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Europe set to approve a new mRNA vaccine for human use

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In late February, the European Medicines Agency (EMA) recommended granting marketing authorisation for a vaccine marketed under the name mCombriax. This is an mRNA "*vaccine*" against COVID-19 and seasonal flu, developed by Moderna, intended for people aged 50 and over. This opinion will be forwarded to the European Commission, which could adopt the marketing authorisation decision. Given that mRNA technology is still in its infancy and has not yet really proven itself in the medical field, this favourable opinion is somewhat surprising.

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The EMA's recommendation[i] is indeed somewhat surprising, given that in the United States, following Moderna's application for marketing authorisation for this vaccine, the Food and Drug Administration (FDA) had requested additional data[ii].

Moderna published the results of its initial trials for this vaccine in 2022. Then, in 2025, it stated that "*mRNA-1083 had an acceptable tolerability and safety profile*" and that "*mRNA-1083 was demonstrated to be at least as immunogenic as recommended standard care vaccines against both seasonal influenza and COVID-19*"[iii].

What is the situation regarding this vaccine and the clinical trial results that led the EMA to make this recommendation? Why is there such a marked disparity on either side of the Atlantic?

mCombriax, a combination of two other Moderna vaccines

The vaccine that Moderna tested in its clinical trials is described as "*combined*". It contains five different mRNA molecules grouped under the name "*mRNA-1083*"[iv].

To combat Covid, this vaccine contains mRNA derived from Moderna's next-generation vaccine, a vaccine called mNEXSPIKE (against the latest known variant of the SARS-CoV-2 virus: Omicron XBB.1.5). mNEXSPIKE has been approved by the FDA and has recently been authorised, notably in Europe[v].

To combat seasonal influenza, this vaccine contains, according to Moderna's protocol, four messenger RNAs from a vaccine targeting seasonal influenza strains: AH1N1, AH3N2, B/Victoria and B/Yamagata[vi]. Prior to this combined vaccine, Moderna had already proposed an mRNA vaccine candidate against influenza under the name "*mRNA-1010*"[vii]. This vaccine was rejected in the United States in February 2026[viii], as the study protocol was deemed insufficient, notably due to a lack of adequate comparison with a high-dose vaccine in people aged 65 and over[ix].

The vaccine tested in clinical trials therefore contains a total of five different messenger RNAs derived from artificial genetic constructs. In mRNA vaccine technology, the mRNAs are predominantly encapsulated in artificial lipid nanoparticles, which is the case here[x].

In this combined vaccine, the mRNA designed to combat Covid is intended to trigger the production of the (modified) viral spike protein in cells, whilst the four mRNAs designed to combat seasonal influenza are intended to trigger the production of the corresponding four modified viral membrane proteins (haemagglutinins). Five modified antigenic proteins will thus be produced simultaneously[xi].

It should be noted that the version of mCombriax intended for marketing will contain only four mRNAs. The one targeting the B/Yagamata viral strain has been removed, as this strain is no longer recommended for use in vaccines by the WHO[xii], the virus is no longer circulating, and the tested vaccine did not elicit a good immune response against this strain.

In Europe, the EMA states that the composition of mCombriax should be updated regularly. This will involve changing the mRNAs corresponding to the viral strains circulating in the community and recommended by the WHO. A new authorisation will not be required.

The EMA emphasises that the advantage of this combination is "*single shot*" vaccination and, according to Caducee's website, "*for healthcare professionals, the operational benefit is immediate: limiting the number of injections, reducing missed opportunities, and facilitating administration, particularly among patients who accept the flu vaccine but are still hesitant about the COVID-19*

booster — or vice versa"[xiii].

Does this EMA proposal conceal a form of compulsory vaccination against Covid-19? Should we expect the flu-only vaccine to disappear? There is a precedent for this with certain vaccines that have been imposed on children.

Unconvincing efficacy data

According to the EMA's summary, which is based on the Phase 3 clinical trial of Moderna's mRNA vaccine, the immune responses induced by mCombriax are considered "*statistically non-inferior*" to those obtained with the separately administered vaccines used as comparators. These comparators are Moderna's COVID-19 vaccine (Spikevax) and traditional (inactivated virus) quadrivalent influenza vaccines from GSK (Fluarix) and Sanofi Pasteur (Fluzone).

It should be noted that for Fluarix, the B/Victoria and B/Yamagata strains targeted are not those targeted by mRNA-1083. Moderna conducted its studies on approximately 8,000 people, with two cohorts: one aged 50 to 64 (the comparator was standard-dose Fluarix for influenza) and the other aged 65 and over (the comparator was high-dose Fluzone for influenza)[xiv].

However, relying solely on partial and purely biological immune responses (the presence and levels of antibodies in the blood) is scientifically insufficient, as other criteria come into play. As the Caducee[xv] website explains: "*this choice of a non-inferiority criterion, which is standard in vaccinology when the aim is to integrate a new formulation into an existing standard, nevertheless calls for a cautious interpretation in medical communications: non-inferiority in terms of antibody titres does not automatically, on its own, translate into a measurable clinical benefit in terms of hospitalisations or mortality in the pivotal trial as publicly summarised. Tolerability data are reported as acceptable in EMA communications and the business press, but the level of detail (subgroups, rare events, the very elderly and those with comorbidities) will depend on the consolidated regulatory documentation*".

It is, however, on the basis of this fragile immunological standard that the EU risks authorising mCombriax. All the more so as no long-term efficacy studies have been conducted, which no longer seems to be a concern.

Incomplete results regarding the vaccine's safety

Safety assessments of the mRNA-1083 vaccine included the monitoring of local and systemic adverse reactions for 7 days following vaccination, and of adverse reactions of varying severity for up to 28 days, and subsequently for up to 180 days following vaccination.

In the EMA's conclusions, only local side effects common to all vaccines are reported. In its press release of February 2026, Moderna states that "*mRNA-1083 demonstrated an acceptable safety and tolerability profile*"[xvi].

However, a closer examination of the phase 3 clinical trial[xvii] shows that, regardless of the vaccine - including the combined vaccine - people aged 65 and over experience more adverse effects of varying severity than those in the 50-64 age group. It also shows more serious adverse events among those vaccinated with the combined vaccine (71 out of 2,011) than among those vaccinated with two separate vaccines (52 out of 2,006) in the oldest age group.

It should be noted that four deaths, which were not attributed to vaccination, occurred during the mRNA-1083 trial.

As the uncertainties surrounding the messenger RNAs used in vaccines and their potential risks have already been documented by *Inf'OGM*, they will not be addressed here[xviii]. There are numerous risks, particularly those relating to the spike protein. The risks of contamination of these vaccines by residual DNA from their manufacture are also a cause for concern. These issues regarding genetic residues not properly removed during the purification phase have been raised for some time. With this type of multi-mRNA vaccine, which therefore requires multiple DNA templates, this problem should be analysed more seriously.

The mRNA vaccine market and politics

According to *Reuters*, Moderna is under financial pressure to bring this vaccine to market, with the agency noting that the differing treatment of its mCombriax vaccine between Europe and the United States can be explained as follows: "*Moderna is banking on the COVID-flu combination shot and also an mRNA-based flu shot to help it return to revenue growth as demand for COVID vaccines has collapsed in the years after the pandemic*"[xix].

Reuters reports that the FDA, which had rejected Moderna's mRNA flu vaccine in early February 2026, reversed its decision a week later after the company amended its application. The FDA is now due to announce its decision by 5 August. Reuters adds that this episode has fuelled "*drugmaker and investor concerns over policy changes at the agency [the FDA]*"[xx].

It is worth recalling that the US Department of Health and Human Services has cut funding for messenger RNA research. Members of the FDA have also resigned from their posts, a move that has not gone down well with the vaccine industry.

In the United States, there is an "*Advisory Committee on Immunization Practices*" (ACIP) made up of independent experts. US states and insurance companies rely on its recommendations to reimburse vaccines. In 2025, the ACIP withdrew its recommendation for the mRNA vaccine against Covid, but in March 2026, a federal judge ruled that the ACIP was incompetent, following a complaint from professional associations, the majority of which are funded by the pharmaceutical industry. Consequently, the judge's decision suspends the change to the vaccination schedule decided by the Department of Health[xxi], and mCombriax could be authorised in the United States next August.

Are financial gains so important that health considerations are being sidelined? In any case, they are the primary concern of those who produce and market mRNA vaccines, whilst in-depth assessments of the risks and actual efficacy of such products are rarely, if ever, carried out properly. The fact that health agencies, such as the European Medicines Agency (EMA) in the case of mCombriax, do not require these assessments – or no longer do so – is extremely worrying.

i EMA, « First combined COVID-19 and influenza vaccine for people 50 years and older », 27 February 2026.
Moderna, « European Medicines Agency's Committee for Medicinal Products for Human Use Adopts Positive Opinion Recommending Marketing Authorization of mCOMBRIAX, Moderna's mRNA Combination Vaccine Against Influenza and COVID-19 », 27 February 2026.

ii Chris Dall, CIDRAP (University of Minnesota), « European regulators recommend approval of combined mRNA vaccine for flu and COVID », 27 February 2026.

iii Amanda K. Rudman Spergel, Iris Wu, Weiping Deng *et al.*, « Immunogenicity and Safety of Influenza and COVID-19 Multicomponent Vaccine in Adults ?50 Years – A Randomized Clinical Trial », *JAMA*, 7 May 2025, Vol. 333, No. 22.

iv *Ibid.*

v Vidal, « Le nouveau vaccin à ARNm de Moderna, mNEXSPIKE, est Mayntenant autorisé en Europe », 24 February 2026.

vi Amanda K. Rudman Spergel, Iris Wu, Weiping Deng *et al.*, « Immunogenicity and Safety of Influenza and COVID-19 Multicomponent Vaccine in Adults ?50 Years – A Randomized Clinical Trial », *JAMA*, 7 May 2025, Vol. 333, No. 22.

vii Moderna, « Moderna Announces Interim Phase 3 Safety and Immunogenicity Results for mRNA-1010, a Seasonal Influenza Vaccine Candidate », 16 February 2023.

viii « Fin de non-recevoir de la FDA à un projet de vaccin antigrippal à base d'ARN messager », *AFP*, 11 February 2026.

ix « mCombriax : l'EMA recommande le premier vaccin combiné COVID-grippe dès 50 ans », *Caducee.net*, 1 March 2023.

x Amanda K. Rudman Spergel, Iris Wu, Weiping Deng *et al.*, « Immunogenicity and Safety of Influenza and COVID-19 Multicomponent Vaccine in Adults ?50 Years – A Randomized Clinical Trial », *JAMA*, 7 May 2025, Vol. 333, No. 22.

xi Pfizer also conducted trials of mRNA vaccine against seasonnal flu.
Annick Bossu et Mireille Lambertin-Martinez, « Will the mRNA flu vaccine come into being? », *Inf'OGM*, 20 February 2026.

xii Moderna, « European Medicines Agency's Committee for Medicinal Products for Human Use Adopts Positive Opinion Recommending Marketing Authorization of mCOMBRIAX, Moderna's mRNA Combination Vaccine Against Influenza and COVID-19 », 27 February 2026.

xiii « mCombriax : l'EMA recommande le premier vaccin combiné COVID-grippe dès 50 ans », *Caducee.net*, 1 March 2023.

xiv Amanda K. Rudman Spergel, Iris Wu, Weiping Deng *et al.*, « Immunogenicity and Safety of Influenza and COVID-19 Multicomponent Vaccine in Adults ?50 Years – A Randomized Clinical Trial », *JAMA*, 7 May 2025, Vol. 333, No. 22.

xv « mCombriax : l'EMA recommande le premier vaccin combiné COVID-grippe dès 50 ans », *Caducee.net*, 1 March 2023.

xvi EMA, « First combined COVID-19 and influenza vaccine for people 50 years and older », 27 February 2026.
Moderna, « European Medicines Agency's Committee for Medicinal Products for Human Use Adopts Positive Opinion Recommending Marketing Authorization of mCOMBRIAX, Moderna's mRNA Combination Vaccine Against Influenza and COVID-19 », 27 February 2026.

xvii ClinicalTrials.gov, « A Study of mRNA-1083 (SARS-CoV-2 and Influenza) Vaccine in Healthy Adult Participants, ?50 Years of Age ».

xviii Annick Bossu, « Une deuxième vague de vaccins à ARNm arrive sur le marché », *Inf'OGM*, 5 November 2024.

[xix] Bhanvi Satija, « EU regulator backs approval for Moderna’s combined COVID and flu vaccine », *Reuters*, 27 February 2026.

[xx] Mariam E Sunny and Michael Erman, « US FDA reverses course, will review Moderna's flu vaccine application », *Reuters*, 18 February 2026.

[xxi] Testimony of Pr. Charlotte Kuperwasser, molecular biologist in : Hélène Banoun, « Ils reconnaissent l’existence de ces sous-produits. Où sont les données ? », AIMSIB, 29 March 2026
