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fpa response to European Commission consultation on
Legal Proposal on Information to Patients

About fpa

fpa (Family Planning Association) is the UK's leading sexual health charity, working to enable people in the UK to make informed choices about sex and to enjoy their sexual health free from exploitation, oppression or physical or emotional harm. **fpa** wants to see a society with open and positive attitudes to sex, in which everyone enjoys sexual health and where sexual and reproductive rights are respected.

fpa provides a comprehensive sexual health information service, including a national telephone helpline, which responds to around 60,000 enquiries a year on all aspects of sexual health. We produce a range of information for professionals and the public and distribute around 10 million pieces of literature each year on sexually transmitted infections, contraception and pregnancy choices, including abortion. **fpa** provides a variety of resources, including training courses, for those involved in the delivery of sexual health services. We also run a series of community based sex and relationships education projects, both for young people and for parents. **fpa** provides a national voice on sexual health and work with professionals and the public to ensure that high quality information and services are available to all who need them.

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fpa welcomes the opportunity to comment on the European Commission's proposals on information to patients. We have restricted the following comments to our areas of expertise.

High quality information

fpa strongly believes that the provision of high quality and evidence-guided information is crucial to enabling people to maintain their sexual health. It is important that this information is truly objective to enable people to make informed decisions about the best option for them. This is particularly important for choices such as contraception. Providing people with sufficient information to enable them to choose the contraceptive method that most suits them is fundamental to encouraging correct and consistent use of contraception and therefore preventing unplanned pregnancies. **fpa** produces a range of information leaflets for adults and for young people on sexual health, including on sexually transmitted infections, contraception and pregnancy choices, including abortion.

It is not clear from the consultation document whether all information produced for patients and members of the public would be covered by the draft proposals, or whether they only relate to information produced by the pharmaceutical industry. It would be helpful for this to be clarified as there are a variety of organisations, including **fpa**, which produce information for the public and which would be affected by changes in the regulation of information for patients.

We are particularly concerned by the proposal that the information provided to the public should be compatible with approved summaries of product characteristics and patient information leaflets and should not contradict or go beyond the elements specified in them. Aside from the issues that exist with the quality of information in summaries of product characteristics and patient information leaflets, this proposal could significantly reduce access to information. We understand the need to ensure that the information available is consistent. However, linking all information produced for patients and the public to the summaries of product characteristics and patient information leaflets would lead to a great deal of duplication and could actually result in less information being available to the public. **fpa's** information is highly respected by professionals and the public alike and goes beyond the details provided in summaries of product characteristics and patient information leaflets. This proposal would mean we could no longer provide this important service. There needs to be greater clarity about the scope of this proposal.

fpa is also aware that many people use the internet to find information about their health and about treatments they may access. It is not clear from the consultation document how these proposals would affect information produced on the internet. As has been stated above, **fpa** strongly believes that people should be able to access high quality, objective, evidence guided information, and this

includes being able to access information online. Therefore it would be helpful for the proposals to be clarified to ensure that they would not impose unnecessary restrictions on people accessing information on the internet.

Advertising and non-promotional information

fpa is concerned that the proposals on advertising and non-promotional information are not sufficiently clear and may be open to different and subjective interpretations. For example, we are unclear how a pharmaceutical company could disseminate information on television and radio and through printed material which was actively distributed, without this being advertising (paragraph 3.3.1 Information passively received by citizens [our emphasis]).

We are concerned that the proposals as they are currently drafted do not give sufficiently clear definitions of and distinctions between advertising and non-promotional information. There is a risk that, if this is not resolved, members of the public will be accessing information that is not objective and does not enable them to make an informed decision.

It is also not clear how the proposals will affect the advertising of products in professional journals. Some advertising of prescription only medicines is allowed in journals for health professionals. Given that the proposals would introduce a new method of regulating information about medicines, it needs to be clarified whether this would have an impact on other forms of information or advertising that currently exist.

Comparative information

fpa understands the need to ensure that information for patients and the public does not make unfair comparisons between products. However, we are concerned that the ban on comparisons between medical products, if it applied to all information not just that produced by the pharmaceutical industry, could have an adverse effect on people's ability to make informed decisions. People need to be aware of and able to compare all of the options available to them to make an informed decision.

For example, **fpa** produces a leaflet which gives an overview of all 14 methods of contraception currently available in the UK. This enables people to consider the advantages and disadvantages of all methods and choose the one that is most appropriate for them. If this leaflet could not be produced, people may not receive information about the full range of contraceptive methods, or may have to read 14 different information leaflets to be able to make an informed choice.

It is vital that the European Commission's proposals do not have a negative impact on people's ability to make informed choices about their health and wellbeing.

Conclusion

fpa fully understands the European Commission's intention to ensure that high quality objective information is available to patients and the public across the European Union and to try to overcome inequalities in access to information. However, we are concerned that the Commission's proposals, as they are currently drafted would not achieve this aim. Instead, the proposals could, in the case of comparative information in particular, have an adverse effect on people's ability to access information and to make informed decisions about their health and wellbeing.