

AmCham's Position on the Data Exchange and Ethical Conduct Contracts of the Croatian Health Insurance Fund

The members of AmCham who are marketing authorization holders, or their local representatives, received the Data Exchange and Ethical Conduct Contract (the Contract) from the Croatian Health Insurance Fund (CHIF). The received Contract already had the CHIF's signature and stamp, which places the authorization holders in an inferior business position as it makes it impossible for both contracting parties to come to an agreement regarding the content of the Contract and the obligations arising from it.

In the following text, we would like to highlight a few key elements of the Contract that should be changed:

1. The proposed Contract is not in accordance with the EU and national personal data protection legislation

Article 2, paragraphs 2, 3, 4, 5 and 6 of the proposed Contract is not in accordance with the personal data protection regulations in force. Any collection and processing of personal data in accordance with the *General Data Protection Regulation* (GDPR) (EU 2016/679) (the Regulation) and the *Act on the Implementation of the General Regulation on Data Protection* (Official Gazette 42/2018) is legal only if at least one requirement from Article 6 of the Regulation is met. The processing of personal data of healthcare workers, pursuant to the text of the Contract, is not justified by the *necessity of processing* within the meaning of Article 6 of the Regulation, which would make such processing lawful. **If authorization holders delivered the data required by the Contract to the CHIF, they would knowingly be in infringement of the regulations regarding the protection of personal data**, which, according to the Regulation, could lead to a penalty of 4% of the global annual turnover for the previous financial year. Moreover, our opinion is that the proposed Contract is in breach of the provisions of the Act on Health Data and Information (OG 14/2019).

2. The proposed Contract stipulates a complete ban on advertising and providing information on medicinal products in the CHIF lists

Article 7 of the Contract stipulates that "*The authorization holder, or their authorized representative, shall not use any form of advertising or providing information on medicinal products in the primary and/or supplementary CHIF list that is prescribed under the provision of the current Ordinance on the manner of advertising and the Medicinal Products Act.*" This begs the question of whether the CHIF is introducing a complete ban on authorization holders advertising and providing information to healthcare workers on their medicinal products, which is permitted according to the *Medicinal Products Act* (OG 76/2013, OG 100/2018) and the *Ordinance on the manner of advertising medicinal products* (OG 43/2015). It is our hope that Article 7 is just an oversight or an example of clumsy wording and that the CHIF will accept the need for its revision. Otherwise, **the application of the Contract provision defined in this**

manner would constitute an unlawful restriction of activities conducted by authorization holders.

3. The proposed expansion of the Contract is not defined by the relevant Ordinance

*The Ordinance amending the Ordinance establishing the criteria for the inclusion of medicinal products in the reimbursement list of the Croatian Health Insurance Fund and the method for determining the pricing of medicinal products paid by the Croatian Health Insurance Fund and the method of reporting (OG 72/2023) (the Ordinance) defines the new name of the Contract constituting part of the documentation to be submitted to the CHIF when including medicinal products in the list in Article 16, paragraph 15. According to the amendment, the words "The Contract on Data Exchange" shall be followed by "and Ethical Conduct". However, the Ordinance does not define the content of the proposed Contract. For this reason, we think that the existing Data Exchange Contract already contains all the elements covering ethical practices and that there is **no need to conclude a new and amended Contract**. We want to draw particular attention to examples of requests for the inclusion of new medicinal products in the list submitted by authorization holders that have not yet signed Data Exchange Contracts so that they would not be put in a disadvantaged market position.*

In light of the aforementioned, we propose that the proposed Contract be withdrawn, that a meeting be organized to allow all parties to address concerns and unresolved issues, and that a working group be formed to find a mutually agreeable solution which would be in accordance with the existing Regulation, legislation and ordinances.

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