Roche feedback to the European Commission Trade Policy Review

Roche welcomes the opportunity to provide feedback to the European Commission's review of the European Union's trade policy (the "Review"). The Commission's objective is to build a consensus around a fresh medium-term direction for EU trade policy, responding to a variety of new global challenges and taking into account the lessons learned from the coronavirus crisis.

Context for Roche feedback:
Recognising that the Review is relevant to the life-sciences sector in many aspects, in this feedback, we have focused on digital trade elements and in particular data policy related aspects, such as cross-border dataflows.

General considerations:
In the light of the central role of data in the context of digital trade, data policies will strongly define the future trade landscape. An effective digital trade policy framework should be aligned with the data policy elements of the future European Data Strategy and as such refer to agreed concepts, models and processes and consistently apply a governance framework for data access, sharing and use, recognising and visualizing the value to individuals and societies of translating data into actionable information.

Policy frameworks should address data transfer and market access issues, including expectations on transparency and protection of personal data and data security while allowing for necessary flexibility to accommodate multiple data access and sharing models (e.g. transactional, partnership, federated) and contexts of data use and consider in particular:

(i) GDPR is leveraged as a baseline approach to protection of personal data that considers practical aspects of compliance and enforcement
(ii) recognition of data partners prerogative to protect commercially or generally sensitive information (also considering competition laws)
(iii) value exchange within data ecosystems is agreed upon
(iv) data standards for quality and interoperability
(v) processes are sufficiently rapid, agile and flexible
(vi) an effective framework for fair (non-discriminatory) competition
(vii) whenever possible, a cross-border approach/commitment to development of scalable ecosystems

In particular in the field of healthcare, the current Covid-19 crisis shows the importance of cross-border exchange of high-quality health data.

> **Question 10:** How can digital trade rules benefit EU businesses, including SMEs? How could the digital transition, within the EU but also in developing country trade partners, be supported by trade policy, in particular when it comes to key digital technologies and major developments (e.g. block chain, artificial intelligence, big data flows)?

Data used in the context of for example artificial Intelligence (AI) has the potential to contribute to earlier disease detection, more accurate diagnosis, further understanding of human physiology and the development of personalised medicines and diagnostics. Examples of practical AI applications can be found in data mining to identify drug targets and molecule interactions, clinical trial design and recruitment, supply chain planning, adverse event recognition, patient support platforms and physician decision support accelerate research for example through better target identification, trial execution, improving regulatory procedures and identification of novel scientific insight generation.

Health data is unique. In contrast to industrial data in other sectors, health data is personal and sensitive, and requires specially strict protection, yet regulating and enabling the access and processing promises to yield

enormous and invaluable insights and benefits for citizens, patients and society. In the healthcare sector, the right to access and control individual data needs to be balanced against the responsibility of healthcare professionals and manufacturers of medical technologies to deliver safe and high-quality care and the opportunity to address unmet needs and deliver better care for people.

Personal data protection is among the local/regional objectives that are most likely to involve a data transfer restriction, however, much of the friction currently experienced in the attempts to establish dataflows is based on apparent misperceptions such as data being better protected in one location or that data localization maximises value for local populations. In fact, disruptions in dataflows may rather limit access to new technologies / therapies for the local population. In this context, it should be noted that also conservative interpretations of GDPR to ensure data stays local have been prohibitive. It should be a priority to ensure a uniform approach to interpretation of the GDPR among EU Member States prior to leveraging GDPR instruments in the context of frameworks for third country dataflows.

We strongly agree with the baseline in the Consultation Note that stability and predictability, including legal certainty, is paramount to improve market access. To fully unlock the value and growth potential inherent in data, any measures to improve market access should in particular address interoperable personal data protection and data security provisions and data standard definitions in line with the principles expressed in the European Data Strategy. Whereas regulatory differences across countries are to some extent necessary and appropriate, there is a clear need for regulatory cooperation to achieve interoperable frameworks that include mechanisms to reduce regulatory overload. A report by the World Economic Forum (WEF) Exploring International Data Flow Governance from 2019, further provides examples on how trade policy, incl. regulatory cooperation can play a critical role in helping achieve the required balance between data transfer and other policy objectives.

Digital trade rules and trade policy can play a major role in addressing regulatory and standards differences and incompatibilities for example in the areas of protection of personal data and data security provisions and data quality standards as barriers to trade and promote harmonised governance frameworks. Existing provisions in regional free trade agreements that prohibit unnecessary and discriminatory restrictions on data flows provide governments with examples of tools to enable the flow of data across borders. We provide more detailed feedback to various digital trade barriers below in our response to Question 11.

Question 11: What are the biggest barriers and opportunities for European businesses engaging in digital trade in third countries or for consumers when engaging in e-commerce? How important are the international transfers of data for EU business activity?

The Consultation Note recognises that it will, perhaps now in the aftermath of the Covid-19 crisis more than ever, be essential for the EU economy to benefit from growth opportunities abroad. In the digital technologies' context, data is the central commodity which hosts enormous potential for innovation also in the health field. According to the WEF platform initiative Shaping the Future of Technology Governance: Data Policy, it is predicted that the global volume of data will double between 2018 and 2022, and double again between 2022 and 2025 but "much of the data needed to tackle the world's most pressing challenges lies siloed in both public and private sources, with an array of regulatory, commercial and social risks preventing the sharing of data, even for social good". According to the WEF report Exploring International Data Flow Governance, "limited services access and higher data processing costs could end up broadly affecting countries' ability to compete in the Fourth Industrial Revolution, within which growth will be driven by technology deployment".

In the field of digital and sustainable technologies, incl. AI and Internet of Things, the innovative industry in Europe has the potential to be global leaders and a major contributor to the future competitiveness of Europe. Roche, as a globally active innovative R&D company largely relies on international data transfers (incl. the internal distribution to its centers of excellence for the particular research) for the purpose of leveraging the potential of digital technologies, such as AI, to accelerate research through better target identification, clinical trial execution and generally for the identification of novel scientific insight generation to the benefit of citizens, patients and society. As stated earlier Roche's access and use of data has the potential to contribute to the development of personalised medicines and diagnostics. AI, as an enabler of personalised medicine, relies heavily on access to

datasets on which the system has been trained. The higher the quality of data that goes into the system, the better the outcome of the AI specific task. Without access to high quality data the potential of AI will not be realized in healthcare. Cloud computing and AI can provide a technology platform that is able to meet the real data security and personal data protection needs of nations without geographical limitations as long as the right legal framework, policies and standards are agreed to on a global/regional basis.

To increase the value of European data and further strengthen Europe's role in the emerging data economy as set out in the European Data Strategy, it is essential to establish and implement internationally acceptable personal data protection, security, interoperability and quality standards. FAIR Principles[1] offer a strong foundation to enabling this and the reusable principle in particular benefits patients and society. Regulatory cooperation and standards harmonisation are key for enabling increased collaboration, insights generation and exchange at scale across borders (note potential e.g. in pandemic scenario) and sectors, where applicable. Increased international and cross-sector exchange and collaboration can accelerate recognition of the value to individuals and societies of translating data into actionable information. Increased consistency, or at least interoperability, between national / regional frameworks especially in the field of protection of personal data, data security and quality standards and certifications helps avoid overregulation and the related legal uncertainty consequences (see especially AI governance context). A governance framework, including FTAs and WTO initiatives, should therefore prioritize regulatory cooperation on personal data protection and security measures and standardization needs to support data quality and interoperability.

To the extent possible, it should be a natural extension of existing structures and take into account the existing global standardisation arena to avoid duplication and leverage systems already implemented within sectors. In particular, there should be a link to all relevant European and international health IT standards development organisations but also include industry consortia that deliver interoperability profiles, with due stakeholder engagement. In the context of any standardisation, harmonisation or coordination efforts, Roche believes meaningful sharing of data is enabled by high quality data and interoperability. Quality data and interoperability set the foundation for delivery of personalised healthcare. We encourage the aspiration of GAIA-X, as the potential infrastructure for the EU Common Data Spaces, to define internationally acceptable interoperability and data quality standards. We strongly encourage leveraging existing standards to avoid additional adoption cost and time to achieve this objective.

In the context of protection of personal data, it is important to consider the different data flows and forms of data (ie. anonymized, pseudonymized, aggregated data and personal data) when considering governance frameworks. Variation in interpretation of GDPR and other regional/local frameworks for protection of personal data and inconsistent country practices including differing expectations of anonymization, pseudonymization and aggregation processes are a barrier to market access to companies offering innovative services.

[1]Wilkinson, M. D. et al. The FAIR Guiding Principles for scientific data management and stewardship. Scientific Data 2016 3:160018 (2016)