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| Logo of the European Commission, 12 yellow stars on a blue background arranged in a circle and framed by two light grey graphic elements representing the Berlaymont building, which is the headquarter of the European Commission. | EUROPEAN COMMISSION |

VACANCY NOTICE FOR A POST OF SECONDED NATIONAL EXPERT

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| DG – Directorate – Unit | DG SANTE: Health and Food SafetyDirectorate D: Medicinal products: policy and supervisionUnit D2: Medical products: quality, safety innovation  |
| Post number in sysper: | 284967 |
| Contact person:Provisional starting date:Initial duration:Place of secondment: | Sylvain Giraud, Head Of Unit3rd quarter 20242 years[x]  Brussels [ ]  Luxemburg [ ]  Other: Click or tap here to enter text. |
| Type of secondment |  |
| This vacancy notice is open to:as well as[ ]  The following EFTA countries: [ ]  Iceland [ ]  Liechtenstein [ ]  Norway [ ]  Switzerland[ ]  The following third countries: …. [ ]  The following intergovernmental organisations: …   |
| Deadline for applications | Latest application date: Click or tap to enter a date. |

**Entity Presentation (We are)**

The mission of the Directorate-General for Health and Food Safety (DG SANTE) is to improve the health and safety of European citizens and to contribute to the Commission’s programme for jobs, growth, fairness and democratic change.

In this context, Directorate D helps to improve and protect human and animal health, to ensure that all human and veterinary medicinal products and medical devices are safe and to protect animal health and welfare.

Unit D2 is particularly responsible in the field of pharmaceuticals and, where necessary, in DG SANTE’s overall public health objectives and strategies for the development and implementation of the EU regulatory framework: develop and manage legislation and guidelines, coordinate with national authorities, ensure effective implementation, etc.

Unit D2 also contributes to the implementation of the EU pharmaceutical strategy and, in particular, to the revision of the pharmaceutical legislation, by providing expertise and ensuring coordination between the various dimensions of the policy area: availability, affordability, accessibility to medicines, revision of legislation, international dimension and trade/industrial aspects, etc.

**Job Presentation (We propose)**

Under the direction of the Head of Unit SANTE/D2, the jobholder will work in a team within the unit and in close cooperation with the relevant Commission services and DG SANTE units in order to:

— Provide technical and regulatory expertise on the implementation of pharmaceutical legislation and compliance with its enforcement and planned monitoring and inspection systems

— Prepare and lead the development of regulation in the unit’s field of activity.

In particular, they will be asked to contribute to:

— Addressing issues relating to the quality of medicines and their constituent substances and good manufacturing practices (GMP) and good distribution practices (GMP) for pharmaceutical products;

— Review of the detailed guidelines and annexes to the GMP and GMP guides and keep Eudralex Volume 4 up to date;

— The implementation of mutual recognition agreements and agreements with other international partners on manufacturing and GMP and GMP;

— The establishment and updating of the list of third countries applying equivalent GMP rules for active substances

The holder will also ensure that DG SANTE’s public health priorities are taken into account in policy proposals put forward by other Directorates-General.

The holder will also follow up the Joint Audit Programme and other cooperative actions between Member States on the quality of medicines and manufacturing. They will assess the collaboration between PIC/S and the Commission, and may participate in the scientific and technical committees of EMA and EDQM.

They will also be able to prepare and/or draft briefings, speeches and/or speaking notes on their specific field of expertise and answer questions from Members of Parliament or EU citizens.

**Jobholder Profile (We look for)**

Diploma of pharmacist, doctor, veterinary surgeon or university degree in the field of science.

Experience of EU legislation on medicinal products and their constituent substances, in particular in the areas of responsibility of the unit: manufacture, distribution, inspection, control, quality of medicines. Experience in European or international cooperation initiatives will be useful.

**Eligibility criteria**

The secondment will be governed by the **Commission Decision C(2008) 6866** of 12/11/2008 laying down rules on the secondment to the Commission of national experts and national experts in professional training (SNE Decision).

Under the terms of the SNE Decision, you need to comply with the following eligibility criteria at **the starting date** of the secondment:

* Professional experience: at least three years of professional experience in administrative, legal, scientific, technical, advisory or supervisory functions which are equivalent to those of function group AD.
* Seniority: having worked for at least one full year (12 months) with your current employer on a permanent or contract basis.
* Employer: must be a national, regional or local administration or an intergovernmental public organisation (IGO); exceptionally and following a specific derogation, the Commission may accept applications where your employer is a public sector body (e.g., an agency or regulatory institute), university or independent research institute.
* Linguistic skills: thorough knowledge of one of the EU languages and a satisfactory knowledge of another EU language to the extent necessary for the performance of the duties. If you come from a third country, you must produce evidence of a thorough knowledge of the EU language necessary for the performance of his duties.

**Conditions of secondment**

During the full duration of your secondment, you must remain employed and remunerated by your employer and covered by your (national) social security system.

You shall exercise your duties within the Commission under the conditions as set out by aforementioned SNE Decision and be subject to the rules on confidentiality, loyalty and absence of conflict of interest as defined therein.

In case the position is published with allowances, these can only be granted when you fulfil the conditions provided for in Article 17 of the SNE decision.

Staff posted in a European Union Delegation are required to have a security clearance (up to SECRET UE/EU SECRET level according to [Commission Decision (EU, Euratom) 2015/444 of 13 March 2015](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015D0444). It is up to you to launch the vetting procedure before getting the secondment confirmation.

**Submission of applications and selection procedure**

If you are interested, please follow the instructions given by your employer on how to apply.

The European Commission **only accepts applications which have been submitted through the Permanent Representation / Diplomatic Mission to the EU of your country, the EFTA Secretariat or through the channel(s) it has specifically agreed to**. Applications received directly from you or your employer will not be taken into consideration.

You should draft you CV in English, French or German using the **Europass CV format** ([[Create your Europass CV | Europass](https://europa.eu/europass/en/create-europass-cv)](http://europass.cedefop.europa.eu/en/documents/curriculum-vitae)). It must mention your nationality.

Please do not add any other documents(such as copy of passport, copy of degrees or certificate of professional experience, etc.). If necessary, these will be requested at a later stage.

**Processing of personal data**

The Commission will ensure that candidates’ personal data are processed as required by Regulation (EU) 2018/1725 of the European Parliament and of the Council ([[1]](#footnote-1)). This applies in particular to the confidentiality and security of such data. Before applying, please read the attached privacy statement.

1. () Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39 [↑](#footnote-ref-1)