

DECLARATION OF INTERESTS OF EMPLOYEES, MEMBERS OF COMMITTEES, EXPERTS AND MEMBERS INVOLVED IN WORK ACTIVITIES WITH THE MEDICINES AUTHORITY

If the provided space is not sufficient or any additional documents need to be attached please use separate sheets and indicate the number of attached sheets in this box

Name and Surname: _____

Position: _____

E-mail: _____

Please list below all interests¹ in the pharmaceutical sector² if any:

1. Employment³ in the pharmaceutical industry (During the previous three years⁴ or current employment):

2. Financial interests⁵ in the pharmaceutical sector:

Name of Company:	Financial Interest:

¹Refer to P-SS 02 (Handling of Competing Interests and Signature Log Generation and Maintenance) for definitions

² If you have no interests for the relevant section, please indicate "NONE"

³ Employment with a pharmaceutical company means any form of occupation, part-time or full-time, paid or unpaid, in the company. Unpaid placements which are part of a course leading to a degree shall be declared in section 4 but do not constitute employment nor a conflict. Pharmacies are not defined as pharmaceutical industry as long as the pharmacy is not part of a structure which includes other licenses issued by or on recommendation by the Medicines Authority such as Good Manufacturing Practice or Good Distribution Practice.

⁴ Three years is the cooling off period but you may provide information on interests over 3 years.

⁵ If these financial interests are in the form of funds and they are not diversified (i.e., they are exclusively based on the pharmaceutical sector) and are not independently managed (i.e., the investor has influence on their financial management), then the interest has to be declared and funds must be divested. If the funds are diversified **and** are independently managed and there is no real or perceived COI, then there is no requirement to divest.

3. Consultancy, Strategic Advisory Role, Principal Investigator, Investigator involvement:

4. Grant/ Funding to organisation/ institution⁶

5. Personal Interests, other than those in pharmaceutical industry⁷

6. Work you previously carried out in return for payment including paid/unpaid traineeships on behalf of the pharmaceutical industry and work related to pharmacies in the three preceding years:

⁶ Grant or other funding to an organisation/institution means any CURRENT funding received from a pharmaceutical company by an organisation/institution to which the employee belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the employee whether or not it is related to research work. (CURRENT is interpreted at time of completion of this form)

⁷ Interests in other entities possibly providing services to the Authority (i.e. in the areas of IT, infrastructure, catering, transport). Positions (either a managerial role or other influential roles) in a governing body (irrespective if such position is paid or not) of a professional organisation with an interest in the field of pharmaceuticals other than a pharmaceutical company.

7. Other interests or facts, which you consider should be made known to the Medicines Authority including research and academic activities and matters relating to close family members⁸:

I do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests in the pharmaceutical industry I have currently (at the time of completion of the form) or have had (in the last 3 years) are those listed above.

I further declare on my honour that, to the best of my knowledge, personal interests, other than interests in pharmaceutical industry, which I have currently (at the time of completion of the form) those listed above.

I understand that appointment to any employment or activity of the Medicines Authority is conditional upon compliance with the conditions of approval.

I further declare that should any changes occur and should it appear that I have or acquire additional interests that should be made known to the Medicines Authority, I shall forthwith declare them and complete a new declaration of interests form.

Signature

Completed at _____ on the _____
(Place where this form was completed) (Date of Completion)

⁸ First-line members of the family of the expert (i.e. a spouse or a partner, children and parents). The names of these persons need not be declared. Matters related to close family members which need to be disclosed include any known financial interests, including any funds or other forms of financial instruments, which are or may be perceived to constitute a CoI. If these financial instruments or funds are not diversified and independently managed, then the employee will be restricted from carrying out any work related to that pharmaceutical company/ies associated with the fund/financial instrument. If the funds/financial instruments are diversified and independently managed, no restrictions will apply.

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Scientific & Regulatory Operations Director

Post-Licensing Director

Inspectorate & Enforcement Director

Advanced Scientific Initiatives Director