# List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector[1]

## 1. Good governance in the pharmaceutical sector

1.1 The List of Guiding Principles is based on recognition by all participants of the need to go beyond bilateral relationships and to address the quintessential role of good governance in the pharmaceutical sector. Adhering to principles of good governance, ethics and transparency, can have a profound positive impact on healthcare policy and practice, and ultimately on patient outcomes. This List of Guiding Principles also aims at contributing to ensure that patients receive proper treatment and are provided with relevant, factual and unbiased information.

1.2 The ultimate goal is to establish reciprocal relations between all stakeholders[2] that are based on mutual trust and led by transparency. Sharing and dissemination of factual and accurate information can prevent misinformation or misleading information and a well-functioning marketplace can be promoted by enforcing standards and preventing anti-competitive behaviour. The List of Guiding Principles covers a series of general principles / core ethical values for all stakeholders. This document will provide guidance to (further) develop codes of practice at national level where appropriate. These may be established by associations, individually, or jointly or in association with other interested parties, taking into account country specificities and traditions. Existing measures or trade practices in Member States relating to prices, margins and discounts[3] as well as relationships between participants outside the pharmaceutical sector are outside the scope of the List of Guiding Principles. European and / or national legislation should always prevail over this present List of Guiding Principles. Any other codes should adhere, at least to equivalent Guiding Principles contained in this document.

## 2. Ensuring all stakeholders' responsible behaviour

In order to ensure good governance, interactions between all stakeholders should be based on fundamental principles of integrity, mutual respect, responsiveness, accountability, collaboration and transparency. Adherence to these principles is the responsibility of each independent party.

A. Integrity

Stakeholders should consistently practise their standards, values and procedures and communicate them appropriately. They should respect the integrity of the standards, values, procedures and decision processes of other stakeholders.

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1 The present document is without prejudice to any existing or future EU/ national and international legislation.

2 For the purposes of this List of Guiding Principles, the stakeholders are the pharmaceutical industry, patients and patient organisations, health professionals, consumer organisations, civil society organisations, wholesalers, hospitals, academia and European, national and regional level competent authorities.

3 Source: Article 94 (4) of Directive 2001/83/EC on the Community code relating to medicinal products for human use http://www.emea.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004481.pdf

B. Respect

Stakeholders should promote an attitude and environment of mutual respect for other stakeholders, for different cultures, for different socio-economic environments, for different views, for diverse ways of working and for the decision-making processes of competent authorities.

C. Responsiveness

Stakeholders should make clear in which respect they will collaborate with other stakeholders, and indicate who is responsible for this within the organisation. They should also be prepared to responsibly and accurately answer questions in this context and to indicate a reasonable time-frame within which a response can be expected.

D. Accountability

Stakeholders should aim to identify those who are likely to be affected by their decisions, where possible communicate their intentions and if necessary engage in an exchange of views with them. They should also justify their objectives, and assume responsibility for the foreseeable and/or actual consequences for them, regardless of whether these concern actions, products, or policies.

E. Collaboration

Stakeholders are encouraged to collaborate with other fellow stakeholders, for instance via public-private partnerships when appropriate, to achieve their goals. The public-private partnerships should be based on clear, transparent, good governance principles. In the context of these partnerships, the participants should share information about their objectives if needed.

## 3. Transparency: public disclosure of relationships and potential conflicts of interest

### 3.1. All Stakeholders

Legitimate relationships between the pharmaceutical industry, patients and patient organisations, health professionals[4], consumer organisations, civil society organisations, wholesalers, hospitals, academia, and European, regional and national level competent authorities, necessary for the benefit of public health, the process of medicines development, medical education, market approval and market entry of medicinal products should be transparent. Stakeholders should have, or develop, a policy on transparency regarding conditions under which professional relations in this area are made accessible to the public.

### 3.2. Pharmaceutical Industry

In order to build trust with the public, the pharmaceutical industry commits to working together with all stakeholders to set out a clear approach to full transparency of financial transactions - including non-monetary benefits - and other declarations of interest. Such disclosure must be compatible with data privacy legislation and shall exclude existing measures or trade practices in Member States relating to prices, margins and discounts[5] . Reporting systems must be manageable and cost effective. Companies should not

[4] Health professionals as defined in article 3(f) of Directive 2011/24/EU on the application of patients rights in cross border healthcare.

[5] Source: Article 94 (4) of Directive 2001/83/EC. http://www.emea.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004481.pdf

approach competent authorities during the course of the decision-making process except when specifically provided by legislation or relevant process. Companies must provide relevant, qualitative, transparent and complete information to the competent authorities.

### 3.3. Health professionals

Transparency concerning relations between health professionals and companies is necessary in order to avoid any conflict of interest. Conflict of interest can be direct (e.g. employment with a company, consultancy for a company, strategic advisory role for a company, financial interests, ownership of a patent) or indirect (e.g. principal investigator, investigator, individual's institution / organisation receiving a grant or other funding)[6]. It is essential that transparency is achieved by openness on these aspects. It is particularly important that relationships with companies are disclosed when health professionals publish or make statements in scientific and non-scientific publications, at a national level. Also, it is important that health professionals disclose relationships with companies when they speak publicly about the company or one of its products.

### 3.4. Patient organisations

Transparency concerning funding of patient organisations is fundamental to building a relationship of trust between all stakeholders as well as the public. Written agreements should be agreed between a funder – whether a public or private body – and the patient organisation, outlining the nature and amount of the funding and the period covered. Funding sources and amounts should be acknowledged on relevant publications including the organisation's Annual Report, and published on their website. Patient organisations should ensure that the funding received from one single company is proportional to the overall budget, and reflects a commitment to diversify funding sources. Companies should be transparent concerning the patient groups they work with, the nature of the collaborations, and the nature and amounts of funding granted

### 3.5. Competent authorities[7] at EU[8], regional and national level

Competent authorities should play a pivotal role in establishing and following good governance principles through the creation of a transparent environment for all stakeholders for adequate access to relevant information while respecting principles and laws, taking into account commercial confidentiality and data privacy. Responsiveness is a key element in a good governance structure of competent authorities. All European, regional and national authorities involved in healthcare policy decision-making such as procurement, pricing and reimbursement, regulatory activities or other, should declare financial or other interests that could affect their impartiality. These authorities should

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6 Source: European Medicines Agency policy on the handling of conflicts of interests of scientific committee members and experts , 3 April 2012. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097905.pdf

7 For the purposes of this List of Guiding Principles, competent authorities are one of the stakeholders and are defined as any European, regional or national authority that is responsible for policy related to pricing and reimbursement of medicinal products, marketing authorisation, post-market surveillance, Good Manufacturing Practice (GMP) and inspections.

8 As regards the European Commission, their staff is subject to binding rules - the Staff regulation (just as the staff of the European Medicines Agency) - which include rules on avoidance of conflict of interest and independence.

also ensure that their staff makes declarations of their direct and indirect interests[9] in the pharmaceutical and healthcare related sectors. These declarations should be made available in a transparent and accessible way. These obligations should also apply to persons and companies acting in advisory roles to competent authorities.

## 4. Information and promotion of medicinal products

The Guiding Principles apply to all information provided to health professionals and - to the extent allowed in each member state – to information to the general public / patients. The information material for health professionals should be distinctly different from those devised for the general public/patients.

High ethical standards on information and/ or promotional behaviour related to medicinal products Directive 2001/83/EC and in particular articles 86 -100 provide the legal framework regarding information, advertising and promotion of medicinal products for human use. There is already a number of legal obligations deriving from EU legislation. A list of examples regarding these obligations is the following:

4.1. Promotional activities for prescription medicines are only allowed if targeted at health professionals. Moreover, the ban on "direct-to-consumer" advertising on "prescription-only" medicinal products shall be respected.

4.2. Promotional activities for non-prescription medicinal products are allowed, subject to regional and national rules. Information to the general public / patients is allowed under regional and national conditions.

4.3. Relevant information should be included. Misleading, distorting and exaggerating information is prohibited.

4.4. In relation to non-prescription medicines, all parts of their advertising must comply with the particulars listed in the summary of product characteristics.

4.5. Principles on information / promotion addressing health professionals:

A. The promotion of a medicinal product prior to the grant of the marketing authorisation is prohibited. [10].

B. Statutory information (e.g. summary of product characteristics, supply classification of the medicinal product or selling/indicative price) should be included in all material for prescription medicines, unless the material is intended solely as a reminder[11].

C. The health professional should be enabled to form his/her own opinion[12].

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[9] Source: European Medicines Agency policy on the handling of conflicts of interests of scientific committee members and experts , 3 April 2012. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097905.pdf

[10] Source: Article 87 (1) of Directive 2001/83/EC.

[11] Source: Article 91 (1) of Directive 2001/83/EC.

[12] Source: Article 92 (2) of Directive 2001/83/EC.

Further to the existing legal obligations the stakeholders commit to the following:

4.6. General principles for all stakeholders:

A. All information should be understandable, unbiased, factual, accurate, fair, objective, complete, based on up-to-date scientific evidence and in line with the marketing authorisation[13].

B. The source, the purpose and the target audience of the information should always be clear.

4.7. Principles on information provided by pharmaceutical companies to the general public/patients:

A. Any misinformation on the quality, safety or efficacy of a competitor's product should be prohibited. Misinformation campaigns should be banned.

B. The information on prescription medicines disseminated by marketing authorisation holders shall not include information on other medicinal products for which the pharmaceutical company is not the marketing authorisation holder. This information on prescription medicines shall not include comparisons between prescription medicines regarding their quality, safety and efficacy and not go beyond the information that is in the patient information leaflet / summary of product characteristics.

C. Relevant information on pharmacoeconomic studies sponsored by the industry could be made public without prejudice to any commercial confidential information.

## 5. Benefits or inducements to influence behaviour related to prescription medicines

5.1. This provision should be based on two overarching principles:

A. Information to health professionals needs to be objective and unbiased, evidence-based, up-to-date, reliable, understandable, accessible, transparent, relevant and consistent with the SPC.

B. Conflict of interest of health professionals needs to be declared and addressed.

5.2. Specifically, pharmaceutical companies shall respect legal obligation deriving from Article 94 of Directive 2001/83/EC[14] and adhere to the following standards in providing support to prescribing health professionals:

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[13] Source: Core quality principles for patient information on diseases and treatment options, Pharmaceutical Forum Conclusions, 26 June 2007. http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/itp_quality_en.pdf

[14] Article 94 of Directive 2001/83/EC:

1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.

2. Hospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended to persons other than health-care professionals.

3. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2.

4. Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected by paragraphs 1, 2 and 3.

A. Appropriate venue for all promotional / scientific / professional events organised by companies. The venue should be conducive to the main purpose of the event. In principle national events should take place in the home country.

B. Hospitality is allowed only when appropriate. It must be reasonable in level and restricted to the main purpose of the event. It must not exceed what invitees normally would be prepared to pay for themselves.

C. Hospitality may not include sponsoring/organising of entertainment (sports, leisure or cultural) events.

D. Hospitality at sales promotion events shall always be strictly limited to the main purpose and must not be extended to persons other than health professionals[15] (e.g. partners or other accompanying persons).

E. Donations / grants / benefits in kind to institutions / organisations / associations are only allowed if: they serve the purpose of supporting healthcare goals, like research and education. They are documented and kept on record and they do not constitute an inducement to recommend / prescribe / purchase / supply / sell / administer a medicinal product. Sponsor must not influence decisions on research programmes and on persons benefitting from donations (unrestricted grants). With the exception of legitimate research and / or educational grants, donations / grants to individual professionals are not allowed.

F. Public disclosure of donations / grants / benefits in kind.

G. In compliance with existing legislation, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy[16].

## 6. Ethical and responsible conduct of medical representatives and other personnel

6.1. In compliance with existing legislation[17]:

A. Companies must ensure that their medical representatives/personnel are up-to-date with relevant applicable codes/legislation, are adequately trained and have sufficient scientific knowledge to provide precise and complete information about the medicinal products they promote.

B. Companies are responsible for the compliance of their representatives with relevant obligations.

Further to the existing legal obligations the stakeholders commit to the following:

Conduct of the medical representative: they must approach their duties ethically and responsibly, a copy of the SPC should always be made available if requested, transmit to the scientific service of their companies any information they receive on the use of their products (e.g. side-effects), ensure that the frequency/timing/duration of their

[15] Source: Article 94(2) of Directive 2001/83/EC.

[16] Source: Article 94(1) of Directive 2001/83/EC
http://www.emea.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004481.pdf

[17] Source: Article 93 of Directive 2001/83/EC).

visits cause no inconvenience, refrain from using any inducement/subterfuge to gain an interview.

## 7. Honest and transparent representation of clinical trials and their outcomes[18]

A. Ensure clinical trials and publications address clinically relevant questions.

B. Make public all results, including negative or unfavourable ones, in a timely fashion, while avoiding redundancy[19]. Raw data should be made available on request.

C. Improve understanding and disclosure of authors' potential conflicts of interest.

D. Educate authors on how to develop quality manuscripts and meet journal expectations.

E. Support disclosure of authorship contributions and writing assistance and continue education on best publication practices to end ghost writing and guest authorship.

F. Report safety data transparently and in a clinically meaningful manner.

G. Provide access to complete protocol information.

H. Transparently report statistical methods used in analysis.

I. Ensure authors can access complete study data, know how to do so, and can attest to this.

J. Support the sharing of prior reviews from other journals.

## 8. Meaningful involvement of patients in clinical research

- In addition to the obligation set out in the Clinical Trials directive (Directive 2001/20/EC) and the Good Clinical Practice Directive (Directive 2005/28/EC), stakeholders commit to:

A. Respect and foster the highest ethical standards relating to involvement of clinical trials subjects in all clinical trials both in the European Union and elsewhere in the world.

B. Companies should be open about their research priorities and proceedures, without being required to disclose confidential proprietary information. They should be ready to discuss with other stakeholders how to meet public health needs.

C. Patient and public awareness of pharmaceutical research and its contribution to the quality of healthcare services should be promoted to build confidence in medical research.

D. Patients must be given access to high quality information regarding all aspects of clinical trials, including informed consent.

E. Patients who have participated in a trial should be facilitated access to treatment at the end of the trials, where possible under national legislation.

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[18] Source: Ten Recommendations for Closing the Credibility Gap in Reporting Industry-Sponsored Clinical Research: A Joint Journal and Pharmaceutical Industry Perspective, Mayo Clinic, May 2012, Mansi BA, Clark J, David FS, Gesell TM, Glasser S, Gonzalez J, et al (2012).

[19] For example websites: https://www.clinicaltrialsregister.eu/ and http://clinicaltrials.gov/.

**9. Facilitation of awareness and education on the existence of the List of Guiding Principles**

A. Stakeholders' awareness and education regarding the List of Guiding Principles should be promoted actively e.g. through guidance / to their member-associations.

B. Relevant support should be provided through: competent authorities, sharing of experience between member-associations of stakeholders or through organisation of regular meetings.

C. Stakeholders should actively promote, through national codes of conduct or other means, these guiding principles.

D. Members, employees, collaborators and society at large should be educated and made aware of the stakeholder's commitments to these principles.

E. Competent authorities have a role in bringing together stakeholders at the national level to facilitate the development of national codes of conduct, where appropriate.

F. The European Commission, having facilitated the development of these guiding principles, will promote further the sharing of information between stakeholders to improve awareness of and compliance with these principles.

G. The progress of these awareness campaigns should be measured on a regular basis.

**10. Establishment of enforcement, complaint and appeal procedures**

A. Establishment of enforcement, complaint and appeal procedures should be addressed and efficiently and appropriately dealt with at national level, preferably by self-regulatory mechanisms, taking into account the positive proven experiences with self-regulation and if appropriate by additional co-regulatory mechanisms.

B. All Stakeholders should have adequate, transparent and rapid procedures (receipt confirmation, bona fide complaint process, decision / outcome communication to complaints) in place for dealing with complaints relating to these principles.

C. In order to ensure enforcement of ethical codes, competent authorities should facilitate all stakeholders coming together, working with them in defining effective measures, appeal procedures and possible remedies.

D. Adjudication results should be made public.