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Ref.: Authorization of a cure for Covid-19 by the Italian Agency AIFA-Agenzia Italiana del Farmaco, consequent forfeiture of the conditional market authorization pursuant to art. 4, lett. c) of the COMMISSION REGULATION (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council

Dear Ms. Kyriakides, dear Madam or Sir,

I'm writing in my capacity as an attorney at law (Bar of Rome n. A21477) and as President of the Italian Association Movimento Libertario. Since the beginning of the Covid-19 crisis our association has been deeply involved in the defence of the civil rights and fundamental liberties under heavy

attack owing to the illegal policies of the Italian government. The situation appears to be particularly serious in Italy where, in spite of the recommendations both by the Council of Europe (resolution 2631/2021) and by the European Parliament and the Council (EU) 2021/953, the government is pushing Covid-19 vaccinations as an obligation for all healthcare workers and doctors and for the general population by the illegal use of the Covid-19 certificates.

According to art. 4 of the Commission Regulation (EC) No. 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council:

> *"1. A conditional marketing authorisation may be granted where the Committee finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all the following requirements are met:*
> *(a) the risk-benefit balance of the medicinal product, as defined in Article 1(28a) of Directive 2001/83/EC, is positive;*
> *(b) it is likely that the applicant will be in a position to provide the comprehensive clinical data;*
> ***(c) unmet medical needs will be fulfilled;***
> *(d) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. In emergency situations as referred to in Article 2(2), a conditional marketing authorisation may be granted, subject to the requirements set out in points (a) to (d) of this paragraph, also where comprehensive pre-clinical or pharmaceutical data have not been supplied.*
> *2. For the purposes of paragraph 1(c), 'unmet medical needs' means a condition for which there exists no satisfactory method of diagnosis, prevention or treatment authorised in the Community or, even if such a method exists, in relation to which the medicinal product concerned will be of major therapeutic advantage to those affected."*

Now, according to the aforementioned Regulation, EMA, the European Commission and the Italian medicines agency AIFA approved all four Covid-19 vaccines actually in use in Italy. The relevant decisions by AIFA are the n. 154/2020 (Comirnaty), 1/2021 (Moderna), 18/2021 (Vaxzevria-AstraZeneca) and 49/2021 (Janssen-Johnson&Johnson). The vaccines, as everywhere in Europe, have received a conditional marketing authorization. As far as Italy is concerned, the main condition to be fulfilled by the producers of the vaccines is the presentation of a study in order to confirm the efficacy and safety of the anti-Covid-19 vaccine; the marketing authorisation holder must submit the final report of the randomised, placebo-controlled blinded clinical trial by the following deadlines: -

Comirnaty, December 2023, - Vaxzevria-AstraZeneca 31.03.2024, - Moderna December 2022, - Janssen-Johnson&Johnson 31.12.2023.

As mentioned, the condition precedent for the upholding of any conditional marketing authorization is the continuing condition of the existence of unmet medical needs, i.e. the inexistence of a cure for Covid-19.

This situation came to an end in Italy and, hence, in the whole European Union. Namely, AIFA approved two resolutions both dated August 4th, 2021, and duly published in the Italian Official Gazette (**see attachments 1, 2 and 3**) whereby two therapies for both severe and light cases of Covid-19, the monoclonal antibodies sotrovimab and casirivimab-imdevimab, have been officially authorized starting from August 7th 2021 for the treatment of the Coronavirus disease (Covid-19).

Hence, unmet medical needs have ceased to exist since the approval of the above mentioned monoclonal antiobodies and the condition set forth in art. 4 of the Commission Regulation (EC) No. 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council isn't applicable.

Accordingly, I ask the Commission and EMA to immediately review the conditional marketing authorizations issued on the European Union level and to revoke the same. The risk of using new vaccines, whose safety and efficacy are still under scrutiny and will remain for the next years is too high and not to be accepted lightly if a cure for the same disease has been found. Further, the immediate stop of the conditional marketing authorizations appears to be the only remedy for the illegal machinations of the Italian government, which is imposing the vaccines, contrary to any principle of the law of the European Union. It is necessary to highlight that the Italian government is in continuous violation of art. 3 of the Charter of Fundamental Rights of the European Union (2000/C 364/01) whose art. 3 has been violated both by the law that made the vaccination of doctors and healthcare workers compulsory (law-decree 44/2021) and the two laws that introduced a modified version of the Covid-19 pass (law-decrees 105/2021 and 111/2021) which substantially makes the vaccination a necessity even for basic needs like entering a restaurant, travelling on means of public transportation or teaching in schools and universities. According to art. 3.2. of the said Charter ***"in the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned."***

Such a principle, that constitutes integral part of civilized countries at least since the Nuremberg trials has been blatantly disregarded by the Italian government and I herewith respectfully

apply for immediate and energic action by each and any European institution and authority, lest our country will be left with the ruins of what used to be the rule of law.

Faithfully yours,

Avv. Alessandro Fusillo
President of the Association
Movimento Libertario