



## EU “Transparency Register” – EFPIA Guidance

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### Background

Following the renewed Inter-institutional Agreement between the European Parliament and the European Commission of 16 April 2014 (published in the Official Journal of the European Union (OJEU) of 19 September 2014), the guidelines governing the “**Transparency Register**” that both institutions operate in common have been reviewed (Version 4.0 dated 21 January 2015). The Inter-institutional Agreement provides for the registration and monitoring of, *inter alia*, organisations and self-employed individuals engaged in EU policy-making and policy implementation.

European Trade Associations, such as EFPIA, are encouraged to develop **guidance for their membership**. The following is the EFPIA guidance, which aims at ensuring consistent and transparent reporting.



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## 1. “Privileges” attached to registration

“Privileges” attached to registration make registration *de facto* mandatory, since it conditions access to input to and interaction with the European Parliament and the European Commission, including:

- meeting with Commissioners, cabinet members and Directors-General<sup>1</sup>;
- access to public consultations initiated by the Commission;
- participating in expert groups ran by the Commission DGs;
- receiving alerts about Commission activities or initiatives (inclusion in mailing lists on topics of interest to the organisation);
- contacts with EU civil servants (contact with non-registered organisations being restricted);
- being invited as a speaker at public hearings held by EP committees<sup>2</sup>.

Registrants sign-off to the **Code of Conduct** attached to the Register, and agree to be submitted to the complaint mechanism and measures to be applied in the event of non-compliance with the Code of Conduct, including the procedure for investigation and treatment of complaints.

## 2. EFPIA Guidance regarding Registration

### EFPIA registration

As an organisation representing the R&D-based pharmaceutical industry, EFPIA will maintain its registration. EFPIA is registered under “II – In-house lobbyists and **trade/business/professional associations**” with **public ID number 38526121292-88**.

The EFPIA specialised groups have registered separately: **EBE** with **public ID number 768792210017-73** and **Vaccines Europe (VE)** with **public ID number 53073567234-18**. Since specialised groups have no legal responsibility, their registration is under the legal responsibility of EFPIA. However, EBE and VE will be registered as separate “subsidiaries”, with cross-referencing links.

### Membership registration

EFPIA recommends that, along with EFPIA, each of its constituent entities – including corporate members, member associations and members of specialised groups – register in their individual capacity.

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<sup>1</sup> Following the Commission’s decisions of 25 November 2014 on the **publication of information on meetings** held between (i) Members of the Commission and (ii) Directors General of the Commission, and organisations or self-employed individuals, information on all meetings held by Members of the Commission (i.e. Commissioners and their services) and Directors General (i.e. Directors General or Heads of Services of the Commission) shall be made public. The information will include the date of the meeting, the location, the name of the Commission representative, the name of the organisation of the self-employed individual and the subject of the meeting.

<sup>2</sup> It has been indicated that the EP is working on further “privileges” reserved to organisations that signed-off to the Register.

Each organisation shall register once only, including any information about subsidiaries or affiliates. However, multiple registrations are permissible if there are good reasons to do so – in such case, the registrant shall clarify which subsidiaries/ affiliates are covered under each registration. EFPIA corporate members are encouraged to cross-reference registrants belonging to their group of companies.

**Constituent entities that are not included in the EU “Transparency Register” shall not be part of EFPIA delegations interacting with the European Parliament and European Commission.**

#### Non-EFPIA members

EFPIA will encourage external organisations with which it collaborates (such as legal consultants and professional agencies) to register as well. When participating in networks that do not have legal status/ personality, EFPIA will encourage partners in such networks to register as such.

EFPIA will also encourage organisations in third countries representing pharmaceutical companies (and with whom EFPIA members has common membership) that interact with EU Institutions to register. If such organisations choose to do so, EFPIA recommends that these organisations comply with the EFPIA Guidance on the EU Transparency Register.<sup>3</sup>

### 3. EFPIA Guidance on the Scope of the register

As a general rule, the scope of the Register covers all activities carried out with the objective of directly (by way of direct contacts or communications) or indirectly (through the use of intermediaries influencing the formulation or implementation of policy and the decision-making processes of the EU institutions). Voluntary contributions and participation in formal consultations on envisaged EU legislative or other legal acts and other open consultations are also in scope.

However, the Register explicitly excludes:

- a. Activities concerning the *provision of legal and other professional advice (including analysis and studies)* on applicable laws and principles – however, if these activities are intended to influence the EU Institutions or seek to change the existing legal framework, will be within scope of activities to be covered.
- b. Activities of entities specifically designated in the Treaties to play an *institutional role* (which include social partners in the social dialogue and entities specifically designated in the Treaties to play an institutional role.
- c. Activities in response to *direct and individual requests* from EU institutions or Members of the EP, such as ad hoc or regular requests for factual information, data or expertise.

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<sup>3</sup> Given registration is *de jure* voluntary, EFPIA Guidance cannot be (legally) binding. However, Guidance issued by sectoral organisations will ensure that operations of the some sector report in a consistent way. *EFPIA will liaise with organisations with common membership to promote consistency among pharmaceutical operations.*

## GUIDANCE

1. As a rule, activities instigated by EFPIA / member organisations would be considered within scope, whilst responding to EU Institutions specific requests would fall outside the scope of the Register.
2. Principles should be applied in a **pragmatic** way, favouring transparency above complexity. Information included in the Register can be **complemented with a descriptive comment**, where appropriate, which will be conducive to transparency.
3. Activities triggered by EU initiatives/ programmes are taking place in 3 steps:
  - i. Analysis of the proposals and assessing implications of legislative initiatives, which may also require data collection and analysis;
  - ii. Preparing industry input, including developing position papers and data evidence in support of industry proposals;
  - iii. Implementing action plans, including outreach to EU Institutions, as appropriate.

In application of the exclusion of activities concerning provision of legal and other professional advice (Section III, 10 of the Inter-institutional Agreement), activities under **(i)** would be **out of scope**, whilst **(ii) and (iii)** would be **within scope**. In case of doubt, it is recommended to include the activity.

4. Activities aiming at complying with legal obligations under EU legislation and national laws (Section III, 10 of the Inter-institutional Agreement) are considered **out of scope**.
5. In application of the exclusion of activities concerning the provision of legal and other professional advice, fees paid to external agencies are **outside scope**. However, legal advice taken in support of proposed amendments to EU legislation will be **in scope**.
6. In application of the exclusion of activities relating to EFPIA's / member associations' institutional role, participation in formal bodies is considered **outside scope** (Section III, 11 of the Inter-institutional Agreement).

Activities of member associations representing the pharmaceutical industry in official committees – including, *inter alia*, pricing committees, reimbursement bodies, HTA institutions, etc. – are not within scope of the Register. Such committees will be typically established in application of legislation or regulations.

However, EFPIA will declare its participation in European platforms coordinated by the European Commission where pharmaceutical pricing and reimbursement policies and HTA are being discussed. Delegates of EFPIA member organisations that take part in such committees/ fora are participating as EFPIA experts, and will therefore be included in the number of persons

involved in EFPIA activities covered by the Register.

7. In application of the exclusion of activities in response to direct and individual request from EU Institutions or Members of the EP, responding to such *ad hoc* or regular requests for formal information, data or expertise, are not covered by the Register.

## 5. EFPIA Guidance on Information Required from Registrants, including Financial Disclosure Requirements

Information required from registrants is described in ANNEX II of the Inter-institutional Agreement published in the OJEU of 19 September 2014. This has been complemented by “Transparency Register Implementing Guidelines” published by the Joint Transparency Register Secretariat (JTRS) on 17 December 2014.

### GUIDANCE

#### Number of persons involved and time spent

1. For the purpose of the Register, the “EU Institutions” should mean: the European Parliament (EP) and the European Commission. EFPIA recommends expanding this definition to include relevant agencies: such as the European Medicines Agency (EMA)<sup>4</sup>, and EU missions (Missions) in third countries, the European Economic & Social Committee (EESC), the Committee of Regions (CoR) – this is because these institutions will be involved, in some capacity, in legislative processes and public policy initiatives.
2. Activities considered are those defined in the Inter-institutional Agreement of 16 April 2014.

Following Section III.19 of the Inter-institutional Agreement, activities directed at Member States, in particular those directed to their Permanent Representations to the EU, are not considered.

3. The number of persons involved in the activities covered by the Register is reported under Section 10 of the template. Information to be completed is the number of persons working 100%, 75%, 50% or 25% of their time on activities within scope (i.e. interactions with the Commission and the EP; interactions with the Council are out of scope). The number of persons (individuals) involved and the resulting Full Time Equivalent (FTE) is automatically calculated by the system.

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<sup>4</sup> Other EU Agencies could be considered when activities with these agencies would be within scope of the Register, such as the European Centre for Disease Prevention and Control (ECDC). However, non-executive agencies that do not set public policy / policy guidelines or recommendations should reasonably be excluded. *For the complete list of all 40 agencies please see the European Commission website.*

As a general rule, time allocation is rounded to the “upper” % category (for instance: a person spending 40% of its time on activities within scope will be reported under the 50% category), which results in overestimation. Therefore, where the proportion of activity of a person involved in activities covered by the Register is not significant, organisations may choose, in the interest of simplicity and reduction of administrative burden, to exclude persons only occasionally involved from reporting.

EFPIA recommends that:

- Persons staff spending less than 10% of their work time with EU Institutions as defined under 1;
- Members’ delegates participating in EFPIA working groups are considered to spend less than 10% of their full time work to supporting EFPIA activities that are covered by the Register.

### **Financial information related to activities covered by the Register**

Financial information should cover a full year of operations and refer to the most recent financial year closed, as of the date of registration or of renewal. Financial disclosure must give an estimate of the cost of the activities falling within the scope of the Register. The amount and source of funding received from the EU institutions in the most recent financial year closed must also be mentioned.

1. The estimate of the cost of the activities falling within scope does not have to satisfy conventional financial reporting and accountancy requirements, and therefore has no legally binding characteristics or effects. However, information provided must be complete, up-to-date and fair.
2. Organisations need to decide on an individual basis what information to disclose and how to calculate their financial disclosure statement.<sup>5</sup> EFPIA recommends providing information on the methodology of calculation included in the estimation of the cost of the activities falling within scope of the Register. It is recommended to keep records of calculation in the event of enquiry / challenge.
3. As a first step, organisations considering registration should identify the work they undertake, either at HQ or at European department / Brussels office level. Organisations, for which significant activity aimed at influencing the political decisions of EU Institutions is based outside Brussels, should include this activity in their calculations. However, companies, for which such

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<sup>5</sup> Whilst EFPIA can provide guidance on the interpretation of the requirements, it would not be appropriate for EFPIA to impose a single methodology for the cost-calculations. However, calculation methods should stand third party scrutiny and be implemented in good faith.

activity does not constitute a significant proportion of interest representation expenses, can base their calculations on Brussels expenses only.

Registrants should be able to justify their calculation methodology.

4. EFPIA will declare costs resulting from its budget implementation, whilst member organisations should declare additional costs they incur in support of (EFPIA) activities within scope, including when these are conducted through EFPIA.
5. Registrants are required to report cost of membership of associations (i.e. subscriptions and contributions). Since membership contributions to EFPIA serve to finance all EFPIA activities, including those not falling in scope of the Register, EFPIA recommends that its individual members report the proportion of their contributions that are allocated to activities that are covered by the Register.

EFPIA will calculate how much of each individual member’s contribution is allocated to activities covered by the Register. Members will report this amount under “contributions to associations”.

6. For those organisations working with a full “activity based” accounting system where activities within scope match account headings, costs allocated to activities within scope can be isolated.

If this is not the case, the following approach / formula should provide a fair estimate of costs relating to activities covered by the Register:

*For organisations with an office in Brussels:*

- Based on the analysis of work falling within scope (*see guidance in previous sections of the present document*), organisations should be able to determine the percentage of activities carried out with the objective of influencing the policy formulation and decision-making process of the European Institutions in a given year related to their total budget.
- The total amount of budget allocated to activities covered by the Register would result from applying the percentage of the total number of man-hours to the total budget available. The total budget would include: salaries & charges, rent & charges for office space, meeting costs, supporting activities (to be defined within each organisation), etc.

*For organisations without office in Brussels*

The calculation method described above could similarly be applied to the HQ department in charge of “European Affairs”.

7. Registrants are required to report financial information about funding received for the EU



Institutions under Section 13.c) of the Register. Such funding is submitted to specific reporting rules, and beneficiaries are under the obligation of holding very detailed activities and financial reports, also relating to the EU Instruments applicable.

EFPIA recommends that beneficiaries of such funds: (i) consult the European Financial Transparency System, which registers all funding provided by EU Institutions; (ii) ensure consistency with their declaration under each Procurement or Grant Agreement they have with the EU Institutions.

## 4. EFPIA’s additional Guidance

Registration shows that an organisation interacts with EU Institutions and provided minimum elements of information, which are required for the purpose of ensuring transparency toward the citizens about who is engaged in this type of activities. The mission of most organisations engaged in interest representation is wider than the activities for which registration is expected.

### GUIDANCE

EFPIA member organisations that would consider registering are advised to declare their affiliation to EFPIA and follow the guidance provided by EFPIA.

1. Organisations complete the Register under their own responsibility and liability. EFPIA recommends that registrants complete the Register in line with provisions of the Inter-institutional Agreement of 16 April 2014<sup>6</sup>, and the complementary guidelines of 23 June 2011 and 27 April 2012<sup>7</sup>.
2. Where compliance with the “Transparency Register Implementation Guidelines” issued by the Joint Transparency Register Secretariat would not reflect a truthful representation of the organisation’s interaction with EU Institutions, EFPIA recommends completing the information with a clear disclaimer, allowing the reader to understand the meaning of the information provided.
3. Organisations that have adopted professional codes / standards that go beyond the Code of Conduct attached to the “Transparency Register”<sup>8</sup> should declare such codes / standards. However, this does not exempt the organisation from signing the Register’s Code of Conduct, which is a compulsory step for registration.

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<sup>6</sup> OJEU of 19 September 2014 (L.277 – p. 11-24)

<sup>7</sup> <http://europa.eu/transparency-register>

<sup>8</sup> Annex III to the Inter-institutional Agreement of 16 April 2014 – OJEU of 19 September 2014 (p. 21)



In addition to compliance with the Code of Conduct of the Register, EFPIA has issued the following **codes and guidelines** (that can be found at [www.efpia.eu](http://www.efpia.eu)):

- a. Guidelines Governing EFPIA Meetings;
- b. Data Collection and Information Sharing Guidelines;
- c. Guiding Principles for Conference Calls;
- d. The EFPIA HCP Code – Code on the Promotion of Prescription-Only Medicines, and interactions with Healthcare Professionals
- e. The EFPIA PO Code – Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations
- f. The EFPIA HCP/HCO Disclosure Code – Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations
- g. Guidance to the “EU Transparency Register”.



EFPIA Brussels Office  
Leopold Plaza Building \* Rue du Trône 108  
B-1050 Brussels \* Belgium  
Tel: + 32 (0)2 626 25 55 \*  
[www.efpia.eu](http://www.efpia.eu) \* [info@efpia.eu](mailto:info@efpia.eu)

