Expression of Interest 01/2018

5th April 2018

EXPRESSION OF INTEREST
Advisors, Experts, External Inspectors and Evaluators

The Malta Medicines Authority (MMA) was established in 2003 as an autonomous body to protect and enhance public health through the regulation of medicinal products and pharmaceutical activities.

The MMA is looking in particular for:

1) Established medicines inspectors in national competent authorities in the EU/EEA and members of the pharmaceutical inspectors cooperation scheme (PIC/S) to support it in its technical requirements. Selected medicines inspectors may be required, amongst others, to carry out third country inspections;
2) Established assessors with experience in Centralised or Decentralised (inc. MRP) pre- and post-authorisation procedures; and
3) Other experts/ advisors in areas related to the work of the MMA.

Evaluators, medicines inspectors, experts and advisors will carry out duties on a contract for service basis, as required based on the exigencies of the MMA.

Interested applicants are to submit the following documentation by e-mail to hr.medicinesauthority@gov.mt

1) Updated CV
2) Experts Form (Appendix 1)
3) Declaration of Interest (Appendix 2)

Gavril Flores
Director, Strategy, Operations and Regulatory Affairs

Appendix 1

EXPERTS FORM

Please note that ♦ indicates a mandatory field

Title

1. ♦ **Family Name**

2. ♦ **First Name**

3. ♦ **Nationality**

4. ♦ **Organisation/ Company Name and Professional Address**

5. ♦ **Business Phone No (incl Int Code)**

6. ♦ **Business email address**

7. ♦ **Passport number**

8. ♦ **Qualifications - Degrees, Diplomas and Professional Affiliations**[i]

9. ♦ **Present position and time spent in current assignment** [ii]

10. ♦ **General Category of Activities**

	H [iii]	V [iv]
MEDICINES EVALUATION		
Biologicals/Biotechnology products	☐	☐
Chemicals	☐	☐
Herbal/Traditional Products	☐	☐
Inspections	☐	☐
Pharmacovigilance	☐	☐
Regulatory Affairs	☐	☐

	YES	NO
♦ **Are you a** member of staff of a competent authority?	☐	☐
♦ **Are you an** external expert (e.g. University, hospital, member of staff of another Organisation, or a pharmaceutical company, etc)?	☐	☐

11. Specific Functional Expertise

	H [iii]	V [iv]
QUALITY		
Immunologicals/Biotechnology products	☐	☐
Vaccines	☐	☐
Blood products	☐	☐
Chemicals	☐	☐
SAFETY		
Immunologicals/Biologicals	☐	☐
Chemicals	☐	☐
ENVIRONMENTAL RISK ASSESSMENT		
Genetically Modified Organisms	☐	☐
CLINICAL		
Immunologicals/Biologicals	☐	☐
Chemicals	☐	☐
Pharmacovigilance and Risk Management	☐	☐
INSPECTIONS		
Laboratory Procedures	☐	☐
GMP	☐	☐
GCP	☐	☐
GLP	☐	☐

12. Availability

- ☐ Dossier Evaluation
- ☐ Scientific Advice
- ☐ Guidelines
- ☐ Other

13. Languages known:

please specify level, including your mother tongue	**R**	**W**	**S**
R: Read, **W**: Written, **S**: Spoken, **P**: Poor, **A**: Average, **G**: Good, **E**: Excellent			

14. Areas of Expertise
(Please select main areas of expertise)

14.a Quality

Chemistry:

- ☐ Analytical chemistry
- ☐ Synthetic chemistry
- ☐ Development pharmaceutics
- ☐ Stability
- ☐ Phytochemistry
- ☐ Radiopharmaceuticals
- ☐ Premixes for medicated feed production
- ☐ Drug/Device combinations
- ☐ Packaging
- ☐ Manufacture of medicines
- ☐ Peptide chemistry
- ☐ Medicinal gasses
- ☐ Structural similarity

Biology:

- ☐ Development genetics
- ☐ Genetic engineering: expression factor
- ☐ Cell culture - Fermentation
- ☐ Protein purification
- ☐ Protein analysis - characterisation; purity testing; biological assay
- ☐ Virology: validation of inactivation/removal steps; cell bank qualification; choice of viruses
- ☐ Microbiological testing
- ☐ Monoclonal antibodies
- ☐ Blood products
- ☐ Allergens
- ☐ Vaccines
- ☐ Gene therapy
- ☐ Cell therapy
- ☐ Tissue engineering
- ☐ Plant biotechnology
- ☐ Nanobiotechnology

Risk Assessment of GMOs:

- ☐ Vaccines
- ☐ Gene therapy/ biotechnology
- ☐ Transgenic plant

Manufacturing Process, Development and Validations:

- ☐ Blood products
- ☐ Biological products
- ☐ Biotechnology products
- ☐ Vaccines
- ☐ Cell therapy

14.b Pre-Clinical

- ☐ Toxicology
- ☐ General toxicology:
  - Acute/chronic toxicity, etc. ☐
- ☐ Special toxicology:
  - In vitro toxicology ☐
  - Immunotoxicity ☐
  - Reproduction toxicity ☐
  - Genetic toxicity ☐
  - Carcinogenicity ☐
  - Toxicokinetics ☐
- ☐ Pharmacology in laboratory and target animals
- ☐ Pharmacodynamics
- ☐ Pharmacokinetics
- ☐ Pathology
- ☐ Environmental Risk Assessment
- ☐ Residue safety assessment
- ☐ Behavioural toxicology
- ☐ Occupational toxicology
- ☐ Microbiology
  - Bacteriology ☐
  - Parasitology ☐
  - Mycology ☐
  - Virology ☐
- ☐ Safety Pharmacology

14.c Clinical

(Please select 2 or 3 main areas only)

- ☐ AIDS
- ☐ Anaesthesiology
- ☐ Biostatistics
- ☐ Cardiology
- ☐ Dermatology
- ☐ Endocrinology
- ☐ Gastroenterology
- ☐ Genetics:
  - Pharmacogenetics ☐
  - Clinical Genetics ☐
- ☐ Geriatrics
- ☐ Gynaecology/obstetrics
- ☐ Haematology
- ☐ Hepatology
- ☐ Immunology:
  - Biological ☐
  - Clinical ☐
- ☐ Infectious diseases:
  - Microbiology ☐
  - Bacteriology ☐
  - Parasitology ☐
  - Mycology ☐
  - Virology ☐
- ☐ Intensive care
- ☐ Internal medicine
- ☐ Metabolic medicine
- ☐ Nephrology
- ☐ Neurology
- ☐ Nuclear medicine
- ☐ Oncology:
  - Blood ☐
  - Breast ☐
  - CNS ☐
  - Gastro-intestinal ☐
  - Gynaecological ☐
  - Head & Neck ☐
  - Lung ☐
  - Renal ☐
  - Other (please specify)
- ☐ Ophthalmology
- ☐ Organ transplantation
- ☐ Orthopaedic Surgery
- ☐ Otorhinolaryngology
- ☐ Other (e.g. rare disease), please specify:
- ☐ Pain Paediatrics
- ☐ Pharmaceutical Medicine
- ☐ Pharmacology
- ☐ Pharmacokinetics
- ☐ Pathology ☐
  - General pathology ☐
  - Chemical pathology ☐
  - Haematology ☐
  - Histopathology ☐
- ☐ Plastic Surgery
- ☐ Pneumology / Respiratory
- ☐ Proctology
- ☐ Psychiatry
- ☐ Public Health
- ☐ Radiology
- ☐ Rheumatology
- ☐ Stomatology
- ☐ Urology
- ☐ Vaccines:
  - Microbiology ☐
  - Mycology ☐
  - Parasitology ☐
  - Virology ☐

14.d Target Species

- ☐ Food producing animals:
  - horses ☐
  - cattle ☐
  - goats & sheep ☐
  - pigs ☐
  - poultry ☐
  - fish ☐
  - bees ☐
  - rabbits ☐
- ☐ (Other) minor species
- ☐ Pet animals
- ☐ Wild (zoo) animals

14.e Pharmacovigilance and Risk Management

- ☐ Epidemiology
- ☐ Pharmacoepidemiology
- ☐ Phase I-III Safety Surveillance
- ☐ Phase IV and PMS Surveillance
- ☐ Spontaneous reporting systems and databases
- ☐ Drug utilisation
- ☐ Statistics
- ☐ Terminology & coding
- ☐ Risk Communication
- ☐ Safety of Viral Vectors
- ☐ Atypical Infections/Zoonoses
- ☐ Vaccine Safety
- ☐ Risk Management

14.f Control/Inspections GMP/GLP/GCP			
Products: Laboratory/Procedure Activities: Chemical ☐ Biological ☐ Biotechnology ☐ Immunologicals – Vaccines ☐ Immunologicals – Others ☐ Radiopharmaceuticals ☐ Other (please specify) ☐ Active Substances ☐ Other Starting Materials ☐ Finished Product ☐ Market Surveillance ☐ Official Batch	**GMP:** ☐ Active Substances ☐ Other Starting Materials ☐ Finished Product ☐ Control Laboratories ☐ Distributors Other (please specify)	**GLP:** ☐ Quality Systems/Assurance ☐ Documentation ☐ Joint Visits/Self Auditing Other (please specify)	**GCP:** ☐ Quality Systems - ☐ (sponsor) Trial Site ☐ Statistics ☐ Computer Systems ☐ Documentation Other (please specify)

[i] Please give a brief description of your qualification (e.g. MD, PhD and your specialisation). A Curriculum Vitae (CV) must be attached.
Do not refer to your CV in this box. Your main areas of expertise are to be addressed in section 14.

[ii] Please give a brief description of your current job position and indicate the year that you started your current assignment.

[iii] Human domain.

[iv] Veterinary domain.

Appendix 2

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 interests[1] in the pharmaceutical sector[2] if any:

1. Employment[3] in the pharmaceutical industry (During the previous three years[4] or current employment):

_____

_____

_____

[1]Refer 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.

2. Financial interests[5] in the pharmaceutical sector:

Name of Company:	Financial Interest:

3. Consultany, Strategic Advisory Role, Principal Investogator, Investigator involvement:

_____

_____

4. Grant/ Funding to organisation/ institution[6]

_____

_____

5. Peronsal Interests, other than those in pharmaceutical industry[7]

_____

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.

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.

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:

_____

_____

_____

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 members[8]:

_____

_____

_____

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.

[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.

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 thus form was completed) (Date of Completion)

For Official Use.

Conditions, Restrictions and Comments of Approval of Appointment/ Selection (if any

_____

_____

_____

_____

_____ _____

Licensing Director Strategy, Operations and Regulatory Affairs Director

_____ _____

Post-Licensing Director Inspectorate & Enforcement Director