

# REFIT Platform Opinion

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## **REFIT Platform Opinion on the submission by businesses on the Traditional Herbal Medicinal Products Directive**

The REFIT Platform has considered the two submissions raised by businesses to revise the Traditional Herbal Medicinal Product Directive (THMPD) in order to facilitate innovation and the entry into the EU market of such products and to implement the Regulation on health claims on botanicals.

Most members of the Stakeholder group are of the opinion that any recommendation on the need to amend the Traditional Herbal Medicines Directive 2004/24/EC should only be made after the outcome of the REFIT evaluation of the Nutrition and Health claims Regulation (EC) 1924/2006 is made public. These members further consider that no actions should be taken that could undermine consumer's safety and protection.

Several members of the Government group recognise that there can be scope for simplification of the THMD. A few members suggest that the Commission collects data to provide additional information and evidence on the performance of the THMPD. Several Member States suggest awaiting the results of the REFIT evaluation of Regulation (EC) No 1924/2006 before deciding on whether there is a need to collect additional evidence on the performance of the THMPD.

# Detailed Opinion

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## 1. Submissions XI.6.a-b by businesses

### ***XI.6.a: Traditional Herbal medicines and health claims made on botanicals used in food (LtL 312)***

#### *Burden on business*

*The Traditional Herbal Medicinal Product Directive is not fit for purpose. I am a regulatory compliance consultant and to date I have told 100s companies they cannot market their botanical/herbal products in the EU, because they are not foods, but do not fit into the extremely narrow definition of traditional use: 30 years on the market, 15 of which in EU. Firstly, traditional use is a term used in herbal medicine and means exactly that. Whereas the THMPD means market data on identical formulas of the same indication, the term traditional use should be changed to market evidence. This law more than any other has stopped innovation and plain prevented many good products from being available to consumers. Another problem is that botanical health claims have been put on hold by the European Food Standards Agency (EFSA) for seven years. The botanical food and herbal medicines market has been unduly prevented from decent business by European law and there is no reasonable justification for this. I have compliance reviewed literally 1000s of natural health care products for the EU market, so this is a genuine problem observed through practice.*

#### *Suggestion for simplification*

*Revise the THMPD to allow for a genuine definition of traditional use. Get EFSA to do their work on Botanicals rather than just putting things on hold for years and years. There is no excuse for this and the motivation behind these directives and why EFSA have put botanicals on hold for so many years is entirely unclear.*

### **XI.6.b: Traditional Herbal Medicines**

*We think the THMP Directive in its current form has various shortcomings and should be revised by the European Commission. The uptake of THMPs varies significantly between Member States. The Directive has not met its objective which is to enhance the harmonization for THMPs between EU Member States (see recital 8 and 11 of Directive 2004/24/EC). The low number of registrations granted in important Member States such as Belgium (21), France (23) and Italy (10) within the 12 years (!) shows the limited impact the THMP Directive had in the past.*

*Two facts are highlighted in a recent study of the European Medicines Agency (EMA) on the uptake of THMP registrations published on 02.05.2016 :*

- 1. The number of THMP registrations is decreasing in all EU Member States (from 296 in 2013 to 139 in 2015).*
- 2. The degree of usage of THMP registrations varies significantly between the EU Member States (some Member States had no THMP registrations over the last 12 years such as DK, LI, LU, MT - others had significantly higher rates such as the UK (344) Germany (263), Poland (197) and Austria (195).*

*The EMA study clearly shows a) that THMP registrations lack the attractiveness needed for companies to use them and b) that the implementation of the Directive in the Member States seems to differ significantly. Both aspects should be addressed in a revision of Directive 2004/24/EC.*

#### ***1. The number of registration of THMPs has decreased significantly over the last years.***

*According to the EMA study the total number of registrations in all EU Member States has been almost steadily decreasing from 374 (year 2011), to 270 (year 2012), to 296 (year 2013), to 125 (year 2014) and has reached 139 registrations in the year 2015. It should not be forgotten that this is due to alternative regulatory pathways available to companies. It is no surprise that all BELFRIT countries (Belgium, France, Italy) have almost no uptake in THMP registrations. These countries have rather liberal regulatory regimes for botanical food supplements (such as the BELFRIT list) and companies might operate with health claims for botanicals due to transition periods in the Health Claims Regulation. In addition, high registration fees for THMP applications - by contrast to food supplements - might deter companies from applying for a THMP registration. In this context it should not be forgotten that THMPs as pharmaceuticals guarantee a higher degree of regulatory scrutiny than food (supplements) due to pharmacovigilance and variation obligations.*

*Diapharm GmbH & Co. KG welcomes the fact that the European Commission is discussing how to increase the uptake in THMP registrations; we recommend to revise the THMP Directive rather than the Health Claims Regulation as this would fulfil both objectives - to help SMEs to bring their products to the market and at the same time to uphold the level of consumer protection foreseen in the Health Claims Regulation.*

## **2. Differences between EU Member States**

*If certain Member States in 12 years have no THMP registrations or very few - such as Belgium (21), France (23) and Italy (10) - it becomes evident that the Directive has not met its objective. The lengthy administrative process to obtain a THMP registration next to the BELFRIT liberalization might be a reason for the slow uptake in those countries.*

*In Belgium 83 applications for THMP registrations have been submitted in 12 years and 46 are still under assessment according to the EMA study. In France 171 applications have been obtained and 137 are still under assessment according to EMA. It is evident why the procedure is not attractive for companies in Belgium and France.*

*For these reasons, an extension of the scope of Directive 2004/24/EC has been proposed by the European Commission and is supported by the Herbal Medicinal Products Committee (HMPC) as underlined in the EMA Action Plan for Herbal Medicines 2010-2011.*

*The Commission should now finally revise the THMP Directive as the data published recently by EMA shows that no improvement has been made but rather that the trend to use the THMP procedure is downwards.*

*The revision of the THMP Directive could have various objectives:*

- The Commission should look into the differences in uptake between the EU Member States and the downward trend on THMP registrations in general; tools should be implemented to increase both - harmonization and consumer protection.*
- Although registration fees and the lengthiness of the procedure are not to be regulated by EU law, an impact assessment should be conducted and suggestions shall be made on how to improve the current situation.*
- The Commission should assess if the simplified registration procedure should be opened to other traditional medicinal products of a long standing tradition in the EU; the THMP registration is open for all botanicals compounds and might be used in the future also for those products which are not able to meet the criteria under the Health Claims Regulation; many botanical substances are used in medicine and food supplements and product switches are very common. This would guarantee the highest level of consumer protection, grant predictability for SMEs while at the same time increase the availability of herbal medicines for patients.*
- The Commission puts the THMP registration concept in the centre of the Roadmap on Botanicals. One option should be to adopt the existing THMP Directive to meet the needs of SMEs to place their products on the market. From the consumer perspective this would be an increase of protection as - for example - pharmacovigilance obligations would apply. The revision of the THMP Directive might be the suitable format to address the question how the concept of tradition can be expanded as a proof of efficacy for other herbal (medicinal) products including herbal products currently marketed as food supplements.*

*Finally, the European Commission should bear in mind that the regimes of food and*

*pharmaceuticals must remain clearly distinguished as otherwise SMEs and consumers would lack the clarity about the product status and the applicable laws.*

### **3. Further shortcomings of Directive 2004/24/EC**

*With meanwhile 12 years practical experience in registering herbal products under the framework of Directive 2004/24/ EC, we identified some further shortcomings in the THMP Directive in its current form which should be addressed:*

- Proof of safety and efficacy of herbal combination products should also be possible based on evidence of the mono component products, e.g. described in HMPC monographs.*
- Definition of a “corresponding product” in Article 16c1 (c) should be adopted accordingly.*
- Dosage and posology of traditional herbal medicinal products, including combination products, should be defined based on defined corresponding products 30 years in medicinal use, and on the state of the art scientific assessment laid down e.g. in HMPC monographs published by EMA.*
- In order to promote harmonization, Member States should mutually recognize any Traditional Registration granted under Directive 2004/24 EC by another Member State.*

*The current wording in Directive 2004/24 EC (11) that Member States shall “... take due account of registrations granted by another Member State...” is too much non-binding, and in practice did not lead to real harmonization in the past 12 years.*

## **2. Policy context**

The herbal products referred to in the suggestion can be marketed either as food or as pharmaceutical product depending on the characteristic of the product and the claimed effect. The suggestion therefore refers to two legislative texts dealing on the one hand with **botanicals falling under the food law** and on the other hand with **herbal medicines falling under the pharmaceutical legislation**. A product presented to prevent or treat a disease or a product with a pharmacological, immunological or metabolic action falls under the pharmaceutical legislation.

**Health claims** made on botanicals marketed as **food** are covered by Regulation (EC) No 1924/2006 on nutrition and health claims. This Regulation was adopted in 2006 to govern the use of these claims in the labelling, presentation and advertising of foods. It aimed in particular at enabling consumers to make healthier choices by protecting them from misleading information and ensuring a level playing field for food business operators within the internal market. The scientific assessment of health claims is performed by the European

Food Safety authority (EFSA).

EU legislation on pharmaceutical products for human use also applies in general to traditional herbal medicines. Herbal medicines shall be authorised by the Member States after an in-depth assessment of the quality, safety and efficacy. However in order to overcome difficulties stemming from the test on animals and clinical trials on humans required by the pharmaceutical legislation, a simplified registration procedure was introduced in 2004.

The simplified procedure was introduced by Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC (THMPD) on the Community code relating to medicinal products for human use.

Herbal medicinal products are defined as any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.

The simplified procedure allows the registration of herbal medicinal products without requiring particulars and documents on tests and trials on safety and efficacy, provided that there is sufficient evidence of the medicinal use of the product throughout a period of at least 30 years, including at least 15 years in the Union. This latter requirement ensures that the simplified registration is applicable to herbal medicinal products with a Union tradition. Such scientific evidence is needed to demonstrate the efficacy of the product to treat or prevent the disease and to ensure a high level of patient's safety.

With regard to the manufacturing of these products and their quality, applications for registration of traditional herbal medicinal products have to fulfil the same requirements as applications for a marketing authorisation.

Directive 2004/24/EC had to be implemented by October 2005. However, a long transitional period of 7 years was granted to register traditional herbal medicinal products that were already on the market on the date of entry into force of that Directive. The transitional period ended on 30 April 2011.

### **Current state of play**

#### **Health claims on herbal food products**

In the context of the implementation of the Regulation on health claims more than 500 claims on plants and their preparations (botanicals) received an unfavourable assessment from EFSA in the context of their scientific assessments and this raised many concerns among Member States and many stakeholders regarding health claims made on plants and their preparations

used in food. To date the remaining over 1500 submissions concerning such health claims have not yet undergone the scientific evaluation by EFSA.

The Regulation provides that all health claims, including those on plants and their preparations used in food, should be assessed on the basis of scientific evidence at '*the highest possible standard*'. In this context, EFSA considers human studies as essential for the substantiation of claims. Hence, EFSA considered that evidence collected on the basis of experience gained over time with the actual consumption of the plants and preparations ('*traditional use*') alone cannot be considered sufficient to allow for the scientific substantiation of a health claim made on foods.

Under the current EU rules, it is possible for a Member State on a case-by-case basis to classify a product as food or as medicine depending on its presentation and claimed effect. Therefore it is possible that differences exist between Member States in the classification of products. In other words, as EU law stands, it is possible that the same product is classified as a food in one Member State and as a medicinal product in another.

Pending further action to regulate health claims on plants and their preparations, health claims made on such substances and which were submitted in the context of the establishment of the list of permitted health claims may still be used pursuant to the transitional periods foreseen in Article 28(5) of the Regulation which requires that health claims comply with the Regulation and with the existing national provisions applicable to them. It is therefore difficult to understand the claim that "the botanical food and herbal medicines market has been unduly prevented from decent business by European law", as far as claims on botanical food supplements are concerned. On the contrary claims on botanical food supplements benefit from a longer transition period compared with other health claims.

In August 2014, three complaints, by three companies, were brought before the General Court asking the Court to declare that the Commission had unlawfully failed to initiate the assessment of health claims on botanical substances by European Food Safety Authority (EFSA) (court cases: T-619/14 Bionorica SE v European Commission and T-620/14 Diapharm GmbH & Co. KG v European Commission) and for annulment of the decision not to initiate the assessment of health claims on botanical substances by EFSA (court case T-578/14 VSM Geneesmiddelen BV v European Commission). In September 2015, the General Court dismissed the three actions for failure to act and for annulment as inadmissible. The three companies appealed (C-596/15P Bionorica, C-597/15P Diapharm and C-637/15P, VSM Geneesmiddelen). On 25 October 2016, the Court rejected the appeal C-637/15P as being clearly inadmissible and unfounded. The order of the Court on the remaining two appeals is still pending.

It should be noted that the Commission is currently undertaking REFIT evaluation of the Claims Regulation, also addressing the issue raised by this contribution (see question on coherence under 2. Plants and their preparations used in foods in the roadmap). The roadmap for this REFIT evaluation is available at [http://ec.europa.eu/smart-regulation/roadmaps/docs/2015\\_sante\\_595\\_evaluation\\_health\\_claims\\_en.pdf](http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_595_evaluation_health_claims_en.pdf).

Further information can be accessed at the following link: [http://ec.europa.eu/food/safety/labelling\\_nutrition/claims/refit\\_en](http://ec.europa.eu/food/safety/labelling_nutrition/claims/refit_en).

### *Simplified authorisation procedure for traditional herbal medicinal products*

In September 2008, the report on the experience with the registration of the traditional herbal medicinal products required by Article 16 of Directive 2001/83/EC was finalised. At the time of the report limited experience had been gained with only 110 applications for registrations submitted to the National Competent Authorities and finalisation of 23 applications. Since December 2015, almost 2629 applications for registration have been received and more than 1577 traditional use registrations granted.

## **3. Opinion of the REFIT Platform**

### **3.1 Considerations of the REFIT Platform Stakeholder group**

Regulation (EC) No 1924/2006 on Nutrition and Health Claims, which applies notably to botanical food supplements, is currently under evaluation. Among other aspects, this evaluation will examine the extent to which the requirements set out in Regulation (EC) 1924/2006 are coherent with EU legislation applicable to plants and their preparations, including the part of the legislation on medicines for human use dealing with THMPs. It concerns notably the type of evidence required to substantiate botanical claims as opposed to the evidence needed to prove efficacy based on “traditional use”.

As a reminder, none of the botanical claims already appraised by EFSA in 2010 against the current high-level standards of Regulation (EC) 1924/2006 received a positive verdict. Against this background and given the uncertain outcome of the REFIT evaluation, some operators might be tempted to secure a way-out for their combined herbal products and the claims made thereon under the THMP Directive, hence the requested amendments.

Therefore some members of the Stakeholder group strongly recommend **not proceeding with any hasty revision of the THMP Directive before the outcome of the REFIT evaluation of Regulation (EC) 1924/2006 is made public**. Indeed the latter is expected to allow for informed and coherent decisions to be made, if and as appropriate, with respect to botanical food supplements and THMPs.

BEUC has long called for botanical claims to be assessed against the same high standards as all other claims made on food. Economic considerations regarding botanicals business operators justify neither undermining consumer safety nor exposing consumers to spurious claims. It is vital to guarantee that consumers can trust claims they find on products and that they do not spend their money on products bearing false promises. There seems to be no justification for a different treatment of botanical claims.

Granting an extra special treatment to combined herbal products would mean another step away from meaningful consumer protection against exaggerated and unsubstantiated claims.

The Stakeholder group takes this opportunity to share with BEUC's position on the Roadmap for the REFIT evaluation of Regulation (EC) 1924/2006 published by the European Commission at the end of 2015: [http://ec.europa.eu/food/safety/docs/labelling\\_nutrition-claims\\_refit\\_beuc.pdf](http://ec.europa.eu/food/safety/docs/labelling_nutrition-claims_refit_beuc.pdf)

**Considerations of some members of the Stakeholder group on the position expressed by the Member States in favour of introducing amendments to the THMP Directive:**

The proposed amendments to the Traditional Herbal Medicines Directive 2004/24/EC should not be taken further by the REFIT Platform as it seems possible that they would undermine the policy objective on consumer safety. It has not been made clear how the proposed amendments would ensure a higher level of patient safety, helping the industry and promoting new and safe innovative traditional herbal combination products.

Some considers that the proposed amendments to the Traditional Herbal Medicines Directive 2004/24/EC would **undermine consumers' safety and protection** and should not be taken further in the REFIT process.

Herbal constituents are likely to interact among themselves just as well as they can interact with conventional medicines - for instance, people on anticoagulants should not take *Angelica sinensis* (Dong Quai) and women taking oral contraception should avoid *Hypericum perforatum* (St. John's wort) -, potentially causing serious side-effects. The fact that herbal constituents are safe when used separately does not guarantee the safety of these constituents when used in combination. Therefore the proposed amendments to the rules for the simplified registration procedure for THMPs are in our view not suitable to guarantee consumer safety. The information provided should refer to the combination as such as foreseen in the existing Article 16 c of Directive 2004/24/EC.

The Stakeholder group notes that the products which are subject referred to by these Member States are often 'borderline' products, the status of which (herbal food supplement vs. THMP) is not clear-cut and can vary according to the Member State where these products are

marketed.

### **3.2 Considerations of the REFIT Platform Government group**

One of the main aims of Directive 2004/24/EC (amending as regards traditional herbal medicinal products Directive 2001/83/EC) is to provide a special, simplified registration procedure for certain traditional medicinal products having regard to the particular characteristics of these medicinal products especially their tradition.

The latter is expected to allow for informed and coherent decisions to be made with respect to botanical food supplements and THMPs.

#### **Individual contributions from Member States:**

##### **Member States in favour of introducing amendments to the THMP Directive**

One Member State considers that a significant number of combination products, despite the long tradition of each of its herbal constituents, do not fulfil the requirements regarding the combination as such. This means that new combinations which bear the necessary guarantees of quality and safety cannot get marketing authorisation as a traditional herbal medicine.

In the last years this strict criterion resulted in a reduced number of applications for the simplified registration procedure of traditional herbal medicines both EU-wide and in Member States. Reports on the uptake of the traditional use registration (hereafter: TUR) scheme in the EU Member States are published by the European Medicines Agency (hereafter: EMA) on a regular basis. According to the recent survey (status 31st December 2015, EMA/HMPC/322570 Rev.6) the number of granted TURs for monocomponent and combination traditional herbal medicinal products (hereafter: THMP) in EU Member States (between the entry into force of Directive 2004/24/EC and 31<sup>st</sup> December 2015) was in total 1577: of which 983 for monocomponent products and 594 for combination products (no TURs granted for DK, IS, LI, LU and MT). Between the entry into force of the Directive and 2015 even in the UK, where the highest number of MAs were granted for THMPs (140 for combinations out of a total 344 MAs), the average amount of MAs for THMP combinations was 12 per year (in 2014, 2 combinations, in 2015, 5 combinations and in 2016 no combinations were authorized).

The vast majority of authorised herbal products consist of 2-4 herbal components, but these statistics do not accurately reflect the practice of any long-standing herbal tradition since formulae in the Western tradition commonly contain 5-10 herbs and those used by Indian

Ayurveda and traditional Chinese medicine (TCM) often contain 12 herbs or more (up to 80 herbs, 40-50 ingredients). The report of the EMA shows that some products with more than 20 components obtained marketing authorization in recent years. Therefore it can be assumed that in these cases the well-established use (WEU) has been proved just for the constituents of the combination product and not for the combination as such.

It is a well-known and accepted fact that, in most cases, during the use of herbs several herbal extracts are used at the same time. This belongs to the essence of phytotherapy. Plant materials have mild effects when using more of them at the same time. That is to say, the effects are the same but the probability of efficiency grows.

This is why that Member State suggests that, for the purpose of granting marketing authorization as traditional herbal medicinal products, the documented traditional use of the individual components be recognized provided that safety and quality is sufficiently demonstrated in relation to the combination itself.

According to the safety concerns of our proposal there might be undesirable interactions between components which can result in adverse effects for the human organism. According to the related literature this concern is not justified. Two detailed studies<sup>1</sup> examined this question and they illustrated that from hundreds of combinations just one showed – not justified – interaction (Hypericum and Valeriana, but the patient got synthetic loperamide and the Hypericum showed interaction with consumed alcohol and caffeine as well).

According to the above mentioned reasoning it can be concluded that, in general, patient safety is properly ensured when assessing the constituents of the combination product, and not the combination as such. Next to it, flagrant cases can be explored by the competent authorities and – as an additional safety requirement – a one-year safety follow up could be prescribed for manufacturers. This follow-up process and documentation could be similar to a Risk Management Plan, in which the manufacturer should previously present the plans for an intensified safety monitoring system and it should prepare a summary exploring the adverse reactions at the end of the monitoring period. Only a conditional MA would be granted to THMPs on the basis of WEU pending evaluation of the summary by the competent authority.

Similar conclusions can be drawn from the number of 'Community herbal monographs' adopted by the Committee on Herbal medicinal Products (HMPC) regarding herbal

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<sup>1</sup> Izzo A. A., Ernst E.: Interactions between Herbal Medicines and Prescribed Drugs. *Drugs* **2001**, 61(15), 2163-2175.

Skalli S., Zaid A., Soulaymani R.: Drug Interactions With Herbal Medicines. *Ther.Drug Monit.* **2007**, 29(6), 679-686.

combinations; in the last 12 years less than 15 monographs were accepted.

Most of the herbal products are authorized as foods, typically they enter the market as food supplements, which must not be labelled, presented or advertised as being able to prevent, treat or cure a disease. However the recommended daily consumption with a warning as to not exceed that dose is signed on the label but the risks of the product are not detailed as in case of medicinal products. This consideration also raises patient-safety related questions. In 2015 in a Member State 350 products were notified as food supplements consisting exclusively of herbal constituents; this data compared with an EU-average 10 MAs for THMP per year indicates the serious barriers for the 'simplified' procedure. By the proper amendment of the Directive more of these 'borderline' products could be marketed as medicines and this way the related general manufacturing practices (GMP) and pharmacovigilance rules could better ensure patient safety.

**Another Member State** supports the proposal to consider a review of the Traditional Herbal Medicinal Product Directive to allow marketing authorization as traditional herbal medicine for new combinations bearing the necessary guarantees of quality and safety. That MS is of the opinion that it would help to retain herbal products in the framework of medicinal products which would enhance public health safety. The majority of herbal products are used by consumers for treatment and prevention of diseases so they are much more eligible to the definition of medicinal products than to the definition of food/food supplements. Being medicinal products they need to comply with strict standards of quality and safety which need to be proven in the registration procedure. National competent authorities for medicinal products in collaboration with the Committee on Herbal Medicinal Products (HMPC) have enough expertise to evaluate quality, safety and plausible efficacy of new combinations to guarantee that such combinations would be safe for consumers, bearing all necessary warnings, precautions and other information for proper and safe use. Such change/amendment in the legislation would enable more herbal medicines to be brought on the market, consumers to have more choices of safe healing products of high quality and would facilitate herbal medicines business operators' development within the single EU market.

#### **Member States against reviewing the Directive**

**Member State 1** understands that the THMP categories have shortcomings and the number of THMP applications is decreasing along Europe, but does not agree to proposed changes in the law concerning THMP.

The Directive 2004/24 concerns only herbal medicinal products which were used traditionally as such for a required period of time and those meeting criteria for traditional herbal medicinal products. The concept of tradition concerns the medicinal product as such (not on substances like well-established use concept). New combinations of substances are regulated

by the Directive 2001/83, Article 10b. In this case the appropriate documentation is required.

MS1 generally does not agree for further proposed changes in a definition of corresponding product in art. 16c 1 (c) of the Directive 2001/83/EC, nor does it agree with the view that "Member States should mutually recognise any traditional registration" without any assessment.

MS1 agrees that traditional registration system may be opened to the other traditional medicinal products or botanicals. However MS1 cannot see the possibility of discussing the issue without changes in food supplement and botanicals definition.

Moreover, the fact that herbal constituents are safe when used separately does not guarantee the safety in the case of the combined use of the products. Herbal medicinal products are medicines as well as other category of medicines, with legal requirements of appropriate quality, safety and efficacy based on long term traditional medical use. MS1 considers unjustified a priori assumption that all interactions between herbal preparations are unimportant to health or negligible. It is in conflict with art. 10b of the Directive 2001/83.

The proposal of new provision to exclude the area of THMP from the pharmaceutical law and to allow developing the activity of EFSA on food supplements can see the crucial legal defect in the definition of "food supplements" in Directive 2002/46, Art. 1 (a) allowing every physiological effects in food supplements, without restrictions. In MS1's view the first task of REFIT will be to change the imperfect definition of the "food supplements" eliminating from the scope of the physiological activities every toxic effects and pharmacological effects and listing of the acceptable physiological nutritional effects.

**Member State 2** does not see the same need to examine this Directive 2004/24/EC at least under the REFIT forum. MS2 also shares the comments provided by the Stakeholder group views regarding consumer protection.

MS2 objects to the proposed amendments to the Directive 2004/24/EC as undermining the consumer's safety and protection. It is important, for consumer safety reasons, to maintain the clear distinction between the treatment of medicines and food.

**Member State 3** strongly agrees with the comment of other Member States on revising the definition of food supplements in Directive 2002/46 in order to exclude or narrow the physiological effects allowed in food supplements and emphasize their nutritional effects. In MS3's view, this will allow for a further development of Directive 2004/24 and minimise the ambiguities with the classification of food supplements and herbal.

**Member State 4** expresses concerns in relation to registration of the new combination of herbal medicinal products (without requiring particulars and documents on tests and trials on

safety and efficacy), and considers that this aspect should be further explored.

**Member State 5** considers that the distinction between traditional herbal medicinal products and foodstuffs containing plants is well reflected in this draft opinion in order to ensure consumer safety. In particular, there is a need to fight against the confusion between medicines and food supplements.

In addition, the safety criteria for each of these products must remain high. In case of doubt as to the nature of a product (traditional herbal medicine or foodstuff), the legislation stipulates that the definition of medicinal product shall prevail.

**Member State 6** supports the approach that no action on amending the Traditional Herbal Medicinal Products Directive should be made before the outcome of the REFIT evaluation of the Nutrition and Health Claims Regulation is made public.

**Member State 7** believes it is important, for consumer safety reasons, to maintain the distinction between the treatment of medicines and food.

**Member State 8** cannot agree with the proposal of revision of the Traditional Herbal Medicinal Product Directive, because the safety and plausibility of efficacy of a combination product have to be supported by the long-standing use of the combination itself. Additionally, the fact that herbal constituents are safe when used separately does not guarantee the safety of their use in a combination product.

Before any revision of the THMP Directive is taken further, the Commission should investigate the reasons of the differences in the uptake of the THMP between Member States which have been shown in submission XI.6.b. Additionally, any revision of the Directive should aim to facilitate THMP registrations and to achieve harmonization without undermining patient's safety. Finally, MS8 agrees that the regimes of food and pharmaceuticals must remain clearly distinguished.

MS8 considers that is important to maintain the clear distinction between medicines and foods. Therefore, it is necessary to establish a harmonized list of plants and their preparations to be used as food supplements under Directive 2002/46. This way, safety and quality issues of botanicals used in food supplements would be covered. Furthermore, Regulation (EC) N ° 1924/2006 should rule efficacy of botanicals used in foods. Thus, this EU harmonized regulatory framework in relation to safety, quality and efficacy of food consisting on plants and their preparations, will allow giving legal certainty to FBO and national control authorities and security and trust to consumers.

**Member State 9** does not support the proposed revision of the THMPD. THMP Directive is not part of the food legislation and, in any case, the proposal would allow supplements to be classified as traditional herbal medicines. In our opinion, instead, regulation of supplements should fall within the scope of food legislation (reg. n. 1924/2006), that could be modified to

regulate also this kind of products (the discussion is now ongoing).

**Member State 10** is of the opinion that any recommendation on the need to amend the Traditional Herbal Medicines Directive 2004/24/EC should only be made after the outcome of the REFIT evaluation of the Nutrition and Health claims Regulation 1924/2006 is made public. Furthermore, Member State 10 finds it important that no actions should be taken that could undermine consumer's safety and protection. In that context, Member State 10 would like to underline that, the fact that herbal constituents are safe when used separately does not guarantee the safety if the combined use of the products.

**Member State 11** considers that a review of the Traditional Herbal Medicinal Products Directive can only be made after the publication of the outcome of the REFIT evaluation of Regulation (EC) No 1924/2006.

**Member State 12** agrees with the opinion of the Stakeholder group that the amendments to the Traditional Herbal Medicines Directive 2004/24/EC should not undermine the policy objectives on consumer safety and that it has not been made clear how the proposed amendments would ensure a higher level of patient safety, helping the industry and promoting new and safe innovative traditional herbal combination products. MS12 agrees with the Stakeholder group recommendation not to proceed with any hasty revision of the Directive before the outcome of the REFIT evaluation of Regulation (EC) 1924/2006 is made public.