STAKEHOLDER CONSULTATION ON SMART REGULATION IN THE EU
FOLLOW UP TO THE 2010 COMMUNICATION ON SMART REGULATION

I. ENHANCING THE QUALITY OF EU LEGISLATION

Questions

Collecting evidence and monitoring results

1. Smart regulation requires monitoring results and collecting high quality data over time. This is neither easy nor free of costs:

(i) How can the Commission best organise this process?

The Commission could (and should) strengthen and formalise the input from relevant stakeholders, i.e. those affected by the specific bits of legislation under investigation. Working closely with organisations that have these data and make use of them for their business planning, such as the industry concerned by a specific piece of legislation could make a huge difference to the development of relevant and appropriate policy and regulation.

These expert stakeholders could also facilitate the gathering and exchange of good practice, which can help develop effective and appropriate legislation. This can be done by consultations such as this current one, but also by means of regular face-to-face meetings or setting up specific 'smart regulation platforms', bringing together relevant stakeholders.

(ii) Do you have concrete suggestions on how to minimise the resulting administrative burden?

As outlined in our general comments, our sector is affected by high cost, duplication of effort and needless bureaucracy. We would advocate to:

- Ensure that the outcomes of consultations better reflect the respective sector´s diversity – especially the smaller 'niche' sectors instead of putting in place. This would lead to regulation more adequate to the specific characteristics of different categories of products and help avoid unnecessary administrative burden. In this context it should be kept in mind, that microenterprises or even SMEs are usually neglected in the course of consultations. Improved of small niches and their needs would significantly contribute to identify inappropriate legislation and unnecessary burden as well as opportunities for simplification.
- Give more responsibility to the entrepreneurs for their products and increase self-regulation
- Develop special rules and regulation for 'low turnover' industrial products (such as homeopathic products),
- Cancel the obligation to send in all documentation on a specific product to competent authorities (in our field, available resources only allow these authorities to store the documents in archive containers; they simply cannot deal with this huge amount of information) and move to a principle where entrepreneurs are obliged to keep the documents available on website for control and assessment by competent authorities. This follows the principle of increased responsibility and self-regulation.

Evaluation

2. Stakeholder involvement can benefit the quality and focus of evaluation even before this is actually carried out:

(i) Do you have good practice examples of how stakeholders can contribute to the definition of evaluation priorities?

The (industry) stakeholders seek to develop quantitative and qualitative data as they need it for effective business planning. They also have daily experience and contact with the demand side and know what citizens want and expect from their products and services as regards quality and quantity.
In addition, more direct contact and cooperation (e.g. company visits) with Commission staff would help them understand the challenges faced by the industry and to identify the priorities in its day to day reality.

(ii) Do you find the planning of Commission evaluation accessible and useful?

As such, the planning is quite accessible and useful. However, most of the time it seems highly theoretical and far removed from the reality of industry as well as citizens' demands and preferences.

(iii) How do you usually become aware of planned EU evaluations?

ECHAMP usually becomes aware through

- email notification of public consultations launched by the European Commission
- screening the official website of the Directorates and the European Commission.
- contacts with other stakeholders and screening their websites

3. Do you find particular shortcomings in any of the following areas in the Commission? evaluation approach and/or practice:

(i) Planning No comments

(ii) Extent and timing of stakeholder consultation

In the section 'Consulting the Public', it is mentioned that 'since 2012, the minimum period for open public consultation has been extended from eight to twelve weeks'. unfortunately however, this rule is not always respected. For instance, in the case of the consultation on Regulation (EC) N0 1234/2008 stakeholders only had one month to submit their response. This is very difficult as internal governance procedures (e.g. consulting membership) need to be taken into account.

Commission bodies such as EMA and HMA should also respect the Commission guidelines as outlined in Communication published on in January 2012[1].

[1] http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/1&format=HTML&aged=1&language=EN&guiLanguage=fr.

(iii) Scope / comprehensiveness: No comments

(iv) Assessment of ex post costs: These are not always clear or realistic nor do they do justice to the

(v) Assessment of ex post benefits: These are not always clear or realistic nor do they do justice to the diversity of a sector.

(vi) Focus on concrete impacts/achievement of objectives: This is also not always clear or realistic – the objectives for homeopathic and anthroposophic medicinal products (HAMPs) have not yet been achieved despite the legislation being in place for almost twenty years.

(*vii) Assessment of stakeholder and/or Member State specific impacts*

In our experience, awareness of the diversity of a sector as well as the specific characteristics of smaller niches is quite low. The specific impact on individual stakeholders in cases where the products are not comparable with the global characteristics of the major part of the sector is generally neglected. Assessing the global requirements only and streamlining the resulting regulation often leads to inappropriate legislation as well as unnecessary administrative and financial burden for certain subcategories of products.

In the case of the category of products represented by ECHAMP, a specific Directive published in 1992 (92/73/EEC) already defined the specific characteristic of our products. Since then pharmaceutical regulation has progressed significantly. However, the results of subsequent consultations and assessment of the use of the existing regulation do not consider the specific impact for our field. A recent report entitled 'Availability of Homeopathic and Anthroposophic Medicinal Products in the EU', prepared by ECHAMP in close cooperation with Price Waterhouse& Coopers underlines the reality of the impact for the industry as well as citizens:

"The enforcement of Directive 2001/83/EC, as implemented in the legislation of the MS, is far from complete for either Articles 14 or 16.2, almost twenty years after the publication of the specific Directive 92/73/EEC on homeopathic medicinal products, consolidated within Directive 2001/83/EC in 2001.
In various Member States the availability of HAMPs is threatened by the lack of registration, or by an incomplete or delayed re-registration process.
In many Member States the demand expressed in terms of the numbers of homeopathic prescribers is not reflected in the number of registrations."

This report was prepared as a contribution to the upcoming Commission report on availability of medicinal products and will be made public as soon as the Commission report will come out.

viii) Final quality of the evaluation:

When the smaller niches are evaluated, the approach is often too theoretical with limited input from those concerned or affected (e.g. Commission Report COM(97) final on the Application of Directives 92/73 and 92/74 about the homeopathic medicinal products, published on 14 July 1997[2]). Despite its conclusions, no solutions were offered to address

[2] http://www.echamp.eu/fileadmin/user_upload/Regulation/Commission_Report_Dir_92-73_and_92-74_Homeo_July_1997.pdf

the challenges that were identified. In most cases, as described under vii) the characteristics and the input of smaller sectors is not considered, if different from the mainstream, or from the largest concern of a sector in need of regulation.

(ix) Extent and transparency of follow up No comments

For any area of concern, please provide concrete examples as well as practical suggestions on how the Commission could address the underlying issues.

As regards the authorisation policy for HAMPs, ECHAMP would like to refer to its 'Better Regulation' document published in July 2008[3]. This provides a more recent picture than the last evaluation, which was carried out by the Commission in July 1997.

Impact Assessment

4. The Commission impact assessment system aims to support well informed policymaking by providing an integrated, transparent and accountable analysis of all the significant economic, social and environmental costs and benefits of possible new initiatives. In your view:

(i) Are these the right aims? Yes; however, some are missing (see ii).

(ii) What can be done to better achieve these aims?

What is missing is an estimate of the 'added value for or impact on the citizen' in the case of new/additional legal provisions. There should be better cost-benefit estimates and assessments as well as more room for self-regulation.

(iii) What use do you make of Commission impact assessment reports?

These reports sometimes provide useful information. However, most of the time they do not reflect the reality in a specific field, especially not in the areas where 'standardisation' is more difficult or where citizens' protection is not required. The Commission should differentiate more in certain cases (i.e. take account of the specifics of each individual area) and strive for more knowledge and awareness of the day to day reality faced by the individual industries as well as the people who make use of their products and services.

Strategy

5. Do you have other recommendations how the Commission's overall approach to enhancing the quality of EU legislation could be further improved?

It would be useful for Commission staff to obtain more knowledge about the challenges and daily reality of individual companies, independent of their size. Company visits (to companies which are representative of their field) could be useful to ensure a more realistic and less theoretical point of view.

[3] Homeopathic and Anthroposophic Medicinal Products in Europe : Proposals for a Better Regulation – ECHAMP July 2008

II. ENSURING THE EFFECTIVE IMPLEMENTATION OF EU LEGISLATION
Questions

Facilitating implementation and compliance

6. Knowledge about the way in which EU law is implemented on the ground in the Member States should play a greater role in the process of policy evaluation and design. From your experience:
(i) Which specific implementation issues should be looked at when evaluating existing legislation?

This could be done by means of a three way process:

- The first question to ask would be whether implementation of EU regulation into the national legislation has taken place?
- The second would be whether the required logistics, expertise and resources are in place in the member states to execute/enforce the EU legislation?
- The third would refer to whether enforcement or execution of the legislation and rules has taken place in line with the original objectives of a certain bit of legislation (i.e. impact assessment after a certain period of time).

A follow-up of the real impact of a piece of legislation three or five years after it has come into force in the Member States should be an essential part of a robust impact assessment policy. In our opinion, this should be an intrinsic part of any standard assessment of a new or amended piece of EU legislation. Ex ante assessment of impact makes no sense if this impact is not measured afterwards as well.

Interestingly, concerning the implementation of the sections relative to the homeopathic and anthroposophic medicinal products in the Directive 2001/83/EC, a Price Waterhouse Coopers study (December 2010) showed that 'some countries are still in a the transition period to implement the legal framework on registration (Art.14) and/or marketing authorisation (Art.16.2) or have not yet enforced the law completely"[1].
This is a clear example of incorrect estimates of the impact of the legislation on our sector, as the huge practical issues regarding practical implementation and enforcement are related to the lack of infrastructure and resources in the Member States.

(ii) What issues should be taken into consideration when designing new legislation so as to facilitate subsequent implementation and compliance?

The existing competence, knowledge and resources in the Member States' bodies in charge of implementing the legislation should be taken into account. If these do not suffice, voluntary work sharing between Member States and agreements on specialisation of national competent authorities for certain fields could be considered and advised.

7. Do you find current Commission assistance regarding the implementation of new legislation sufficient? If not, how could it be further improved? See under 6 (ii)

Member States, together with the Commission, should look at their own capacities/resources to implement and to enforce a new piece of legislation. This particularly applies to small but

also to mid-size Member States. (In our case, only the large national medicinal products agencies can afford to assess product application dossiers as required by law).
If resources are lacking, work sharing, specialisation and mutual trust policy building amongst Member States and the development of centres of excellence could be considered. The Commission could have a coordinating role in this. Member States could be motivated to participate on a voluntary basis, accepting the expertise from other Member States.

8. Should the availability of information from Member States explaining how they implement EU legislation be further improved, and if so, how?

See above.

Informing the public

9. Do you get all the information you need on the application of EU law? If not, please specify which improvements are needed using concrete examples.

The information is available as such. However, a lot of effort is required to collect it and to follow the development and process of application (e.g. the implementing/delegated acts in the field of pharmacovigilance, falsification and variations within the pharma legislation are a good example). It would help it there was a more central, transparent and accessible place to obtain the information required.

Improving enforcement

10. Do you have concrete ideas on how the Commission could make better use of the instruments that are at its disposal to ensure timely and correct implementation of EU legislation by the Member States (e.g. shorter transposition periods, financial sanctions, other)?

The transition period should be in line with the level of urgency of the legislation.
As legislation that is not fit for purpose or that is not being implemented will have a negative impact on European industry, it will affect competition and the strength of the industry. It also puts the European industry in a weak position compared to non-EU competitors. Sanctions are not always the answer. Because of legislation that is not fit for purpose, companies need to spend a sizeable amount of their budgets on regulatory affairs; budget which could have been spent on innovation. This means that innovation is losing out as well as compared to competitors from other continents.

The Commission could ensure the structure and the resources to evaluate and assess the implementation in the Member States during the transposition period (e.g. after 2 years) and at the end of the transposition period in order to evaluate the willingness to implement as required.

III. CONSULTING THE PUBLIC

Questions

Minimum standards

11. In your view, are the current set of general principles and minimum standards appropriate or are there any changes you would like to see?

The period for responding to EU level consultations should be no less than 12 weeks, as stipulated in the 2012 Commission Communication (see above).

12. Are they applied to the right types of initiatives? If not, could you explain why and provide specific examples?

Differences within one area (e.g. pharma) are sometimes so important that a more detailed, targeted/focused approach is needed. Standardisation is not always the best approach; in our industry, with its much larger scope, vast product range and products developed for specific personal use, it can even be counterproductive as regards the objectives to be achieved. This is what we experience: as our specific field , homeopathic and anthroposophic remedies, are considered part of the overall pharmaceutical area, our specific concerns and characteristics are not being accounted for. Minimum standards should also consider minorities with different characteristics. It is part of the 'creativity' and 'diversity' of the European Union.

Scope

13. Stakeholders should be consulted on the right issues and in the right ways. From your experience:
(i) Are you generally consulted on all relevant elements of impact assessment (i.e. problem definition, objectives, policy options and their impacts)?

Yes. ECHAMP is being consulted but on the whole, the consultations remain quite general; on the particularities or exceptions are usually not considered.

(ii) Are consultation documents clear and complete?

Consultation documents are clear on the whole. However, they are usually quite general, and do not pay attention to minority categories, to particularities of certain products or services, nor to different circumstances. We fully understand that it is difficult to take all specific issues of a certain legislative area into account and stakeholders do have the opportunity to refer to their particular interests in their responses to consultations, in order to have the Commission take these on board. However, even when raised, in most cases they do not show in the resulting consultation overviews or reports – which means that they are not taken on board. This happens even in the case of areas where the legislator already stated a need for separate consideration by a specific Directive (92/73/EEC).

(iii) Is the mix of targeted and open consultations used by the Commission appropriate? If not, could you explain why and provide specific examples?
No comments

Timing

14. *Early consultation has the greatest potential to influence policy reflections but suffers from the lack of well-defined policy ideas. Conversely, when policy reflections are advanced, stakeholders can be consulted on the specificities of a proposal but may be unable to exert much influence on its overall need and design. From your experience:*
(i) Do Roadmaps facilitate your involvement? What use do you make of them?

Roadmaps are useful as general outlines for action. However, for many specific problems and challenges they are too general.

(ii) Are your views usually sought at the right moments in the process of policy? formulation?

That is often not the case as the challenges we face as an industry are very specific and not considered in general policy development. Our area needs a differentiated approach in several policy areas.

(iii) Should open consultations preferably take place in one go or in separate stages? In the latter case, how could excessive costs (for the public and the Commission) be? avoided and minimum standards respected?

There could (and should) be more 'face to face' consultation meetings with stakeholder groups, including those that are facing specific problems and challenges. Commission staff working in a certain area (e.g. pharma) should also be more aware of the day-to-day reality and difficulties of the enterprises in other medicinal fields (mainly but not all SMEs) and take account of their issues. It should not be forgotten that SME's and special niches within a sector hold a great growth potential – a major objective under Europe2020.

Outreach

15. How do you generally become aware of consultations? Are you satisfied with this? If not, how would you like to learn about upcoming or current consultations?

As a European Association it is our role and task to be aware of upcoming and ongoing consultations; therefore we actively monitor all possible sources and ensure close follow-up. We succeed in finding what we need via the relevant websites and subscriptions for information. Mail notifications of the Commission are very helpful.

16. Reaching all affected stakeholders and facilitating high-quality input is essential for ensuring the benefits of consultations:
(i) How do you think the coverage of Commission consultation could be further extended in a cost-effective manner?

Attention should be paid to particular situations in order to be effective and beneficial to the industry, especially the SME and the special niches within a sector. Standardisation is not always possible (sometimes even counterproductive for innovation) in all fields/areas. Commission staff could be more aware of the specificities of the industries they are dealing with in order to serve growth in the EU. Cost-effectiveness should be looked at before measures are taken and should be evaluated afterwards

(ii) How could consultation channels in Member States be mobilised to this end?

Trade associations and EU level health representative groups (patients, health professionals ...) could be in close contact with the Commission and their task could be to disseminate the information and call upon their members to respond. Currently, all too often it is only those that are already 'in the know' that will be aware and respond.

(iii) Can the use of internet-based applications be improved?
No comment.

17. What is your experience with consultations targeted to specific stakeholders (including public hearings)?

ECHAMP usually responds to general consultations but would be happy to participate in specific stakeholder consultations. This could be highly useful in our highly specific field.

Representativeness

18. Are you aware of any good practices in the Member States or elsewhere on how to assess the representativeness of different respondents to a public consultation?
No comment.

Feedback

19. The Commission provides information on the results of public consultation and their impact on policy choices in its public summary of the consultation, in impact assessment reports and in the explanatory memorandum accompanying final initiatives.
(i) Are you satisfied with the quality and transparency of this information?

The transparency as such is sufficient. However, the summaries of submissions are often very general and too theoretical, and sometimes quite far removed from the reality of our specific industry.

(ii) As a participating stakeholder, would you want to be automatically alerted to the publication of these documents?

That would be very helpful.

Results

20. Do you think current consultation practices ensure the effective and transparent participation of all relevant stakeholders? Do they lead to improved policy-making?

Participation is possible, but very often responses remain limited to those that are close to the Commission and already very much involved with policy development. In other words, efforts should be made to include the largest possible number of stakeholders and go beyond the 'Brussels bubble'. Often, a large majority of the concerns expressed by stakeholders are not being addressed, and as a result not reflected in policy development.

ECHAMP European Coalition on Homeopathic and Anthroposophic Medicinal Products E.E.I.G.
Rue Gray 100 – 1040 Brussels – Belgium - Tel: +32-2-649.94.40 - Fax: +32-2-649.41.77
office@echamp.eu – www.echamp.eu – VAT BE 0467 826 644 RPR Brussels

In our specific case we note that Commission staff are not sufficiently aware of the particular situation of our industry and the specific nature of our products; we are subjected to a set of general and standardised rules which have proven to be ineffective and inappropriate for our industry. Because of this generalisation/standardisation, Member States are confronted with a situation where the rules cannot be applied and in which enforcement is impossible. As a result, application files are not being dealt with and a whole – typically European - industry is blocked in its development. This also impacts on export because of the lack of certifications/authorisations from our own authorities.

IV. PROGRESSING TOGETHER

Smart regulation is a shared responsibility of the European institutions and of Member States. All must play their part and collaborate effectively if smart regulation is to achieve its objectives.

21. Smart regulation is a shared responsibility: what more can be done to advance this important dimension of the agenda?

What is needed is practical work sharing and specialisation amongst Member States; a move from mutual mistrust to mutual trust is required for European regulation if our area is to function properly. The current operation of the Homeopathic Medicinal Products Working Group (HMPWG) is a clear example of where cooperation could and should be improved.

V. OPEN QUESTIONS

22. Is there anything else you would like to comment upon as an input to the Commission reflections on smart regulation?

There are two issues we would like to underline:

1 Smart regulation and consideration of particularities for specific fields such as homeopathic and anthroposophic medicines is the only possibility to make progress and to address the current challenges to our medicinal products (used by almost 1/3 of the citizens) which we have been experiencing for nearly 20 years now.

2 Attention should be paid to particular situations in order to be effective and beneficial to the industry, especially the SMEs. Standardisation is not possible (sometimes even counterproductive for innovation) in all fields/areas.
Commission staff should be aware of the specificities of the industries they are dealing with in order to serve growth in the EU. This also relates to impact assessment: while impact assessment is currently being carried out before the introduction of a certain piece of legislation, it would be imperative to also do an impact assessment of legislation some time after is has been implemented, to see where the real impact has take place and what the implications for the area concerned are. Only then can effective and appropriate regulation be put in place. Cost-effectiveness should be looked at before measures are taken and should be evaluated afterwards

23. Is there anything you want to comment upon concerning the quality and process of this specific public consultation?

Once again, we would like to underlines ECHAMP's appreciation of this consultation which reflects a willingness to change and stimulate progress on the part of the Commission.
We remain at your disposal for further information and hope to be actively involved with the next stages.

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Rue Gray 100 – 1040 Brussels – Belgium - Tel: +32-2-649.94.40 - Fax: +32-2-649.41.77
office@echamp.eu – www.echamp.eu – VAT BE 0467 826 644 RPR Brussels