for medical devices.
3. Introduce innovative payment models and value-based arrangements as part of multi-annual budgeting.
4. Adopt a clear definition of 'value' in the context of a value assessment framework

In light of the post COVID-19 economic crisis, Industry will need to continue to engage with policymakers to generate new solutions to improve access to medicines



Tailored approaches to value assessment across different technologies

1. Although there is no one-size-fits-all approach – a joined-up approach to early dialogue procedure and horizon scanning is required for integrated, combined products.
2. Consider the correct instruments to conduct value assessment and where a hybridised process is relevant for co-dependent technologies.

This include the introduction of an industrial strategy incorporating the whole life sciences sector in 2020

COVID-19 crisis has highlighted gaps in digital health and the need for larger structural changes



Introducing robust data protection and security

1. Develop clear and practicable interoperability for health information sharing across Europe via a consistent digital health strategy.
2. Promote health care professions (HCPs) awareness of the legal aspects around data sharing, incl. certification mechanisms to enhance citizen's trust in digital health services.
3. Promote education and training programmes to improve electronic (eHealth) and mobile (mHealth) skills and enhance information and communication technologies (ICT) literacy.
4. Implement a Digital Health Action Plan to deliver a harmonised health data network across Europe.



Adapting to new healthcare business models

1. Building on the March 2018 industrial strategy Council conclusions and introduce an EU life sciences sector strategy in 2020.
2. Foster the development of partnerships between private healthcare providers and healthcare systems such as 'Managed Equipment Services'.
3. Develop alternative regulatory pathways and ensure constant interaction with scientific discovery.

In order to maintain its competitiveness edge as a highly innovative industry, Europe will need to introduce a comprehensive industrial strategy

Thank you for your attention



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