Strategic Approach to Pharmaceuticals in the Environment

CONSULTATION STRATEGY at 06.10.2017

Introduction

This consultation strategy relates to the development of the above initiative, whose roadmap¹ was published on 28 April 2017, and for which a supporting study is underway (as at 06.10.2017).

In the roadmap, the section on the consultation strategy says:

"In the context of the study being undertaken to inform the development of the strategic approach, some targeted consultation of experts has already been carried out, and the Commission will conduct a 12-week open public consultation to involve as wide a range of relevant stakeholders as possible. The consultation is expected to be launched in the first half of 2017. Emails and web-based publicity are foreseen. The launch of the public consultation will be announced in the consultation planning document that can be found at http://ec.europa.eu/yourvoice/consultations/docs/planned-consultations_en.pdf"

The roadmap also mentions a Commission workshop² held in 2014 to discuss with stakeholders the findings of an earlier study report³ on pharmaceuticals in the environment. These and other relevant stakeholders will be invited to contribute to the open public consultation and to a targeted stakeholder consultation.

Consultation objectives

Directive 2008/105/EC as amended by Directive 2013/39/EU obliges the Commission to develop a Strategic Approach to Pharmaceuticals in the Environment. The Approach is likely to take the form of a Commission Communication outlining a range of legislative and non-legislative policy options for possible follow-up; the intention, as required by the Directive, would be to adopt measures in a second stage, subject if necessary to impact assessment.

It is important to ensure that the actions and options included in the Commission Communication are the most promising available, so that follow-up effort (to further investigate the options/carry out impact assessment if necessary) is appropriately directed.

¹ http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-2210630_en
² https://circabc.europa.eu/w/browse/5d532921-1e1f-48f5-b0e0-3057798423ca
In the study, a background document has been drafted to support the abovementioned open public and targeted stakeholder consultations. It has drawn on the earlier study report and workshop report mentioned above, and on telephone interviews conducted with selected stakeholders (from Member State authorities, industry and NGOs) to gather additional information and clarify points regarding a range of options (30), grouped in 10 action areas.

The public and targeted stakeholder consultations will be undertaken as part of the study, to help the Commission decide on which options to include in the Communication. A report will be prepared on the consultation results as one of the outputs from the study, and this will feed into the Commission's decision-making, i.e. as regards which actions to prioritise and which specific options to include in the Communication. The outputs of the consultation will likely include information that can be used also in the second stage of the policy-making process, i.e. the further investigation of selected options as a basis for proposing measures.

**Stakeholder mapping**

The initiative has a wide range of stakeholders because it concerns the whole lifecycle of pharmaceuticals, from design and production through to disposal. It directly involves two separate broad policy areas in the Commission (health and environment), including different sectors within each. There are also links to other policy areas, including agriculture, aquaculture, biocidal products and chemicals policy, food safety, enterprise and trade.

The following table lists the main categories of stakeholders

<table>
<thead>
<tr>
<th>Primary activity</th>
<th>Human health</th>
<th>Animal health</th>
<th>Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation/implementation</td>
<td>Member States' health ministries/medicines agencies</td>
<td>Member States' animal health ministries/medicines agencies</td>
<td>Member States’ environment ministries/agencies</td>
</tr>
<tr>
<td></td>
<td>Food safety agencies</td>
<td>Animal health inspectorates</td>
<td></td>
</tr>
<tr>
<td>Service provision</td>
<td>Health authorities</td>
<td>Veterinarians</td>
<td>Water authorities/companies</td>
</tr>
<tr>
<td></td>
<td>Doctors/surgeons</td>
<td></td>
<td>Hospital managers</td>
</tr>
<tr>
<td></td>
<td>Nurses</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dentists</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pharmacists</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Although not listed explicitly, it follows that organisations representing individual stakeholders or categories of stakeholder mentioned above will be relevant to the consultation process, for example patients' and doctors' organisations, animal welfare and environmental NGOs and industry bodies.

The initiative could include a wide range of possible policy options in which different stakeholder categories are likely to have different levels of interest and on which they will be able to exert different levels of influence, however the following figure indicates how the influence/interest levels might appear overall.

<table>
<thead>
<tr>
<th>Production/supply</th>
<th>Pharmaceutical companies</th>
<th>Pharmaceutical companies</th>
<th>Pharmaceutical companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumption</td>
<td>Patients</td>
<td>Farmers</td>
<td>Farmers/Citizens in general</td>
</tr>
<tr>
<td>Research</td>
<td>Research institutions</td>
<td>Research institutions</td>
<td>Research institutions</td>
</tr>
</tbody>
</table>

Although not listed explicitly, it follows that organisations representing individual stakeholders or categories of stakeholder mentioned above will be relevant to the consultation process, for example patients' and doctors' organisations, animal welfare and environmental NGOs and industry bodies.

The initiative could include a wide range of possible policy options in which different stakeholder categories are likely to have different levels of interest and on which they will be able to exert different levels of influence, however the following figure indicates how the influence/interest levels might appear overall.

![Graph showing levels of influence and interest for different stakeholders]
**Consultation methods and tools**

The following activities have already been conducted:

June 2014: Commission stakeholder workshop to discuss the 2014 BIO IS report on pharmaceuticals in the environment

2016: Targeted telephone interviews of selected stakeholders (as part of the ongoing study to support the preparation of a background document for public consultation)

April-May 2017: Commenting period on the roadmap for the initiative

The following activities are planned:

October 2017 – January 2018 (12 weeks): Open public consultation (in all EU languages) on possible actions to address pharmaceuticals in the environment, to help the Commission formulate the strategic approach.

This consultation will be aimed at gathering information on the level of awareness of the issue, and on the public's perception of the need for action. It will seek views on the prioritisation of a limited number of actions selected from the action areas presented in the background document. Respondents will be invited to propose additional actions not already presented in the questionnaire or background document.

October 2017 – December 2017 (8 weeks): Targeted stakeholder consultation (in English only) on possible policy options for inclusion in the strategic approach, aimed at stakeholders with relevant expertise/technical knowledge.

This consultation will be based on the 30 options presented in the background document prepared for the consultation. The questions will aim at gathering views and information on the options, including on the effectiveness, cost and feasibility of implementing them. Respondents will also be invited to propose additional options if relevant, with evidence.

**The aim is to launch the open public and targeted consultations by the end of October 2017.** Statistical summaries of the results and a more detailed report will be prepared. These will inform the Commission's drafting of the Communication, which the Commission aims to adopt in the spring of 2018.

The Commission expects further bilateral contacts with key stakeholders (eg Member States, business organisations, NGOs), who are likely to approach us during the consultation period. Currently, no other activities are envisaged, because we consider that
the planned activities will provide a sufficient basis for developing the strategic approach. Additional consultation may be necessary at the later stage of developing proposals for specific measures.

**Consultation publicity**

The open public consultation will be publicised via the Commission’s list of public consultations. A consultation webpage referring to both consultations will be created on the DG ENV site, linked to EU Survey and other relevant pages. Relevant stakeholder organisations will be informed by email. Participants in the 2014 Commission workshop, Member State representatives in the relevant medicinal products regulatory committees, and members of the Working Groups under the Common Implementation Strategy for the Water Framework Directive (WFD) will be contacted, as well as Member State and stakeholder group representatives involved in other relevant policy areas. Social media will be used to inform the general public.