9th United Nations Conference on Competition and Consumer Protection
Room XIX, Palais des Nations
Geneva
7-11 July 2025

Managing Competition in Digital Health Ecosystems: Competition Law and Regulatory Alternatives

Presentation

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MANAGING COMPETITION IN DIGITAL HEALTH ECOSYSTEMS: COMPETITION LAW AND REGULATORY ALTERNATIVES

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Personal views – do not engage the UK CAT

HEALTH DATA AND PERSONALISED MEDICINE

- Big data and algorithms are playing a key role as they enable the development of custom/tailored solutions "beyond the pill" that combine drugs, sensors that collect information about the patient's condition and different kinds of analytics (e-medicine records, including diagnostic results, medication history and genomic or gene expression data, lifestyle data)
- With this data, medical providers are able to offer personalized medication and patient care
- The different parts of the human health value chain (medicine, preventive medicine, care, etc.) can also form a single picture for the consumer/patient – new business models
- Healthcare providers and health insurance companies are increasingly relying on the data they collect to personalize their offering and limit their risks when managing costly medical conditions, exacerbating the information asymmetry they already benefit from versus of their customers
- Focus on promoting competition in data transactions: issues of exploitation and fairness become paramount (as increasing data transactions may conflict with broader social contract commitments to protecting privacy – focus on ‘quality’)

Type of data	Examples	Data holder
Clinical data	Patient data, such as demographics, medical history, diagnoses, immunizations, medical notes, laboratory and radiology data and vitals	Doctors Hospitals
Clinical trial data	Clinical trials, early-stage R&D data	Pharmaceutical companies
Lifestyle data	Search results, mental state and emotions: fears and attitudes, health related data (e.g. diet, exercise)	Online marketplaces Search engines Mobile apps Digital device manufacturers (e.g. smart watches, smartphones)
Healthcare data	e-healthcare applications in which smart sensors and microscopic devices outside or inside the human body collect necessary medical information and exchange data related to health care and contribute to finding ehealthcare solutions	Medical device companies
Medical data record and history	Information on the patient's injuries, surgeries, immunisations, medicines taken, results of physical exams and tests	Health care and insurance providers
Genetic and other 'omics' data	DNA (genomics), RNA analysis (transcriptomics), proteomics (proteins), metabolomics (metabolites)	DNA testing companies (such as Illumina, Ancestry DNA), metabolomic services companies such as Metabolon, biobanking companies etc.
Data on costs, quality and consumption of pharmaceuticals and healthcare	Pharmaceutical prescription activity, data on hospitalisation activity, mortality data, healthcare surveys, national statistics	Public health authorities, insurance companies and specific health data companies (e.g. IQVIA)
Healthcare-related financial data	Payments to doctors, for hospital care, pharmaceutical consumption	Financial institutions (banks, payment cards companies)

HEALTH PLATFORMS & COLONIZATION OF THE DIGITAL HEALTH SPACE

H. Özalp et al., How Big Tech is breaking into the healthcare sector | Saïd Business School

COMPETITION RISKS

- The use of personal health data by companies with market power or through a central position in an ecosystem may, under certain conditions, have effects of both anti-competitive exclusion and effects of an exploitative nature
  - Human health data sources are heterogeneous - qualitative and quantitative, with these data collected at different time intervals and in different contexts, as they come from different stakeholders
  - Population-based datasets from public health authorities, insurance companies, and specific health data companies (eg, IMS Health) that have data on the cost and consumption of pharmaceuticals or healthcare use over the lifetime
  - Health Data as an Essential Facility (IMS/NDC Health)
- Special status legal protection: Article 7 & 8 of the Charter of Fundamental Rights of the European Union & GDPR (including lex specialis ePrivacy Directive and now ePrivacy Regulation)
  - Health data as a distinct "category of data"
  - Recital 35 GDPR defines health data as "all data relating to the health status of a data subject which discloses information about the past, current or future physical or mental state of health of the data subject"
  - Article 4 GDPR highlights and defines three important categories within which the lawfulness of their processing requires further discussion: "genetic data" , "biometric data" and "health-related data"
  - Article 6 GDPR – Conditions for the processing of general data

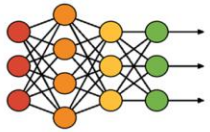
HEALTH DATA AND GDPR

- Article 9 imposes further requirements on specific categories of personal data, including genetic data, data that concern health and biometric data related to identification
  - The use of such data is prohibited unless
    - the data subject has given explicit consent to the processing of those personal data;
    - the performance of the obligations and the exercise of specific rights of the controller or the data subject in the field of labor law
    - the protection of the vital interests of the data subject or other natural of a person, if the data subject is physically or legally unable to consent
    - is carried out, with appropriate safeguards... and that the personal data is not shared outside the specific body without the consent of the data subjects
    - concerns personal data that has been expressly made public by the data subject
    - for the establishment, exercise or support of legal claims
    - for reasons of substantial public interest
    - for the purposes of preventive or professional medicine, assessment of the worker's capacity for work, medical diagnosis, provision of health or social care or treatment or management of health and social systems and services
    - for reasons of public interest in the field of public health, such as protection against serious cross-border threats to health or the assurance of high standards of quality and safety of health care and medicines or medical device
    - for archival purposes in the public interest, for scientific or historical research purposes or for statistical purposes

Synthetic Data

Definition *(by the Royal Society and Alan Turing Institute)*: "data that has been generated using a purpose-built mathematical model or algorithm, with the aim of solving a (set of) data science task(s)".

How are synthetic data generated?



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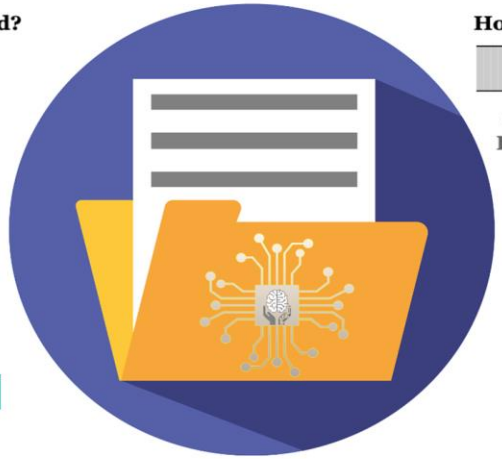


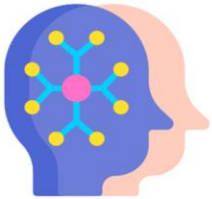
How are synthetic data classified?

Partially Synthetic

Fully Synthetic

DIGITAL TWINS

Virtual replicas of physical systems or processes that can be used to simulate and predict their behavior in real-time.

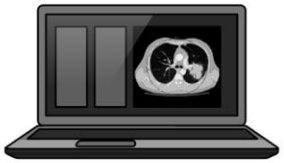


BIAS & QUALITY

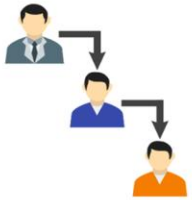
Lack of robust method to audit the perpetation of bias, accuracy and representativeness or real-world medical scenario.

DATA TYPE

Synthetic data can enrich the volume and diversity of datasets including tabular data and imaging alone or combined.



PRIVACY CONCERNS



1 Regulatory Agencies

GDPR and HIPAA are not sufficient or up-to-date to cover possible leakage of patients' information from synthetic dataset.

2 Differential Privacy

Based on a mathematical constraint that adds noise to the original dataset to protect individuals privacy.

3 Chain of Custody

To ensure the integrity, security, and privacy of data throughout its lifecycle (data sharing, storing, and disposal).

SYNTHETIC DATA CANNOT SOLVE THE ACCESS TO DATA PROBLEM

COMPETITION LAW - POSSIBLE THEORIES OF HARM

- Exploitative concerns
  - Excessive data extraction and personalized personalized (over)pricing
  - Unfair unfair commercial practices regarding terms imposed on users, in a disproportionate way, especially users business-ecosystem partners

- Exclusionary concerns: Bottleneck or delay in the development of digital health applications and services due to the protection of health data and the inability to (and/or protection from) easy access and sharing with the development of potential anti-competitive blocking strategies
  - Practices of offensive or defensive leverage (e.g. tied sales, tied discounts, agreements or exclusivity discounts) which may lead to anti-competitive effects
  - Refusal to provide interoperability: horizontal/vertical, technical, syntactic, semantic (e.g. Android Auto)
  - Envelopment strategy: a platform can monopolize a multi-sided market where user data generates revenue (the source market) by profitably enveloping another platform with overlapping users (the target market) by linking data protection policies and across the two platform marketplaces in order for the platform to (a) combine data generated by common users in both marketplaces without violating privacy regulations and (b) generate new revenue streams from a rich and difficult-to-replicate source data on the dominant platform of origin
  - A business can block/restrict competitors' access to data (or data-driven technological facilities/algorithms) in the platform it controls under the guise of protecting user privacy while simultaneously providing access to them to companies it controls in the same markets
  - Refuse its competitors' access to secondary data markets, allowing it to better target its products and services (e.g. . especially in personal medicine services), with the consequence of extending its power to vertical markets and imposing unfair conditions that limit the ability of users to choose the way their data is used but also unfair commercial practices on intermediate users (complementors)
  - Through vertical integration, a merged entity may gain access to commercially sensitive information about the activities of its competitors operating in the upstream or downstream markets, which would allow it to apply a less aggressive pricing policy in the downstream market to the detriment of consumers, or put its competitors at a competitive disadvantage, thereby discouraging entry or expansion them in the vertical market but also in the market of the same tier (Apple/Shazam, Google/Fitbit, CVC/Ethniki)

THE "END" OF BRONNER FOR DIGITAL ECOSYSTEMS?

- Interoperability and the limits to the Bronner indispensability test

- Case C-233/23, Alphabet and Others (Android Auto), ECLI:EU:C:2025:110
  - Request by in 2018 ENEL X to make its JuicePass App enabling drivers to find and reserve charging stations for their electric vehicles compatible with Google Android Auto
  - Templates developed by Google to ensure interoperability – and transfer the search to Google Maps app
  - Refusal by Google – multimedia and messaging apps are the only thir- party apps that are interoperable with Google Android Auto
  - In 2020 Google publishes a template for the design of experimental versions of electre vehicle charging apps that interoperate with Android Auto
  - Refusal to provide interoperability contrary to Art. 102 (Magill and IMS/NDC Health) by AGCM – case to Consiglio di Stato
  - "Genuine" competition between Google Maps and JuicePass apps
  - Indispensable or not? Note that the app was working without having access to Android Auto
  - Does Bronner indispensability test apply or is it possible to conclude that refuse to provide interoperability may be contrary to 102 TFEU even if access is not indispensable?

THE "END" OF BRONNER FOR DIGITAL ECOSYSTEMS?

- Bronner conditions justified by the "specific circumstances of the case"
  - right to property – development of the infrastructure for use for its own needs and ownership of it

- Para. *47*: "in order to establish whether the conditions laid down by the Court in […] *Bronner* […] apply to a case concerning a refusal of access to infrastructure, **it is necessary to establish whether that infrastructure** (i) **was developed by the undertaking in a dominant position solely for the needs of its own business** and (ii) **is owned by that undertaking in a dominant position** or whether, on the contrary, that infrastructure was developed in order to enable third-party undertakings to use it, which is evidenced by the fact that that undertaking in a dominant position has already granted such access to such third-party undertaking"

- Paras 50-51:
  - Refusal is capable of constituting an abuse of a dominant position **even though that digital platform is not indispensable** for the commercial operation of the app concerned on a downstream market […]
  - (Android Auto test) (i) whether **the refusal** by the dominant undertaking, which owns the digital platform concerned, to allow a third-party undertaking which has developed an app to access that platform, by ensuring that platform is interoperable with that app, **has the actual or potential effect of excluding, obstructing or delaying the development on the market of a product or service which is at least potentially in competition with a product or service supplied or capable of being supplied by the undertaking in a dominant position** and (ii) **constitutes conduct which restricts competition on the merits, and is thereby capable of causing harm to consumers**

THE "END" OF BRONNER FOR DIGITAL ECOSYSTEMS?

- Paras 73-74: "the refusal by the undertaking in a dominant position to ensure that an app is interoperable with a digital platform on the ground that there is no template for the category of apps concerned **may be objectively justified** where to grant such interoperability by means of such a template would, in itself and in the light of the properties of the app for which interoperability is sought, **compromise the integrity or security of the platform concerned, or where it would be impossible for other technical reasons to ensure that interoperability by developing such a template.** […] the fact that there is no template for the category of apps concerned or the difficulties involved in its development which the undertaking in a dominant position may face cannot in themselves constitute an objective justification for that undertaking's refusal to grant access"
- Para. 75: of particular relevance are (i) the **degree of technical difficulty in developing the template** for the category of apps concerned, which permits the access requested, (ii) **constraints related to the fact that it is impossible for it to equip itself, within a short time, with some of the resources,** in particular human resources, necessary to develop that template in the light of the needs of the undertaking requesting that access, or even (iii) **constraints external to the undertaking in a dominant position** which have an impact on its ability to develop that template, such as, for example, constraints **relating to the applicable regulatory framework**
- Para. 76: Article 102 TFEU **does not, however, preclude that undertaking from requiring an appropriate financial contribution** from the undertaking which requested interoperability. Such contribution must be **fair and proportionate,** allowing the undertaking in a dominant position, having regard to the actual cost of such development, to derive an appropriate benefit from it.

CVC/ ETHNIKI INSURANCE MERGER

Non-Horizontal Merger Guidelines (EU) https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:265:0006:0025:en:PDF (vertical mergers)

78. The merged entity may, by vertically integrating, gain access to commercially sensitive information regarding the upstream or downstream activities of rivals. For instance, by becoming the supplier of a downstream competitor, a company may obtain critical information, which allows it to price less aggressively in the downstream market to the detriment of consumers. It may also put competitors at a competitive disadvantage, thereby dissuading them to enter or expand in the market

86. Vertical integration may facilitate coordination by increasing the level of market transparency between firms through access to sensitive information on rivals or by making it easier to monitor pricing.

CVC/Ethniki

- Would HHG patients' health data and rival hospital doctors' billing data (commercially sensitive information) provide Ethniki a competitive advantage over rival health insurers?

- Ability & Incentive framework (patient's health data)
  - (paras 151-154) There appear to be certain enhanced legal limitations on the use of patients' data by Ethniki post-Transaction: Pursuant to GDPR, personal data concerning health should include all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject. This type of data is considered falling into one of the special categories of personal data, the processing of which shall be prohibited
  - If HHG sought consent allowing it to disclose patient data to Ethniki (or any other insurance company) for use for purposes other than administration of claims, it is likely that it would be refused in a large majority of case – would damage HHG reputation
  - majority of health insurer respondents explains that they target all healthy customers with no chronic medical conditions, irrespective of age or of having been admitted to a hospital
  - reaching out directly to customers to sell health insurance products is not common in Greece

BEYOND FORECLOSURE: ECOSYSTEMIC TOH

- The ecosystem "glue" as theory of harm
  - Adobe/Figma & aggressive entrenchment
  - Booking/eTraveli & defensive entrenchment
- Beyond vertical foreclosure & leveraging? Products may not be related (substitutes, complements)
- No need for bundling theories of harm (as for conglomerate mergers) – the problem is <u>not</u> a bundling strategy/conduct to be adopted in the future but the reinforcement of the ecosystem "glue" (structural/behavioural characteristics)
- Difficult issues regarding the integration of the so called "efficiencies" in the analysis as some may consider that they may form part of the theory of harm. Trade-offs?
  - Consumer welfare standard
  - Extended consumer welfare standard
  - Competitive process and 'competition on the merits"
- Essential issue is compatibility in the creation of shared networks/resources
  - N. Economides & I. Lianos, A Co-opetition theory of harm for Ecosystems, work in progress (2024)

See also, Coat of Many Colours—New Concepts and Metrics of Economic Power in Competition Law and Economics | Journal of Competition Law & Economics | Oxford Academic

Ecosystems and competition law in theory and practice | Industrial and Corporate Change | Oxford Academic

REGULATORY INITIATIVES I

- DMA
  - **Digital health services are not considered essential platform services** (according to s. 2 of the Act). The obligations imposed by articles 5 and 6 of the Act apply in respect of each of the essential platform services of the gatekeepers that were listed in the designation decision pursuant to Article 3(9) DMA
  - However, **they may also have an impact on other markets and services** in which the gatekeepers are active and in which the gatekeeper may use the disproportionate advantage conferred by its position in the core platform service (presence of large platforms subject to the Digital Markets Act and digital health or insurance services)
  - **Significant advantages** arise from i) the combination of end-user personal data collected by a core platform service with data collected by other services, ii) the cross-use of personal data from a core platform service to other services provided separately by the gatekeeper, in particular services that are not provided together with or in support of the relevant core platform service, and further, or iii) connecting end users to various gatekeeper's services for the purpose of combining personal data.
  - In accordance with **art. 5(2) DMA, providers may not combine personal data from the relevant core platform service with personal data from any further core platform services** or **from any other service they provide or with personal data from third party services** and are required to allow for end users to freely choose to participate in such data processing and login practices by **offering a less personalized but equivalent alternative** and without making the use of the core platform service or certain features thereof dependent on the end user's consent

REGULATORY INITIATIVES II

- DMA
  - Provision **of access rights and portability free of charge to data provided or generated in the context of the use of the relevant core platform service** or other services in support of the relevant core platform services**.**
  - **These rights benefit end-users and third-parties authorised by an end-user.**
  - They also **benefit third-parties business users/complementors that provide related services to the core platform and thus co-generate this data, if the end-users engaged or are still engaging with the products or services provided by them (Art. 6(9) DMA.**
  - Access should be effective, high-quality, continuous and done in real-time, for example by putting in place "high quality application programming interfaces or integrated tools for small volume business users"
  - **A more circumscribed access right is recognized in Art. 6(11) DMA to the benefit of third-party business users that have not taken any part in the generation of the relevant data (online search engines)**
  - **But what about other third-party users?**

REGULATORY INITIATIVES III

- **Data Act (2022) - Regulation (EU) 2023/2854**
- Complements the Digital Markets Act (DMA)
- The Regulation also recognizes the principle that all individuals can have access to the data they create
- Art. 3: imposes an obligation to manufacturers to technically design and provide the connected product/device data and related service data, including the relevant metadata and use those data, "free of charge, in a comprehensive, structured, commonly used and machine-readable format" so that these are directly accessible to the end-user and easily shared with third parties.
- Art. 4(1) establishes a non-waivable right to the user of the connected product/device to access and use the product and related service data for the provision of services agreed with the user (Art. 5(1), again free of charge to the end-user)
- Derived right
- Data Act applies for online product-related usage of data (e.g. through the use of a medical device or sensor) and does not cover situations of online-service related use of data (in the context of healthcare services provision).
- Data Act does not effectively deal with the relation between third-party actors external to the ecosystem and ecosystem actors (data holders, business and end-users) concerning data access.

REGULATORY INITIATIVES IV

European Health Data Space Regulation

- Vertical data regulation under 2020 Commission Data Strategy.
- Published in March 2025
- The European Commission focuses on the creation of an ecosystem that allows the secure exchange and use of healthcare data in the European area. Its proposal "supports individuals to gain control over their own health data[·] supports the use of health data for better healthcare delivery, better research, innovation and policy-making[·] and enables the EU to make full use of the that provides a secure and protected exchange, use and re-use of health data"
- Promoting a true single market for electronic health record systems, related medical devices and high-risk artificial intelligence systems (primary use of data) in providing a coherent, reliable and efficient framework for the use of health data for research, innovation, policy-making and regulatory activities (mainly in secondary data use)
- Provisions related to the interoperability of certain health related datasets
- Common infrastructure MyHealth@EU is designed to provide the infrastructure to facilitate cross-border exchange of electronic health data for primary use
- Implementation of a mandatory self-certification scheme
- Facilitation of the secondary use of electronic health data, e.g. for research, innovation, policy making, patient safety or regulatory activities and general provisions on transparency of fees calculation
- Common infrastructure HealthData@EU for secondary use (Art. 75 EHDS)

REGULATORY INITIATIVES V

EHDS Regulation (cont.)

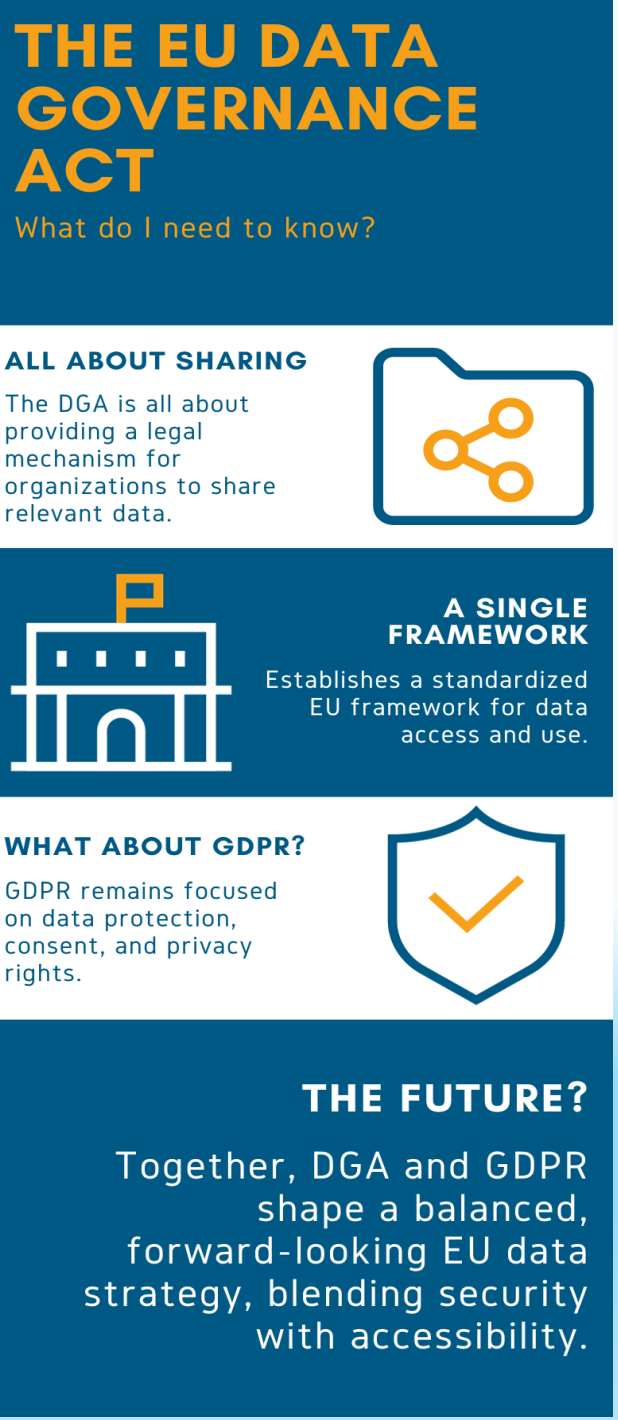
- Balance with Privacy
  - *Article 10* **Right of natural persons to opt out in primary use:** Member States' laws may provide that natural persons have the right to opt out from the access to their personal electronic health data registered in an EHR system through the electronic health data access services referred to in Articles 4 and 12. In such cases, Member States shall ensure that the exercise of that right is reversible
  - *Article 71* **Right to opt out from the processing of personal electronic health data for secondary use:** Natural persons shall have the right to opt out at any time, and without providing any reason, from the processing of personal electronic health data relating to them for secondary use under this Regulation. The exercise of that right shall be reversible

- Access plus to data and computational infrastructure access

REGULATORY INITIATIVES VI

Data Governance Act (2022) – Regulation 2022/688

- Reuse of public sector data that is subject to certain protections.
- Measures to ensure that data intermediaries will function as trustworthy organisers of data sharing or pooling within the common European data spaces
- Introduction of concept of **data altruism**: individuals and companies giving their consent or permission to make available data that they generate – voluntarily and without reward – to be used in the public interest
- Art. 2(16) of Regulation (EU) 2022/868 : defines 'data altruism' as 'the voluntary sharing of data on the basis of the consent of data subjects to process personal data pertaining to them, or permissions of data holders to allow the use of their non-personal data without seeking or receiving a reward that goes beyond compensation related to the costs that they incur where they make their data available for objectives of general interest as provided for in national law, where applicable' with healthcare mentioned as one of the areas



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