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Single Market barriers continue limiting the EU's potential for the twin transition

Executive summary

The Single Market is the beating heart of EU integration. 56 million jobs in the EU depend on it.[1] Yet, it remains a work in progress and a critical element to make the EU more resilient and sustainable. Removing Single Market barriers in goods and services could amount to €713 billion by 2029.[2]

At the height of the COVID crisis, the Commission made strengthening the Single Market in digital products and services one of its top 3 priorities to relaunch Europe.[3] Unfortunately, there are three worrying trends that threaten digital trade across the EU:

- **Derogations or largely divergent interpretations** of EU laws, effectively creating fragmentation in areas where the EU supposedly brought harmonisation;
- **Unilateral legislative actions** at national level in areas where the EU already has existing provisions, or is creating relevant ones;
- **Substantial regulatory compliance costs for SMEs**, even when EU rules intend to facilitate cross-border trade.

Unfettered access to the Single Market is vital to achieve the Digital Compass targets that address climate change, societal, health and economic challenges of our time. It is also about European start-ups and SMEs capable to generate economies of scale and commercialise technology in Europe, not outside of it.

Below we offer examples of concrete Single Market barriers in a variety of key areas, including healthcare and the environment. The goal of this paper is to feed into the work of the Industrial Forum and inspire the vision of the next Annual Single Market reports of the Commission. We stand for an open, integrated Single Market with digital at its core.

[1] Danish Business Authority, 25 years of the European Single Market, 2018
[2] European Commission, A single market that delivers for businesses and consumers, 2020
[3] Communication from the Commission, Europe's moment: Repair and Prepare for the Next Generation, 2020

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Digital Health

- *Europe's fragmented Single Market for digital health and data:* Europe is home to some of the best healthcare systems and leading health companies. Still, many health innovations start off as ideas in Europe and then move to other markets.

  The upcoming European Health Data Space[4] initiative will be an opportunity for the EU to address some major barriers. Companies looking to scale up in Europe have to deal with national and regional fragmentation in data protection rules (GDPR and additional rules), data standards (semantic, syntactic etc.) and reimbursement systems.[5]

  Another reason why innovative medical research, products and services depend on clear and aligned data rules is that, increasingly, they make use of large- or hyperscale cloud services that are generally not present in every individual region

- *Health data processing for Research and Innovation*: Medical research is data-driven. Different national rules and exemptions to the GDPR have become a deterrent for R&D investment, roll-out of new diagnostics, cures and treatments.[6] Indeed, the chances that Europeans will have timely access to the latest life-saving innovations remain undesirably small for the foreseeable future.

  GDPR Guidance from the European Data Protection Board should address the different interpretations for processing health data for research. It must also

[4] The European Health Data Space "will promote better exchange and access to different types of health data (electronic health records, genomics data, data from patient registries etc.), not only to support healthcare delivery (so-called primary use of data) but also for health research and health policy making purposes (so-called secondary use of data)."

[5] Listing all the different obstacles experienced is outside of the scope of this paper, please refer to our report: 4 pillars for a trusted and collaborative health data space.

[6] European Commission, Assessment of the EU Member States' rules on health data in the light of GDPR and Study on eHealth, Interoperability of Health Data and Artificial Intelligence for Health and Care in the European Union; 2021; EIT Health, Learning from health data use cases, 2021

address the compounding of loopholes Member States are using to derogate from the main purpose of the GDPR, which is to harmonise data protection rules in Europe. For example, myriad legal bases are used across Member States to process health data for research across both public and private sector. This has an impact not only on the effectiveness and ease of use of digital health products and services, but also on the proliferation of job-creating R&D in Europe.

Europe's fragmented landscape, both in terms of data standards and rules, limits the capability to collaborate and share health data across Member States. This was seen during COVID, where it was difficult to conduct clinical trials in the EU and had to be done in third countries.[7]

We disagree with the European Data Protection Board (EDPB)'s position that this 'lack of homogeneity cannot be solved in the EDPB guidelines or by means of Codes of conduct.'[8] Moreover, while certainly Member State laws cannot be circumvented, the upcoming Guidelines should seek, to the fullest extent possible, to conciliate different approaches in order to facilitate compliance and coherence. In particular, the upcoming Guidelines should seek to overcome constraints due to Member States' use of Art. 9(4) GDPR. For instance, divergences in the concept of public interest of the research, the impossibility or the disproportionate effort to obtain consent or the concept of research institute or body.

Without a solution, problems will persist, for example for:

- **Innovations in clinical trials:** An SME from our Executive Council for Health noted that "Dealing with different local legal requirements in the area of clinical trials (e.g., eConsent is not clearly defined on a European level) – despite the overarching EU laws – also makes it difficult to enter new markets. As a result, we have had to invest more internal time and resources to compensate for missing agreements on data privacy."

- **Complying with the Medical Device Regulation:** Germany, for instance, requires consent for the processing of personal data for any clinical evaluation and research. This is at odds with the possibility of relying on public interest or legal obligation flowing from the Medical Device Regulation (MDR) to guarantee the safety and efficacy of medical devices (Regulation (EU) 2017/745).

- **Conducting vaccine research:** Consent can form a barrier to obtaining necessary new knowledge on the efficacy and safety of vaccines, which is

[7] The Lancet (2021) The European clinical research response to optimise treatment of patients with COVID-19: lessons learned, future perspective, and recommendations.

[8] Para. 15, *EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research* (February 2021), available at https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf.

essential to limiting risks. A pertinent example can be found in the continuously evolving needs for the development of COVID vaccines. Such as, when rare safety-related concerns arise, responding to increased risk for individuals with certain biomarkers, and developing a vaccine for new mutations. Consent has many requirements, including specific and informed, which are challenging in this context and generally in evolving research.

Read more on DIGITALEUROPE's position on the GDPR's implications for health data here and our paper "A digital health decade: from ambition to action" here.

Construction and Building Management

- *Energy Efficiency Directive (EED):* Under the proposed revision of the EED, Article 7 on public procurement proposes to grant the Member States the flexibility to set "wider sustainability, (…) environmental and circular economy" criteria in public procurement practices, potentially leading to Member States introducing diverging provisions. These developments risk erecting barriers to the green and digital transition, hampering the ability of companies to generate economies and scale and thus reduce the cost of shifting to greener and more digital solutions. For example, a recent German General Procurement Order limits the use of F-Gases in heating/cooling equipment[9] despite their central role in underpinning the electrification and ultimately decarbonisation of heating/cooling. This fragmentation is especially important as the EED revision seeks to extend the 3% annual renovation target for public buildings to include regional and local government, significantly increasing the size of this public procurement market.

Taxation

- *VAT registration and compliance:* there exist distinct requirements in Member States for businesses storing and selling goods in multiple EU countries. They result in a high compliance burden for SMEs.

  Businesses often want to store inventory in multiple EU locations to serve customer demands faster and reduce logistical complexity and environmental footprint. Importantly, the EU VAT reform that entered into effect on 1 July 2021 (the Ecommerce VAT Package[10]) introduced a simplified VAT collection system

[9] Allgemeine Verwaltungsvorschrift zur Beschaffung klimafreundlicher Leistungen (AVV Klima), https://www.bmwi.de/Redaktion/DE/Downloads/A/allgemeine-verwaltungsvorschrift-zur-beschaffung-klimafreundlicher-leistungen-avv-klima.html [Accessed 01 February 2022]

[10] https://ec.europa.eu/taxation_customs/modernising-vat-cross-border-e-commerce_en

for VAT registration by businesses. It allows to file VAT returns and pay for the VAT due in multiple EU countries through a single EU country (the so-called VAT One Stop Shop System or VAT OSS).

Importantly, the VAT OSS excludes the pan-EU storage of inventory and local sales from this place of storage. This means businesses storing inventory across the EU still face high VAT compliance burdens. They still need to handle VAT registration and compliance requirements in every EU country where they store inventory. This requirement for multiple VAT registrations is costly, time consuming and comes with a heavy compliance burden for SMEs. Companies that sell goods online pay around €8,000 per year in VAT compliance costs for every EU country into which they sell, based on Commission's estimates[11]. This high cost is a barrier to intra-EU trade.

- *Costs of tax compliance:* Compliance costs linked to business taxation for SMEs can be up to 30% of taxes paid[12]. Implementing new globally different taxes (e.g., EU digital levy, BEFIT[13]) would cause double taxation and harm tax certainty for numerous years, thus eroding EU's growth prospects.

  It is key to put in place a taxation framework that makes the EU a competitive, appealing and well-functioning environment for all businesses, as well as a fair and effective jurisdiction for all Member States. We point to best practices from Member States in the Nordic and Baltic region, centred around taxation digitalisation, automation and real-time economy.

Waste

- *Obligatory use of alphanumerical codes set out by Decision 97/129/EC:* A number of Member States have introduced, or are planning to introduce, the obligation to use the alphanumerical codes for labelling[14]. These countries include Italy[15], Portugal[16], Slovenia[17], and Bulgaria[18]. The requirements could lead to specific

[11] European Commission, *Modernising VAT for e-commerce: Question and Answer* https://ec.europa.eu/commission/presscorner/detail/en/MEMO_16_3746 [Accessed 01 February 2022]

[12] European Commission, *Communication (SWD 2020/54), Identifying and Addressing Barriers to the Single Market*: https://ec.europa.eu/info/sites/default/files/communication-eu-single-market-barriers-march-2020_en.pdf [Accessed 01 February 2022]

[13] Business in Europe: Framework for Income Taxation

[14] European Commission, *Decision 97/129/EC* https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A31997D0129&from=EN [Accessed 01 February 2022]

[15] Legislative decree nº 116 of 3 September 2020. The date for planned entry into force was 01 January 2022.

[16] Draft Decree-Law (fifth amendment to Decree-Law No 152-D/2017).

[17] Decree on Packaging and Packaging Waste. The date for planned entry into force is 01 January 2022.

[18] Постановление № 420 от 31 декември 2020 г. за изменение и допълнение на нормативни актове на Министерския съветн (eng.: Decree № 420 of 31 December 2020) Available at https://dv.parliament.bg/DVWeb/showMaterialDV.jsp?idMat=154886 [Accessed 01 February 2022]

packaging being necessary for the respective national markets, putting European enterprises at a competitive disadvantage in comparison to locally established producers. As sorting instructions are not harmonised across the EU, there exists a possibility of these markings being confusing for consumers in other Member States, which neither enforce nor prohibit the codes' use.

- *Use of the "Green Dot" logo:* There exist conflicting regulations on the use of the "Green Dot" logo within the EU. In some EU countries (e.g., Spain), use of the sign is mandatory on certain products. In others, instead, the use of the logo may be financially penalised (e.g., France[19]). These conflicting requirements imply unnecessary costs and risks that arise from displaying relevant information in some Member States, all while others actually require to display it.

- *Use of the "Tri-man logo":* In France, there is an obligation to use the "Tri-man logo" and include sorting instructions on the packaging and in user manuals. Manufacturers need to change all their packaging to add this information solely for this national market. As the sorting of instructions is not harmonised across the EU, this information could also be confusing in other Member States.

- *National unilateral efforts to increase the share of reusable packaging despite harmonised measures being revised at EU level:* At least three Member States (France[20], Spain[21], and Austria) have set multiannual plans to increase the share of reusable packaging on their national markets. Producers exporting to these EU countries would need to create an entirely new logistic chain to be able to comply with the reuse targets. This would put them at a competitive disadvantage compared with local producers, for whom these new provisions would be easier to comply with. Unilateral national targets risk undermining the upcoming revision of the Packaging and Packaging Waste Directive, which is looking at ways to boost reuse through harmonised measures at EU level. Different rules in each EU country on packing and packing waste (Directive 94/62/EC) impede the free movement of goods and create bureaucratic costs.

- *Unilateral repairability indices requirements:* Some EU countries, including France[22], have introduced repairability indices despite work at European level covering the same product categories (e.g., smartphones). Other Member States,

[19] Decree of November 30, 2020 relating to signs and markings that may lead to confusion on the rule for sorting or bringing in waste from the product and Decree of December 25, 2020 amending the decree of November 29, 2016 relating to the approval procedure and laying down specifications for eco-organizations in the household packaging sector. As of 23 November 2021, these two French legal orders have been temporarily suspended by the French Council of State until a judge makes a decision on their validity

[20] Article 67 of the Law 2020-105 regarding a Circular Economy and the Fight Against Waste

[21] Draft Royal Decree on packaging and packaging waste, https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/participacion-publica/Residuos-2021-PRD-Envases-2021.aspx [Accessed 14 February 2022]

[22] Article 16 of the Law 2020-105 regarding a Circular Economy and the Fight Against Waste

such as Spain[23], are also working on the introduction of their own systems. This may lead to divergent national criteria, or an overlap between European and national measures. The risk for consumers lies in the introduction of labelling requirements which would create confusion.

- *Mixture-in-mixture provisions:* Several Nordic countries have established national registration obligations for chemicals. Companies are now registering their products in the Norwegian database, and are required to disclose all ingredients without any concentration limit. This constitutes a barrier for exporters to Norway, whose suppliers do not provide the complete composition of their products. Some companies will be at an unfair disadvantage if the EU does not enforce its provisions on mixture-in-mixture products.

- *Implementation of the Waste Framework Directive (WFD):* The 2008 revision of the WFD encouraged the manufacturing sector to register some of its co-generated materials with the initial view of proving that they had no toxic or hazardous properties. It also obliged them to identify tailored approaches for re-using or recycling their co-generated materials. Although this approach has become normal practice for the industry, interpretations of this regulation differ at national and even regional level across the EU.

- *Implementation of EU Classification, Labelling and Packaging (CLP) Regulation and REACH:* A number of Member States have implemented legislation requiring companies to provide information on products to place on their market, which are misaligned with existing CLP and REACH provisions. Examples include:

    - Belgian legislation establishing high fees for notifications of a range of chemical products[24]. These fees were initially proposed for the national notifications to the Belgium National Appointed Body. Yet, they have been maintained after the adoption of Annex VIII of the EU CLP Regulation, despite the latter already covers to a large extent the same groups of products.

    - Croatian legislation requiring to submit a Material Safety Data Sheet (MSDS) to a national authority for registration[25] before the first launch of a chemical for which a MDSD is required. This obligation still applies after the implementation of the Poison Center Notification (PCN) under the EU CLP Regulation, even though Annex II of REACH already regulates the content and format of Safety Data Sheets.

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[23] Consumo etiquetará los productos eléctricos y electrónicos en función de su reparabilidad, https://www.lamoncloa.gob.es/serviciosdeprensa/notasprensa/consumo/Paginas/2021/150321-etiqueta_reparabilidad.aspx [Accessed 01 February 2022]

[24] The Royal decree of 13 November 2011

[25] Croatian Chemicals Act of 2013 (OG 18/13)

- Danish legislation requiring volume reporting and specific labelling for a range of products[26]. Once the notification is done, the product receives a registration number which must be included on the label. These provisions add complexity, as the EU has already harmonised labels.
- Finnish legislation obliging to regularly submit notifications on a range of products[27]. In addition, annual information on the quantity of these chemicals produced or imported must be submitted. The EU PCNs regulated by Annex VIII of the EU CLP Regulation are akin to these measures.
- Latvian legislation stipulating that importers and manufacturers notify the national authorities of the properties and quantities of products shipped into the country[28]. These notifications are similar to the EU PCNs regulated by Annex VIII of the EU CLP Regulation that Latvia is also receiving.
- Swedish legislation stipulating that, once a threshold of 100kg/year is crossed, certain imported chemical products must be reported to national authorities[29]. The notifications are very similar to the EU PCNs regulated by Annex VIII of the EU CLP Regulation that Sweden is also receiving.

- *Implementation of the WEEE Directive:* it has been fragmented across the EU until now, hindering the free movement of goods and creating new bureaucratic costs. For example, the ElektroG in Germany classifies certain goods as “electronic waste”, which means they cannot be delivered to other countries even if there are buyers in those other countries who would repair or continue to use those products.

Product safety

- *Refrigerant gasses:* There are sophisticated safety standards on the use of flammable/toxic refrigerant gases. Today, they facilitate the uptake of safe refrigerants with lower Global Warming Potential (GWP) in heating, cooling and refrigeration technologies, as the EU’s F-Gas Regulation requires. However, mandatory safety requirements in national building codes are problematic from a harmonisation perspective. For example, legislation in France[30] continues to

[26] BEK 1794 of 18/12/2015

[27] Chemicals act 9.8.2013/599 22§ and 711/2020 amending the Chemicals Act

[28] Regulation of the Cabinet of Ministers of 22 December 2015 No. 795 "Accounting order of chemical substances and mixtures and the Database“

[29] KIFS (2017:7) Regulation

[30] Please see *: L'arrêté du 10 mai 2019 a modifié l'arrêté du 25 juin 1980 portant approbation des dispositions générales du règlement de sécurité contre les risques d'incendie et de panique dans les établissements recevant du public, les ERP* and *Arrêté du 10 mai 2019 modifiant l'arrêté du 30 décembre 2011 portant*

restrict the use of flammable refrigerants more than in other Member States, requiring market specific design changes or preventing placing on the market in France. We need more harmonisation at EU level to reduce fragmentation on building codes among countries and even regions and local territories. Beyond the use-phase, there are similar harmonisation opportunities on safety requirements, during manufacturing, transport (including tunnel codes), warehousing, installation, servicing, and end of life treatment.

- *Spare parts:* Legislation in France, Spain and Portugal requires the provision of spare parts for a certain period. Such legislation imposes burdensome requirements on the management of additional spare parts stock and delivery to these markets. Similar requirements are under consideration at EU level. But they are not always in line with these national efforts, especially on aspects like specific parts to keep in stock or number of years required for the provision of the parts. The overlap between national and EU-level efforts may lead to significant differences between EU countries.

- *Mains plug standardisation:* There is a lack of harmonisation on the use of main plugs across EU countries. Having a harmonised type of mains plug would facilitate logistics operations for manufacturers of electric and electronic equipment. In addition, the lack of harmonisation makes it complicated to implement a common EU charger at the alternating current (AC) side, whereas the USB-side has been standardised for many years.

- *Specific Absorption Rate (SAR) value disclosure:* Manufacturers of mobile phone and other products that perform SAR testing (essential requirement “health & safety”, art 3(1)(a) of the Radio Equipment Directive) must provide the SAR value to place their products on the French market. No other Member State requires this information, as manufacturers can demonstrate compliance with RED (and, by consequence, appropriate SAR values) by affixing the CE mark. This causes a significant fragmentation in the Single Market, despite the disclosure being redundant with regards to EU legislation.

- *Software updates:* Legislation in France contains a number of provisions on software updates, including requirements to provide information on the period of compatibility of the updates with the functionalities of a product and, for each update, the storage space it requires and its impact on the performance of the products.

  In addition, end-users should be able to refuse or uninstall the updates which are not necessary for conformity of the equipment if such updates have a negative

règlement de sécurité pour la construction des immeubles de grande hauteur et leur protection contre les risques d'incendie et de panique

impact on their access to digital content. It is also required that products contain the latest version of a digital element (i.e. software, firmware) at the point of sale.

These specificities of software updates for the French market pose risks of Single Market fragmentation. Other countries may have contradictory requirements, or none at all.

- *Interoperability of consumer radio receivers:* EU legislation introduces flexibility for Member States to adopt measures to ensure the interoperability of consumer radio receivers. This leads to differing legislation in Member States making use of this option, for example France, Italy, Germany and Belgium (Flanders). Crucially, this is the case even if the EECC[31] harmonises at EU level car radio receivers requirements. Barriers to intra-EU trade ensue. For example, some CE-marked products can be placed on the EU market but cannot be offered for sale in France.

- *Automated Driving System (ADS) type-approval:* the Implementing Act on the ADS will outline procedures and technical specifications for the type-approval on motor vehicles with regard to their ADS. The latest published iteration of the draft fails to lay out how it relates in practice to legislation in Member States, such as France or Germany. These countries already intend to have SAE[32] Level 4 Automated Vehicle (AV) frameworks in place in 2022 for ride hailing and shuttles.

  The Commission should include language describing the separation of powers between the Commission and its Member States in setting AV operating requirements and include specific guidance on the interpretation of this Act at a domestic level. Failing to include such language risks confusion for certification authorities, as to whether they should follow domestic AV requirements, EU requirements, or both. This poses a serious challenge to the ability of the EU Single Market to spur innovation in the mobility space by maintaining regulatory coherence. It requires urgent action to ensure industry can effectively implement safe automated driving solutions.

[31] European Electronic Communications Code
[32] Society of Automotive Engineers

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About DIGITALEUROPE

DIGITALEUROPE represents the digital technology industry in Europe. Our members include some of the world's largest IT, telecoms and consumer electronics companies and national associations from every part of Europe. DIGITALEUROPE wants European businesses and citizens to benefit fully from digital technologies and for Europe to grow, attract and sustain the world's best digital technology companies. DIGITALEUROPE ensures industry participation in the development and implementation of EU policies.

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National Trade Associations

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Belgium: AGORIA
Croatia: Croatian Chamber of Economy
Cyprus: CITEA
Denmark: DI Digital, IT BRANCHEN, Dansk Erhverv
Estonia: ITL
Finland: TIF
France: AFNUM, SECIMAVI, numeum
Germany: bitkom, ZVEI
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Portugal: AGEFE
Romania: ANIS
Slovakia: ITAS
Slovenia: ICT Association of Slovenia at CCIS
Spain: AMETIC
Sweden: TechSverige, Teknikföretagen
Switzerland: SWICO
Turkey: Digital Turkey Platform, ECID
United Kingdom: techUK