

Deliberation 2020-032 of March 19, 2020 National Commission for Computing and Liberties Nature of the deliberation: Opinion

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providing an opinion on a draft Conseil d'Etat decree relating to the benefits offered by persons manufacturing or marketing health products or services

(request for opinion no. 20002987)

The National Commission for Computing and Liberties, Request by the Ministry of Solidarity and Health of a request for an opinion on a draft decree from the Council of State relating to the advantages offered by persons manufacturing or marketing products or health services; Having regard to Convention No. 108 of the Council of Europe for the protection of individuals with regard to automatic processing of personal data; Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation or GDPR); Having regard to the Public Health Code, in particular its articles L. 1431-3, L. 1453-3 et seq. and L. 4113-9; Having regard to Law No. 78-17 of 6 January 1978 as amended relating to the information technology, files and freedoms; Having regard to ordinance no. 2017-49 of January 19, 2017 relating to the benefits offered by persons manufacturing or marketing health products or services ratified by Law No. 2019-774 of July 24, 2019 relating to the organization and transformation of the health system; Decree No. 2019-536 of May 29, 2019 taken for the application of Law No. 78-17 of January 6, 1978 relating to data processing, files and freedoms; On the proposal of Mrs. Valérie PEUGEOT, commissioner, and after having heard the observations of Mrs. Nacima BELKACEM, Government Commissioner, Issues the following opinion: The Commission has been asked by the Ministry of Solidarity and Health for a request for an opinion on a draft decree in Council State relating to the benefits offered by persons manufacturing or marketing health products or services known as an anti-gift device. This project is implemented pursuant to Ordinance No. of the law of 24 July July 2019 relating to the organization and transformation of the health system. The ordinance reorganizes and supplements the provisions of the Public Health Code relating to the principle of prohibition for persons exercising a regulated health profession, students, associations, civil servants and agents, to receive benefits, in cash or in kind, directly or indirectly, from persons who provide health services, produce or market products covered by compulsory social security schemes or certain products referred to in Article L. 5311-II of the Public Health Code, such as drugs, contraceptive products, biomaterials and medical devices, blood products, etc. These provisions also provide for exceptions to

the principle of prohibition, s with regard to research, research promotion or scientific evaluation activities in the context of which certain advantages may be consented. The offer of a benefit is then conditional on the conclusion of an agreement between the beneficiary and the person manufacturing or marketing health products or services. This agreement is subject to a system of declaration or authorization, depending on the amount of the benefits granted, to be made with the professional order concerned or, in the event that the person does not depend on an order, with the competent regional health agency. The draft article R.1453-13 of the Public Health Code clarifies the notion of persons providing health services: this concerns natural or legal persons who carry out an activity within the health establishments, medico-social establishments and services or providing a service provision covered by social protection and state medical aid (AME). the agreement. The content of the information to be included therein, the time limits for transmission by teleprocedure and the progress of the declaration and authorization procedures are thus determined. The data to be entered in the agreements relate to the identity of the parties to the agreement, to the subject of the agreement, to information enabling the identification of the indirect and final beneficiaries who have not signed the agreement, to the nature and amount of the benefits, to the date of signature of the agreement and to its effectiveness, to the authorization of accumulation of activities for public officials, the event program if applicable, the documentation specific to a scientific research project if applicable. Provided that the documentation relating to research projects does not contain personal data concerning participants, in particular information relating to patients which would be covered by medical secrecy, the Commission considers that these categories categories of data are adequate, relevant and limited to what is necessary with regard to the purposes for which they are processed, in accordance with the provisions of Article 5.1.c) of the GDPR. A new remote procedure tool will be put in place to allow the fulfillment and management of all these administrative formalities. This tool, currently being developed with the players concerned, will be submitted to the Commission, which it takes note of. Subject to these reservations, the draft does not call for any other observations from the Commission. President Marie-Laure DENIS