Insights into the European public data on conditional marketing authorisations for the four COVID-19 vaccines (30 March 2021)

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The complete file of this article can be downloaded in PDF format here (French).

Note from the translator:

- *This text was originally published in French and largely consisted of excerpts from English-language source documents.*
- *Items of particular public concern are highlighted in the English translation.*

As a Doctor of Pharmacy and as a former international regulatory director in the pharmaceutical industry, my aim is to help you understand the official source data relating to the four COVID-19 vaccines. I loved my job of analysing legal texts to know how best to develop medicines and work in synergy with the different parts of the company and the health authorities in France and internationally (up to 83 countries).

On 30 March 2021, Pfizer, Moderna, AstraZeneca and Janssen obtained a conditional marketing authorisation (MA) for four COVID-19 vaccines (between December 2020 and March 2021).

In order to fully understand the current situation, it is necessary to access source data that are difficult to identify by someone who does not work in the field. The objective of this article is therefore to present an overview of the public information for these 4 COVID-19 vaccines with a reference to each source to allow validation of the authenticity.

In this article you will find links to the official Marketing Authorisation documents and summaries of scientific studies as assessed by the European Medicines Agency (EMA).

I would like to clarify that I have no conflict of interest with the pharmaceutical industry.

1. First, it is important to know what a conditional marketing authorisation is:

A Marketing Authorisation (MA) is granted when a product has proven its quality, efficacy and safety with a positive benefit/risk ratio (i.e. it has more benefits than risks). Obtaining marketing authorisation is a prerequisite for selling a medicine, including vaccines.

The four MAs issued are so-called conditional MAs, valid for one year, because they were obtained on the basis of allegedly incomplete data. To obtain a standard 5-year MA, the laboratories must provide dossiers completed with studies in progress and studies planned for the coming years. Throughout this development, close monitoring between the manufacturing companies and the health authorities is organised through regular discussions. The conditional marketing authorisation is re-evaluated each year according to the input and critical analysis over a full year.

All the studies submitted during the MA application are summarised in the EPAR (European Public Assessment Report). This is published on the website of the European Medicines Agency (EMA). Planned studies that have not yet been completed are also published there. This schedule, which runs from 2021 to 2025 depending on the COVID-19 vaccines, is defined in the annexes of the conditional MA and in the EPAR.

The MA is granted to a laboratory called Marketing Authorisation Holder (MAH). The conditional MAs were obtained on the basis of quality, clinical and non-clinical data from "**vaccine trials and/or literature**". Literature data are studies published in recognised scientific journals, written by teams that may or may not be other than those of the laboratory applying for the MA.

The European MA, obtained through the centralised accelerated procedure, allows simultaneous marketing in the following 30 countries (European Union and European Free Trade Association): Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden.

For example, the EPAR (European Public Assessment Report; pages 67 and 114) of 19 February 2021, relating to Pfizer, the most widely administered COVID-19 vaccine to date with the broadest treatment indication (individuals above 16 years of age) states that the main clinical study, known as the pivotal study, is a phase 1/2/3 study, still ongoing.

Original EPAR data in English

“Study C4951001: A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-COV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals

“The safety evaluation is based on one ongoing Phase 2/3 study that at the time of data cut-off (14-Nov-20) included 43,448 subjects who received either two doses of BNT162b2 30µg (n=21,720) or placebo (n=21,728). Overall, the reported reactogenicity profile are [sic] in line with any authorised vaccine. In addition, the frequency of reported AEs and SAEs were [sic] low. The emerging safety profile is presently considered favourable. Long term safety data, interaction with other vaccines, data on use in pregnancy and other subgroups (e.g. frail subjects, or subjects with pre-existing autoimmune diseases) are missing at this stage.

“The lack of long-term follow up renders the data provided non-comprehensive. Therefore, the delivery of the final C4951001 study report, including a 2-year follow up of the studied population, is classified as a specific obligation in the context of a conditional marketing authorisation.

“The plan for the generation of further safety data post authorisation is described in the section below.”

2. Summary table of official data from the four COVID-19 vaccine conditional MAs published on the EMA website

An overview is needed of the progress of the registration procedure and the studies still to be provided. The table below shows the various official data published on the EMA website: These data were taken from the official texts on 22 March 2021 (the underlined texts refer to the corresponding links on the official EMA website and all the links are summarised at the end of this document).

Marketing Authorisation Holder (MAH)	**BioNTech/ Pfizer**	**Moderna Biotech**	**AstraZeneca**	**Janssen**
Date of obtaining the possibility to apply for a European Marketing Authorisation (eligibility date)	23 July 2020	12 Oct 2020	9 June 2020	28 July 2020
Date of submission of the Marketing Authorisation Application to the European Medicines Agency	30 Nov 2020	30 Nov 2020	11 Jan 2021	15 Feb 2021
Date of conditional European Marketing Authorisation	21 Dec 2020	6 Jan 2021	29 Jan 2021	11 Mar 2021
Date of the European Public Assessment Report (EPAR) of the marketing authorisation dossier, which summarises all the studies submitted in terms of quality, safety, tolerance, efficacy and benefit/risk ratio.	23 Dec 2020 Version used: 19/02/2021 (140 pages)	20 Jan 2021 Version used: 11 March 2021 (169 pages)	29 Jan 2021 Version used: 181 pages	11 Mar 2021 Version used: (218 pages)
Date of Risk Management Plan report	23 December 2020 (114 pages)	20 January 2021 (95 pages)	18 February 2021 (106 pages)	11 March 2021 (103 pages)
Additional studies to be provided as requested in the annexes of the European MA	**See Table 1 below**	**See Table 2 below**	**See Table 3 below**	**See Table 4 below**
Deadline for submission of supplementary quality evidence for the active substance and the finished product	July 2021 Note: Use of 2 new excipients	June 2021 Note: Use of 2 new excipients	December 2021	August 2021
Deadline for submitting confirmation of efficacy, safety and tolerability of the vaccine	December 2023	December 2022 to June 2025 (see EPAR pp. 134, 139)	May 2022 (main analysis) March 2024 (elderly and underlying disease)	December 2023

3. From the analysis of these public data, it can be seen that:

- These vaccines received a conditional marketing authorisation, **valid for one year instead of the 5 years for standard MAs**. Ongoing and planned studies must be finalised in order to obtain the standard MA.
- **Clinical trials, even if they have been planned, have not been completed and some have not yet started.** Depending on the vaccine, the final deadlines are expected **between 2022 and 2025** (see table above).
- **No data are available on the interchangeability of a COVID-19 vaccine** from one laboratory with other COVID-19 vaccines from other laboratories to complete the vaccination schedule.
- **Vaccines are indicated for use from 18 years of age**, except for Pfizer's vaccine which is indicated from **16 years of age**.
- **"The safety and efficacy of the vaccines in children and adolescents under 18 years of age have not yet been established."** This is the case for Moderna, Astra-Zeneca and Janssen for which "**no data are available**". The same is true for Pfizer "in children and adolescents under 16 years of age with limited data available".
- **Data on pregnant women are very partial** (exclusion criteria for clinical trials): little or no safety and efficacy data are known to date. (See **Table 5** as an example). **Vaccination in pregnant women can only be considered on a case by case basis.** For the three Pfizer, Moderna and Janssen vaccines, the scientific notice represented by Annex I of the MA (summary of product characteristics) indicates that *"there are limited data on the use of the vaccine in pregnant women. Studies in animals have not shown direct or indirect deleterious effects on gestation, embryonic/foetal development, parturition or postnatal development (see section 5.3 of Annex I of the MA). Use in pregnant women should be considered only if the potential benefits outweigh the potential risks to the mother and the foetus." There is no information similar to this mentioned in AstraZeneca's package insert: "If you are pregnant or breastfeeding, think you might be pregnant or are planning a pregnancy, ask your doctor, pharmacist or nurse for advice before receiving this vaccine."*
- Experience has shown that any drug marketed can bring to light large-scale side-effects that were not or only slightly seen in clinical trials. **This specifically means that side effects linked to vaccination can appear over time** (which no doubt explains the AstraZeneca episode of mid-March 2021).
- The conditional marketing authorisation of vaccines under the European centralised accelerated procedure was "*granted in the interest of public health to meet an unmet medical need*". Some professors and doctors have stated that they have observed in the field the effectiveness of treatments consisting of drug combinations: antivirals, antibiotics, vitamins, food supplements, etc. We know the debate that has been going on since then about the difference in treatment between scientific publications which could be acceptable in terms of meeting regulatory criteria as part of an application for a conditional marketing authorisation for new vaccines, and could be unacceptable for the use of drugs that have been used for many years (cf. hydroxychloroquine) ... The argument remains unresolved.

In conclusion, the European conditional marketing authorisation obtained in 30 countries on the basis of incomplete and/or literature studies and forthcoming studies enables us to understand why the administration of the COVID-19 vaccine in 2021 is a large-scale investigation procedure.

People who are vaccinated as part of ongoing or future studies (such as children, pregnant women, and all populations targeted in the tables presented in the EPARs) are therefore part of research and experimental protocols.

Before being vaccinated, everyone has the right to request all the information necessary for informed consent, including the package insert (see the annexes to the Marketing Authorisation, links provided in annex 6 at the end of this document). Moreover, a precautionary principle must prevail even before consent is obtained.

The current focus of my professional activity is maximising the health and quality of life of people and organisations according to their raison d'être and I am very committed to respecting each. As a Doctor of Pharmacy and holistic work psychologist (CV attached), I bring together the rational sciences with approaches to consciousness in all its forms.

By looking at these documentary and regulatory sources, I wanted to enable you to accurately understand the texts yourself and in so doing shed light on these new vaccines.

Dr. Catherine FRADE, Curriculum vitae here.
Doctor of Pharmacy, Psychologist & Occupational Psychopathologist

Table 1: Annex IIE of the Pfizer MA, pages 18 and 19

E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE CONDITIONAL MARKETING AUTHORISATION

This being a conditional marketing authorisation and pursuant to Article 14-a of Regulation (EC) No 726/2004, the MAH shall complete, within the stated timeframe, the following measures:

Description	Due date
In order to complete the characterisation of the active substance and finished product, the MAH should provide additional data.	July 2021. Interim reports: 31 March 2021
In order to ensure consistent product quality, the MAH should provide additional information to enhance the control strategy, including the active substance and finished product specifications.	July 2021. Interim reports: March 2021
In order to confirm the consistency of the finished product manufacturing process, the MAH should provide additional validation data.	March 2021
In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0315.	July 2021 Interim reports: January 2021, April 2021
Description Due date In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0159.	July 2021 Interim reports: January 2021, April 2021
In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled, observer-blind study C4591001.	December 2023

Table 2: Annex IIE of the MA Moderna, page 15

E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE CONDITIONAL MARKETING AUTHORISATION

This being a conditional marketing authorisation and pursuant to Article 14-a of Regulation (EC) No 726/2004, the MAH shall complete, within the stated timeframe, the following measures:

Description	Due date
In order to complete the characterisation of the active substance and finished product manufacturing processes, the MAH should provide additional data.	January 2021
In order to confirm the consistency of the active substance and finished product manufacturing process (Initial and final scales), the MAH should provide additional comparability and validation data.	April 2021 Interim reports will be provided monthly prior to this date.

In order to ensure consistent product quality, the MAH should provide additional information on stability of the active substance and finished product and review the active substance and finished product specifications following further manufacturing experience.	June 2021
In order to confirm the efficacy and safety of COVID-19 Vaccine Moderna, the MAH should submit the final Clinical Study Report for the randomised, placebo-controlled, observer-blind study mRNA-1273-P301.	December 2022

Table 3: Annex IIE of the AstraZeneca MA, pages 14 and 15

E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE CONDITIONAL MARKETING AUTHORISATION

This being a conditional marketing authorisation and pursuant to Article 14-a of Regulation (EC) No 726/2004, the MAH shall complete, within the stated timeframe, the following measures:

Description	Due date
In order to confirm the consistency of the active substance and finished product manufacturing process, the applicant should provide additional validation and comparability data and, introduce enhanced testing.	December 2021 with interim monthly updates beginning February 2021
In order to ensure consistent product quality, the applicant should provide additional information on stability of the active substance and finished product and review the finished product specifications following further manufacturing experience.	June 2022 with interim monthly updates beginning February 2021
In order to confirm the efficacy and safety of Vaxzevria, the MAH should submit the final Clinical Study Reports for the randomised, controlled, COV001, COV002, COV003 and COV005.	31 May 2022
In order to confirm the efficacy and safety of Vaxzevria, the MAH should provide the primary analysis (based on the 7th December data cut-off (post data-base lock) and final analysis from the pooled pivotal studies.	Primary analysis: 5 March 2021 Final pooled analysis: 31 May 2022
In order to confirm the efficacy and safety of Vaxzevria in the elderly and subjects with underlying disease, the MAH should submit the overview and summaries of the primary analysis and final clinical study report for study D8110C00001.	Primary analysis: 30 April 2021 Final CSR: 31 March 2024

Table 4: Annex IIE of the Janssen MA, page 18

E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE CONDITIONAL MARKETING AUTHORISATION

This being a conditional marketing authorisation and pursuant to Article 14-a of Regulation (EC) No 726/2004, the MAH shall complete, within the stated timeframe, the following measures:

Description	Due date
In order to confirm the consistency of the finished product manufacturing process, the MAH should provide additional comparability and validation data.	30 September 2021 Interim report: 31 March 2021 Interim report: 19 April 2021 Interim report: 27 April 2021

	Interim report: 31 May 2021
In order to confirm the efficacy and safety of Ad26.COV2.S COVID-19 Vaccine, the MAH should submit the final Clinical Study Report for the randomised, placebo-controlled, observer blind study VAC31518COV3001.	31 December 2023

Table 5: Pregnancy data from Pfizer EPAR, as an example

The term "pregnant" or "pregnancy" appeared in 10 pages of the EMA EPAR. The exact sentences from the report are included in this table.

Excerpts from the Pfizer EPAR

Page 14
A study in pregnant women is also planned in the EU. A Post-Approval Active Surveillance Safety Study to Monitor Real-World Safety of Comirnaty (Study C4591010) will be conducted in the EU using primary data collection that monitors a cohort of vaccinees and evaluates risk of AESIs [adverse event of special interest].

Page 68
2.5.2. Main study, Title of study: Study C4951001: A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-COV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals
Methods: Study Participants - exclusion criteria - Women who are pregnant or breastfeeding.

Page 93
Immunocompromised subjects and pregnant or breastfeeding women were excluded from the study.

Page 109
Pregnancy. At the time of the data cut-off in the Phase 2/3 study (14 Nov 2020), a total of 23 participants had reported pregnancies in the safety database, including 9 participants who withdrew from the vaccination period of the study due to pregnancy. These participants are being followed for pregnancy outcomes. Thus, data on pregnancy are very limited at this stage.

Page 113
23 participants reported pregnancies in the safety database, nine of them were withdrawn from the study due to the pregnancy status. These participants will be followed up for pregnancy outcomes.

Page 114
Clinical safety. Long term safety data, interaction with other vaccines, data on use in pregnancy and other subgroups (e.g. frail subjects, or subjects with pre-existing autoimmune diseases) are missing at this stage.

Page 115
Safety concerns. Missing information: Use during pregnancy and while breast feeding.

Page 119

Additional pharmacovigilance activities. Planned. Atypical COVID-19 in a cohort of people within the Department of Defense Healthcare System. Due date: December 2023.

Page 120
Additional pharmacovigilance activities. Planned: C4591015. Planned clinical study to assess safety and immunogenicity in pregnant women who receive COVID-19 mRNA vaccine
Safety and immunogenicity of COVID19 mRNA vaccine in pregnant women.
Safety concerns addressed: Use in pregnancy and while breast feeding.
Protocol draft submission due date: 28-Feb-2021
Final CSR [Clinical study report] submission due date: 30-Apr-2023

Page 120
Additional pharmacovigilance activities. Planned: ACCESS/VAC4EU. Assessment of occurrence of safety events of interest, including severe or atypical COVID-19 in real-world use of COVID-19 mRNA vaccine.
Safety concerns addressed:
Anaphylaxis
AESI-based safety events of interest including vaccine associated enhanced disease
Use in pregnancy
Use in immunocompromised patients
Use in frail patients with co-morbidities (e.g, chronic obstructive pulmonary disease (COPD), diabetes, chronic neurological disease, cardiovascular disorders)
Use in patients with autoimmune or inflammatory disorders
Protocol draft submission due date: 28-Feb-2021
Final CSR [Clinical study report] submission due date: 31-Jan-2024

Page 136
3.7: Benefit-risk assessment and discussion. 3.7.1: Importance of favourable and unfavourable effects.
There are no data on use in pregnant women, but a protective effect is anticipated. In the light of the reassuring data from the DART study, noting that pregnancy as such is a risk factor for severe COVID19, and that pregnant women may additionally belong to other risk groups, vaccination may be considered on a case by case basis.
Based on biological plausibility no risk in breastfeeding is anticipated.

Appendix 6. References available on the internet (non-exhaustive list)

There is a large number of interesting documents on this subject:

European Medicines Agency (EMA): https://europa.eu/european-union/about-eu/agencies/ema_fr
National Agency for the Safety of Medicines and Health Products (ANSM): https://ansm.sante.fr/qui-sommes-nous/
Questions and answers: Conditional marketing authorisation for COVID-19 vaccines in the EU: https://ec.europa.eu/commission/presscorner/detail/fr/QANDA_20_2390
https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-8-11-march-2021

Documents for	Pfizer vaccine	Moderna vaccine	AstraZeneca vaccine	Janssen vaccine
Information available in open access on EMA	https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty	https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna	https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-astrazeneca	https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-janssen
Annexes to the MA	https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_fr.pdf	https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-epar-product-information_fr.pdf	https://www.ema.europa.eu/en/documents/product-information/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-product-information_fr.pdf	https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_fr.pdf
EPAR evaluation report - medical review	https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf	https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf	https://www.ema.europa.eu/en/documents/overview/covid-19-vaccine-astrazeneca-epar-medicine-overview_fr.pdf	https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-janssen-epar-public-assessment-report_en.pdf
Summary of the CHMP positive opinion	https://www.ema.europa.eu/en/documents/smop-initial/chmp-summary-positive-opinion-comirnaty_en.pdf	https://www.ema.europa.eu/en/documents/smop-initial/chmp-summary-positive-opinion-covid-19-vaccine-moderna_en.pdf	https://www.ema.europa.eu/en/documents/smop-initial/chmp-summary-positive-opinion-covid-19-vaccine-astrazeneca_en.pdf	https://www.ema.europa.eu/en/documents/smop-initial/chmp-summary-positive-opinion-covid-19-vaccine-janssen_en.pdf
Risk management plan	https://www.ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf	https://www.ema.europa.eu/en/documents/rmp-summary/covid-19-vaccine-moderna-epar-risk-management-plan_en.pdf	https://www.ema.europa.eu/en/documents/rmp-summary/covid-19-vaccine-astrazeneca-epar-risk-management-plan_en.pdf	https://www.ema.europa.eu/documents/rmp-summary/covid-19-vaccine-janssen-epar-risk-management-plan_en.pdf
Authorised submissions	https://www.ema.europa.eu/en/documents/all-authorised-presentations/comirnaty-epar-all-authorised-presentations_fr.pdf	https://www.ema.europa.eu/en/documents/all-authorised-presentations/covid-19-vaccine-moderna-epar-all-authorised-presentations_fr.pdf	https://www.ema.europa.eu/en/documents/all-authorised-presentations/vaxzevria-vorher-covid-19-impfstoff-astrazeneca-alle-autorisierte-präsentation_fr.pdf	https://www.ema.europa.eu/en/documents/all-authorised-presentations/covid-19-vaccine-janssen-epar-all-authorised-presentations_fr.pdf

Catherine Frade – Curriculum Vitae

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SES PUBLICATIONS

- **L'Homme et son environnement**, Chambre nationale des praticiens de santé durable, 2020
- **EMDR, thérapie intégrative**, Journal militaire le Conscrit (Oct 2019)
- **Des clés pour le bien-être et l'épanouissement au travail**, Soins infirmiers, Elsevier-Masson, Nov 2018, 830, p.49-51
- **(Re)prendre en mains sa vie**, Pratiques RH, 76, Janvier 2017
- **Donner envie de réaliser ensemble**, L'Express magazine, 21 septembre 2016, p.19-20
- **Développement des individus et des organisations et Prévention du stress**, Journal Polytechnique de Milan, Alumni MIP, 2012
- **Etude Prospective RH Spécial Santé à 2030**, impacts sur les acteurs et les métiers, Préface de Xavier Bertrand, Ministre du travail, de l'emploi et de la santé, Novembre 2011, Groupe RHM

Autres publications et conférences ici

FORMATIONS

2017 - Thérapie EMDR *(EFPE Paris)*

2017 - Méditation, épigénétique, neurosciences *(Joe Dispenza Paris, Milan)*

2016 - Enseignante certifiée en Santé Parfaite en Ayurveda (sciences de la vie : yoga, méditation, alimentation, santé, neurosciences, épigénétique *(Deepak Chopra Center, Californie)*

2016 - Accords Toltèques *(José Ruiz-Mexique)*

2014 - Psychopathologue du Travail *(CNAM de Paris)*

2008 - Systémique, Transgénérationnel et Phénoménologie *(Suisse)*

2007 - Psychologue du Travail *(CNAM de Paris)*

2006 - DESU Coaching RH *(Université de Paris VIII)*, AT, PNL, CNV, systémique…)

2000 – DESS Contrôle des médicaments (*Université de Paris XI*)

1990 - DESS Droit de la Santé *(Université de Paris XI)*

1987 - Dr en Pharmacie *(Université de Paris V)*

EXPERIENCES PROFESSIONNELLES INDUSTRIES DE SANTE

2001- 2015 : IFIS
Formatrice à l'Institut de Formation des Industries de Santé

2005 – 2015 : UPHARM – BIODIM
Consultante affaires réglementaires internationales

2004 – JANSSEN CILAG
Affaires Réglementaires France

2000-2003 – PRO-MED
Directeur Management de Produits et Communication
Obtention du prix Pharmapack 2003 (meilleur conditionnement innovant)

1998-2000 : GROUPE GUERBET
Directeur Affaires Réglementaires internationales et chef de projet technique de la fusion d'entreprise internationale (83 pays, 3000 produits)

1993-1998 : UPSA-BMS
Manager Affaires Réglementaires Europe et Amérique du Nord

1990-1993 : LILLY France
Affaires Réglementaires France. Participation au projet de rationalisation internationale des sites de fabrication.

1990 : BIOPROJET
Affaires Réglementaires

1987-1989 : SERVIER
Pharmacien de production

1986-87 : Hôpital Pitié-Salpêtrière

EXPERIENCES PROFESSIONNELLES HUMAINES

2003 – STELIAXE
Fondatrice, gérante et intervenante - **Créer du lien et du sens pour la santé et la société.**

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Transformation selon la Raison d'être en Santé Qualité de Vie
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Trouver et réaliser sa raison d'être et éliminer ce qui la freine (travail, santé, relations)

2019 : Présidente de l'association EMDR France

2001 - Conférences et Formations
Salon du Travail, Mairie de Levallois, Comundi, IFIS…
Outils psychologiques et techniques d'écoute des salariés/agents en difficulté, Transformation selon la raison d'être, Trouver sa voie, Nouveau départ, Conscience et Santé, Burn-Out, Intuition & discernement, Reconversion : réinventer sa vie professionnelle après la crise…

Enseignante vacataire pour les Universités de Pharmacie de:

- Depuis 2015 : Université PARIX XI de PARIS Saclay, Travailler et communiquer ensemble, Santé & Qualité de vie au Travail. (Masters II de Management de la qualité, Contrôle de la qualité, Contrôle des dispositifs médicaux)

- 2012-2014 : Universités de Nantes et Nancy

- 1990-1993 : Université PARIS V :
Développement du médicament et débouchés dans l'industrie pharmaceutique