



The Unincorporated Association of Humanitarian and Social Activities. Monitoring, analysis.

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Prilohas 8/34-40

The sphere of respect for the PO. Box č. 21 198 21 Prague 98 human rights and obligations. e -mail: sdruzenicancer@seznam. cz

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13. 3., 2021

Number of pages: /6/Packet Attachments:

EUROPEAN MEDICINES AGENCY

Domenico Scarlattilaan 6 1083 HS Amsterdam The Netherlands

Our ref. no.: 2912/2020-Všeob-HC, a contact person: Ing. Jiří Plicka, HC commissioner, the holder of an international prize "In recognition of his courageous stand and personal engagement protecting democratic form of governance and his significant contribution to the Cause of Social Justice" Baden-Baden 2014, an international special prize "For outstanding educational leadership and dedication to Social Justice In Europe", Baden – Baden 2015 and an international prize "To the man of freedom and Independence for his participation and engagement in democratic changes in Europe" Jastrzebie-Zdroj 2014, international award "Outstanding Scholarly Contribution to the Advancement of Social Justice Award," Baden-Baden 2018, international award "in recognition of his outstanding legal defence work in Mycology and Human Ecology" Baden-Baden 2019, tel: 00420 773880075, e-mail info@voxpopuli.sk , e-mail: sustrova.Jaroslava@seznam.cz

CZECH VERSION ENGLISH VERSION Od (stěžovatel a poškozený): From (complaining and injured party): HABEAS CORPUS, spolek (dříve občanské HABEAS CORPUS, society (formerly citizens' sdružení) association), se sídlem Ocelkova 643/20 (dříve Jamská residing at: Ocelkova 643/20 (formerly: Jamská 355/16), 198 00 Praha 9, 355/16), 198 00 Praha 9, IČO: 70108102, Business reg/Id.No.: IČO 70108102, jednající Ing. Jiří Plickou, předsedou spolku represented by Ing. Jiří Plicka, the Chairman (též žadatel o poskytnutí dokumentů dle čl. 6 (also being the claimant demanding access to Nařízení Evropského parlamentu a Rady (ES) the documents according to the Article 6 of the č. 1049/2001) Regulation the European Parliament and Council (ES) No. 1049/2001) adresa pro doručování pošty v ČR: HABEAS CORPUS, P.O.Box č.21, 198 21 Praha 98, Delivery address in the Czech Republic: e-mail: info@voxpopuli.sk HABEAS CORPUS, P.O.Box č.21, 198 21 Praha 98, e-mail: info@voxpopuli.sk

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- Žádost o poskytnutí dokumentů a 1. informací dle čl. 6 Nařízení Evropského parlamentu a Rady (ES) č. 1049/2001 ze dne 30. 5. 2001 o přístupu veřejnosti k dokumentům Evropského parlamentu, Rady a Komise ve věci řízení o registraci očkovacích vakcín proti nemoci označované jako SARS-CoV-2 (Covid 19), a dozoru nad řádným průběhem tohoto řízení.
- Request for the provision of 1. documents and information in accordance with Art. 6 Regulation of European Parliament and of the Council No. 1049/2001 at 30. 5. 2001 regarding public access to European Parliament, Council and Commission documents in the case of the procedure for the authorisation of vaccines against the disease known as SARS-CoV-2 (Covid 19), and the supervision of the proper conduct of that procedure.





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Vážení,

ve věci řízení o registraci očkovacích vakcín proti nemoci označované jako SARS -CoV-2 (Covid 19), dále jen Covid 19 a dozoru nad řádným průběhem tohoto řízení Vás v souladu s čl. 6 Nařízení Evropského parlamentu a Rady (ES) č. 1049/2001 žádáme o zpřístupnění – zaslání níže uvedených dokumentů a informací, a to:

- a) kdo, kdy a na základě čeho u Vašeho úřadu zahájil řízení o registraci – schválení uvedení očkovací vakcíny proti covid 19 do prodeje (užívání)? Doložte konkrétní skutečnosti.
- b) kdo, kdy a na základě čeho dal zadání na vývoj a výrobu Vaším úřadem schvalované očkovací vakcíny proti Covid 19 a jak toto zadání znělo? Doložte konkrétní skutečnosti.
- c) kde probíhal vývoj Vaším úřadem schvalované vakcíny proti Covid 19, kdo byl (či je) vedoucím vývojového a výrobního týmu? Kdy a kde probíhaly klinické studie a klinické zkoušky dotyčné vakcíny a s jakým výsledkem?
- d) zda byly při zadání, klinických studiích či jinde či jinak u Vaším úřadem schvalované vakcíny proti Covid 19 zohledněny alternativní postupy ochrany populace s využitím tradičních rostlinných či jiných přípravků či jiné alternativní postupy za účelem posílení imunity populace přirozeným způsobem? Pokud ano, uveďte. Pokud nikoli, z jakého důvodu.
- e) jaké jsou vedlejší účinky Vaším úřadem schvalovaných vakcín proti Covid 19?

Dear,

in the case of the procedure for the registration of vaccines against the disease known as SARS-CoV-2 (Covid 19), hereinafter referred as Covid 19, and the supervision of the proper conduct of this procedure, in accordance with Art. 6 Regulation of European Parliament and of the Council No. 1049/2001, we are asking You for access - sending the documents and information mentioned below:

- who, when and on what basis did in Your office initiate an authorisation procedure - approval of the placing on sale (use) of a covid 19 vaccine? Proof specific facts.
- b) who, when and on what basis gave the assignment for development and production of, Your office-approved vaccine against Covid 19 and what was the wording of this assignment? Proof specific facts.
- c) where the development of your officeapproved vaccine against Covid 19 took place, who was (or is) the head of the development and production team? When and where were the clinical studies and clinical trials of the vaccine in question conducted and with what result?
- whether alternative procedures, using traditional herbal or other preparations or other alternative practices for the protection of the population to enhance the immunity of the population in a natural way, have been taken into account in the design of clinical trials, or elsewhere or otherwise with Your office-





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- kdo konkrétně má na Vašem úřadě zodpovědnost za schvalovací proces Vaším úřadem schvalovaných vakcín proti Covid 19?
- na jakém základě působí Vaším úřadem schvalované vakcíny proti Covid 19 (kupř. na základě oslabených či mrtvých původců choroby, na základě manipulace s RNA či DNA, popř. jiné)?
- h) zda a jak dlouho vakcíny schvalované Vaším úřadem proti Covid 19 chrání před nákazou Covid 19?
- zda vakcíny schvalované Vaším úřadem proti Covid 19 procházejí či prošly u Vašeho úřadu řádným schvalovacím řízení ve všech etapách, jak ukládá zákon?
 - Pokud nikoli, z jakého důvodu? Jaké části schvalovacího procesu byly popřípadě vynechány či "urychleny" a z jakého důvodu a na základě čeho se tak stalo?
- jaké garance poskytuje výrobce (či žadatel o registraci) u vakcín schvalovaných Vaším úřadem proti Covid 19 proti vedlejším (nežádoucím) účinkům vakcíny?
- doložte již konkrétní vydaná rozhodnutí Vaším úřadem o povolení (schválení) užívání vakcíny proti Covid 19 včetně odůvodnění.

- approved vaccine against Covid 19. If yes, state which. If not, state for what reason.
- e) what are the side effects Your officeapproved vaccines against Covid 19?
- who specifically has in Your office responsibility for the approval process of Your office-approved vaccines against Covid 19?
- on what basis does the vaccine (approved by Your office) against Covid 19 work? (e.g. based on weakened or dead disease agents, based on manipulation of RNA or DNA, or other)?
- whether and for how long do the vaccines against Covid 19, approved by Your office, protect against Covid 19?
- whether the Covid 19 vaccines approved by Your office undergo or have undergone a proper authorisation procedure at all stages at your office, as required the law?
 - If not, for what reason? Which parts of the approval process have been omitted or "accelerated", if any and for what reason and on what basis did it happen?
- which guarantees are provided by the manufacturer (or registrant) for Covid 19 vaccines, approved by Your office, against side effects of the vaccine?
- give us the evidence of the specific decisions made by Your office on the authorisation (approval) of the use of the vaccine against Covid 19 including justifications.





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Odůvodnění:

Byla dána společenská objednávka na legitimitu, kvalitu a dostupnost rozhodovacích procesů v rámci EU a členských zemí EU.

Vzhledem ke skutečnosti, že EU vznikla na základě dohod, jejímž základem je mimo jiné integrace, kooperace a to vše transparentně ve prospěch občanů EU a členských států EU, legitimita, kvalita a dostupnost rozhodovacích procesů musí býti v souladu mimo jiné i s příslušnými mezinárodními dokumenty, včetně Listiny základních práv EU (Ú.v. EU C 303, 14. 12. 2007, s. 1-16, zde zejména čl. 36 – přístup k službám všeobecného hospodářského zájmu, čl. 38 – ochrana spotřebitele, čl. 41 – právo na řádnou správu věcí veřejných atd....), není možno v rámci EU a členských států EU připustit a tolerovat svévolné, nelegitimní a netransparentní rozhodovací procesy či vytváření podhoubí k těmto.

Organizace HABEAS CORPUS dostala od mezinárodního kongresu zadání mimo jiné prozkoumat legitimitu, kvalitu, transparentnost a dostupnost kolem rozhodovacích procesů shora uvedených orgánů EU a národních orgánů.

Ve věci nejsou dány důvody k odepření zpřístupnění podřaditelné pod čl. 4 Nařízení EP a Rady (ES) č. 1049/2001, naopak, jak žadatel popsal ve svém podání shora, chování orgánů a států EU je velmi netransparentní a podezřelé.

Justification

Social demand for legitimity, quality and availability of decision-making processes within the EU and EU the member been formulated.

With regard to the fact, that the EU had come into existence on the basis of agreements which rest, among other things, upon integration and cooperation, and that all dealings must be transparent for the benefit of EU citizens and EU memberesates, the legitimity, quality and availability of decission-making processes must be in accordance with the respective international documents, including the Chart of . Basic Rights of the EU (OJ EU C 303, 14th Dec. 2007, pp. 1-16, here especially Article 36 - Access to services of general economic interest, Article 38 - Consumer protection, Article 41 - Right to proper administration of public affairs, etc...) within the EU and its member states, it is not possible to admit and tolerate arbitrary, unlawful and intransparent decision-making processes or creation breeding ground for such.

The organisation HABEAS CORPUS was given by the international Congress a commission to survey, among other things, legitimity, quality, transparency and availability concerning decision-making processes of the above mentioned organs of the EU and national organs.

In this matter, there are not given any reasons to deny access which could be classified under the Article 4 of the Regulation of European Parliament and the European Council No. 049/2001 - on the contrary, the conduct of the EU organs and states highly intransparent and suspect.





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Očekáváme zjednání nápravy a Vaše písemné stanovisko, které zašlete prosím na adresu:

We expect that the situation be remedied and we expect your statement in writing to be sent to the address:

HABEAS CORPUS, spolek P.O. BOX č. 21 198 21 Praha 98 Česká republika

e-mail: info@voxpopuli.sk

Děkujeme za pochopení S pozdravem

Thank you for your kind consideration. Your sincerely

Ing. Jiří Plicka předseda spolku HC komisař spolku HC HABEAS CORPUS (HC)



Ing. Jiří Plicka Chairman of HC Commissioner of HC HABEAS CORPUS (HC)



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