EUROCAM

Ensuring the availability of CAM medicinal products

Building on recommendations of the Matrix Insight report, highlighting the need for additional measures

This document reflects the position of EUROCAM, the alliance of European umbrella organisations of patients, physicians and practitioners in the field of Complementary and Alternative Medicine (CAM).

The following European umbrella organisations work together in EUROCAM:
Association for Natural Medicine in Europe – ANME
European Ayurveda Association – EUAA
European Ayurveda Medical Association – EURAMA
European Central Council of Homeopaths – ECCH
European Committee for Homeopathy – ECH
European Council of Doctors for Plurality in Medicine – ECPM
European Federation of Homeopathic Patients' Associations – EFHPA
European Federation of Osteopaths – EFO
European Federation of Patients' Organisations for Anthroposophic Medicine – EFPAM
European Herbal & Traditional Medicine Practitioners Association – EHTPA
European Traditional Chinese Medicine Associations – ETCMA
International Council of Medical Acupuncture and Related Techniques – ICMART
International Federation of Anthroposophic Medical Associations – IVAA

The objective of EUROCAM is to promote and facilitate CAM's role in maintaining citizens' health, highlight the health promotion and illness prevention aspects of CAM for EU public health policy and programmes, to advance the accessibility, affordability and availability of CAM, and generally promote CAM at European level.

Brussels, July 2015

EUROCAM

Rue du Trône 194

1050 Brussels

Belgium

T: +32 2 644 00 20

E: info@cam-europe.eu

TABLE OF CONTENTS

1. Introduction

In several EU Member States the availability of CAM (Complementary and Alternative Medicine) herbal, homeopathic, and anthroposophic medicinal products is unnecessarily restricted. The lack of availability of these products inhibits increasing demand by EU citizens for low risk, health enhancing CAM medicines, hampering the ability of doctors and practitioners to provide effective CAM treatments. It also undermines the potential benefit of these products in helping to tackle specific health issues prioritised by the Commission e.g. combating anti-microbial resistance, managing chronic conditions and sustaining healthy ageing.
The Matrix Insight report[1], an external study commissioned by DG Health and Food Safety for the Pharmaceutical Committee, was published on the Committee's website in November 2014. The report acknowledges problems affecting the availability of CAM medicinal products and further work is 'expected to inform policy options for the Commission to consider in order to address the issue of unavailability.'

From the point of view of EUROCAM the Matrix Insight report identifies three key features:

- In spite of the growing importance of the CAM health sector for European citizens and its potential economic benefits to the EU, the European pharmaceutical market is blighted by shortcomings and inconsistencies. The Matrix Insight report presents a general survey that highlights the problems of this market.

- In commissioning such a report, the Commission demonstrated its concern about the way this sector is functioning, revealing its awareness of possible irregularities in the availability of medicinal products.

- Despite its brevity, the report convincingly highlights particular difficulties herbal, homeopathic and anthroposophic medicinal products currently meet with in accessing the European pharmaceutical market so that these products are restricted in various ways for patients and the public. These problems are not new and have been identified repeatedly by the stakeholders concerned. Now confirmation of these problems by an independent research-group provides an impartial and noteworthy overview that cannot be ignored.

EUROCAM welcomes the Matrix Insight report's findings that confirm the experience of health professionals and patients in the CAM sector that there are availability problems for CAM medicinal products and that there is a need for further action in this area. Such action the report says 'should focus on ensuring that the process of authorisation of herbal, homeopathic and anthroposophic medicinal products is more consistent, both with the text of the existing provisions and between Member States.'

Paradoxically the Matrix report also states that 'the availability of such products in all Member States is not particularly problematic'; this is a conclusion with which EUROCAM does not agree. Unfortunately the Matrix report did not identify the community of patients, doctors and practitioners in the CAM sector as stakeholders and therefore did not scope their requirements. In the light of this, this EUROCAM document describes the needs of patients and health professionals seeking to make use of CAM medicinal products specifically suggesting measures that can improve the availability and use of CAM medicines.

[1] http://ec.europa.eu/health/files/committee/73meeting/73plus/study_report.pdf

2. Herbal medicinal products

In 2004 the European parliament adopted Directive 2004/24/EC which introduced a new category of medicinal product, that of Traditional Herbal Medicinal Products (THMP). At the time this was hailed as a landmark decision for CAM products, ensuring their availability throughout Europe. *The Matrix Report highlights the fact that despite a common regulatory framework for THMPs) as laid down in Directive 2004/24/EC, the approach of the Member States (MS) is both heterogeneous and scattered.*

This remains the case more than 10 years after the Directive 2004/24/EC came into force. Surprisingly few THMPs are registered in the EU with only a few hundred THMPs registered in all the MS. This is a totally inadequate outcome for more than 10 years work under Directive 2004/24/EC. The MS with the most THMP–registrations are Poland, United Kingdom, Germany and Austria. The majority of MS have only registered up to 10 THMPs; some have registered only one while some have not registered any THMP products at all (Fig.1, see below).

In view of this it is fair to say that *Directive 2004/24/* has failed in its intention to make herbal medicinal products available to EU citizens across the European Union and to provide herbal products for the use of CAM health professionals for the benefit of their patients.

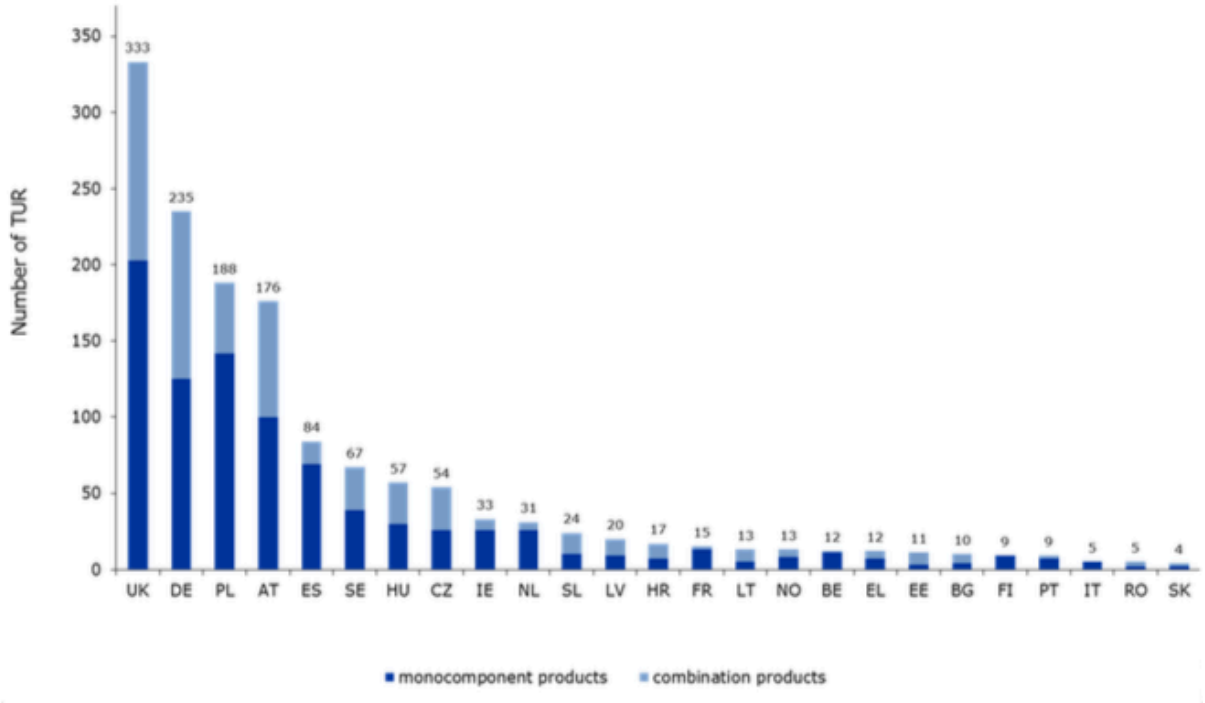

Fig.1: Number of granted THMP-registrations during the period 2004 – 2014. Total registrations numbered 1,438 (889 for mono-component products, 549 multi-component products).[2] This means that only 1438 registrations have been recorded after 10 years and only about 5 MS have actually made any serious use of the THMP-registration scheme. In the majority of the MS only an insignificant number of herbal medicines are available as THMPs.

[2] Uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States. Status: 31 December 2014. EMA/HMPC/322570/2011 (13 May 2015)

Suggested options for the European policy makers, to address these shortcomings:

Strengthening the role of HMPC

The Herbal Medicinal Product Committee (HMPC) at the European Medicines Agency (EMA) was established with inception of Directive 2004/24/EC. It seeks to unify the different MS standpoints. The HMPC prepares monographs and guidelines for registration. Despite the best efforts of the HMPC, the MS have so far failed to apply these guidelines in a coherent manner. As a result THMPs registered in one MS face difficulties when an application is filed in another MS using the same data. Despite the fact that the same HMPC guidelines apply, the national competent authorities too often interpret them in completely different ways.

Such heterogeneous approaches undermine the intention of Directive 2004/14/EC, which states that MS should take 'due account' of positive decisions taken by another MS. Currently positive decisions on registering a herbal product taken by one MS are more often than not ignored by other MS for no apparent reason. In order to achieve a harmonised market, the recognition by all MS of positive decisions taken with regard to a THMP by a single MS should be the rule rather than the exception.

Support is needed from DG SANTE and the European Parliament to enable the HMPC to:

a) strengthen its status and coordinating power with respect to the MS. As the HMPC has to work on the basis of majority voting, MS with a poor record of THMP-registrations often inhibit the implementation of Directive 2004/24/EC across the EU;
b) guide MS to adopt a consistent application of the THMP scheme;
c) clarify the 'due account' rule as given in Directive 2004/14/EC;
d) extend and interpret the scope of traditional herbal registrations to enable a much more flexible TUR registration scheme.

Mutual recognition Procedure

For more than a year there has been an agreement that THMPs can enter a Mutual Recognition Procedure (MRP) on a voluntary basis. Here again the HMPC guidelines should facilitate mutual recognition. In fact, the MRP procedure results in controversy and thus this route of THMPs registration is difficult. This demonstrates the lack of European integration in this matter, as the MRP is one of the cornerstones of the European cooperation in the pharmaceutical field.

Support is needed from DG SANTE and the European Parliament to monitor MRP progress, identify obstacles and encourage the MRP procedure.

Broadening interpretation of indications

The current interpretation of possible therapeutic indications permitted by the HMPC is limited. Directive 2004/24/EC states that THMPs 'have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment.'

Support is needed from DG SANTE and the European Parliament to encourage the HMPC to broaden the indications for THMPs: the scope of indications for THMP should be

extended to say 'after being diagnosed by a physician or health practitioner.' Such wording is already in use in some MS.

Support needed from DG SANTE and the European Parliament to clarify the borderline between food and medicine.

The potential of the THMP registration scheme can only be achieved if the therapeutic scope and differences as well as the borderline between herbal products marketed as food supplements and herbal medicines is clarified.

Health professionals and patients require medicines to treat illnesses and health problems. The lack of availability of THMPs hinders European citizens who wish to make choices about their treatment options. Some MS have chosen a different route to the market: they classify herbal products as Food Supplements (FS), which are regulated by the European Food Safety Authority (EFSA). By definition FS are intended to improve health and contribute to the normal function of the body. In the light of this definition FS cannot replace medicines.

France, Belgium and Italy currently favour the classification of herbal products as FS. Consequently MS following this approach do not register any THMPs. The European Commission has failed to clarify this situation. As a consequence EFSA and the HPMC lack a coherent strategy to give clear and definite guidance to MS.

Support is needed from DG SANTE and the European Parliament to assist the Commission to extend the scope of Directive 2004/14/EC.

To further strengthen the position and availability of CAM medicines in Europe an initiative is necessary to broaden the scope of Directive 2004/14/EC. The Commission clearly recognised the shortcomings already in 2008.[3] It reported:

> 'Medical traditions such as those mentioned above (i.e. traditional Chinese medicine, Ayurveda etc.) are based on a holistic approach, and the set of requirements for the simplified registration procedure under Directive 2004/24/EC is not appropriate for a global regulation of such medical practices. The regulation of such traditions would demand a different approach from that introduced by Directive 2004/24/EC. Therefore, the Commission does not envisage extending the scope of the simplified registration procedure to cover traditional medical systems as such. Nevertheless, independently of this report, the suitability of a separate legal framework for products of certain traditions should be assessed.'

3. Homeopathic medicinal products

The two principal bodies of prescribers of homeopathic medicinal products (HMPs) in Europe, the European Central Council of Homeopaths (ECCH) representing practitioners and the European Committee for Homeopathy (ECH) representing homeopathic doctors and the European Federation of Homeopathic Patients' Associations (EFHPA) representing patients and users of HMPs welcome the commissioning of the Matrix

[3] Communication from the Commission to the Council and the European Parliament concerning the Report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal products. 2008. (Document on the basis of Article 16i of Directive 2001/83/EC).

Report by the European Commission. Furthermore we endorse the findings of the report with regard to HMPs. Their conclusions confirm our own understanding of the current situation with regard to the threats to continuing full availability of HMPs in Europe.

Use and availability

HMPs are widely used across Europe by citizens and homeopathic medicine is widely practised across Europe by thousands of medical doctors and practitioners. Past surveys have indicated that some 25% of the European population use homeopathy and HMPs as an important and integral part of their health maintenance and treatment. It is therefore of considerable concern that the threats to availability of HMPs outlined in the Matrix report should exist.

In 2010 ECCH and ECH jointly published their own report on the availability of HMPs based on surveys carried out across Europe with our own national member associations. That report concluded: **'Revision of laws, new regulations and the increasing registration requirements on a European and national level have already resulted in a drastic reduction in the availability of the variety of homeopathic medicinal products in some countries.'**

In 2013 ECCH carried out an online survey with its membership on the availability of HMPs to which associations in 17 countries responded. The survey revealed wide variability between countries as to the availability of HMPs to members of the public and wide variability in availability of HMPS for practitioners needing them to prescribe for their patients, particularly with regard to the range of single medicines as well as in the range of potencies available. Many users and prescribers already have to source the HMPs they require across EU borders or outside the EU.

These findings also confirm the results of a Price Waterhouse Cooper study commissioned by the HAMP manufacturers group European Coalition on Homeopathic and Anthroposophic Medicinal Products (ECHAMP) in 2012 which similarly found wide variability in availability of HAMPs between MS.

The Matrix Report Case Study 6: homeopathic medicinal products

The Matrix report features a specific study into herbal, homeopathic and anthroposophic MPs. Although the € 1.05 billion market for HMPs constitutes less than one per cent of the EU pharmaceutical market, the report states 'sales of such products remain significant and warrant an exploration of the availability issues associated with these product groups.' It points out that despite the common EU regulatory basis for HMPs through Articles 14 and 16.2 of Directive 2001/83/EC, the different national medical traditions and difference in national approaches have led to their 'ineffective or inconsistent application.'

Homeopathic prescribers and users are particularly concerned about the diminishing availability of all single HMPs that are regulated under Article 14. Given the criteria for simplified registration which includes a baseline dilution of 1:10,000 set down by Article 14 as a guarantee of safety as well as the fact that therapeutic indications are not required, it is difficult to understand why availability of such products in all EU MS is not a straightforward affair involving minimal costs.

Specific points of concern

A. The **centralised registration scheme** does not work for HMPs. It is hard to get agreement on homeopathic products across the EU with regard to each country agreeing on a registration status. **Mutual recognition works** between some countries agencies but not between others. These positive examples can be studied and successful models applied across the sector.Similarly with **national rules schemes,** we recommend that agencies cooperate across MS border to avoid duplication of paperwork. For example, it does not make sense that the UK's MHRA and Ireland's HPRA require completely separate new applications for national rules products. Divergent implementation, interpretation and enforcement policy in MS make it difficult for companies to operate across Europe. **A homeopathic product beyond the 1:10,000 dilution that meets EU criteria for good GMP and is registered in one MS should easy to register in other Member States.**

B. The Regulatory environment is not appropriate or proportionate to the large range of stocks and multiple finished medicinal products required for use in homeopathy. Not only are there some established 3000+ source materials for HMPs but each source material can be developed into a number of potentised products and complex products. While many of the single HMPs are used frequently many others are used infrequently but because of the personalised nature of homeopathic treatment, when a lesser-used HMP is required by a patient its availability is crucial. This means manufacturers need to keep a full range of HMPs in stock. Unfortunately due to the constraints of inappropriate and disproportionate regulatory requirements and costs imposed by some medicines agencies in a number of countries the required range is no longer available throughout Europe. This has lead to patients and prescribers increasingly having to source HMPs across EU borders or from outside the EU.

We consider that

- **For Article 14 products it should be possible to limit the administrative burden and costs required to a level that is proportionate to their simple status and safety profile so that manufacturers can maintain the full range of HMP source materials in stock.**
- **Article 16.2, regarding homeopathic products not covered by Article 14, should be implemented in all MS, also taking into account the traditional use of these products analogous to recognition of traditional use as with Traditional Herbal Medicinal Products. A more harmonised regulatory approach to Article 16.2 products should be made and an assessment policy be established to facilitate their supply across the EU.**

C. Strengthening and supporting the role of the Heads of Medicines Agencies Homeopathic Medicinal Products Working Group (HMPWG) Despite HMPs being included in the Directive 2001/83/EC, EU legislators at the time chose not to establish a separate committee for HMPs under the aegis of the EMA as they did for herbal medicinal products. For this reason we the Commission to support the work of the HMPWG, which although under-resourced, is carrying out the work an EMA committee would have done had it been established.

One of the major causes of varied availability of homeopathic products between MS

identified by the Matrix Report is a lack of understanding of homeopathic pharmacy by national medicines agency officials, many of whom approach HMPs with only a conventional pharmaceutical background. The HMPWG is in the process of producing a set of commonly agreed guidance documents on all aspects of HMPs such as 'first safe dilution', in order to provide guidance on the assessment of HMPs and to facilitate the resolution of procedural, regulatory, and scientific issues arising from variation procedures pertaining to homeopathic medicinal products. **We urge DG SANTE to support and strengthen the work of the HMPWG in order to smooth and improve the full availability of HMPs across Europe.**

4. Anthroposophic medicinal products

The Federation of Anthroposophic Medical Associations IVAA notes that the Commission has no intention of making use the findings of the Matrix Insight report to reform the Community Code for medicinal products for human use. Nevertheless the IVAA wishes to emphasise that the report demonstrates the pressing need to tackle the unsatisfactory legal situation of Anthroposophic Medicinal Products (AMPs). Moreover, consulting the professional as well as the patient organizations of Anthroposophic Medicine might have provided the authors of the report with further data for a thorough assessment of the particular problems of the availability of AMPs.

Despite the fact that the Matrix Insight report did not focus on AMPs, the report assessed the market problems of AMPs in a general review of these products with HMPs, (referred to as HAMPs) pointing out that HAMPS are 'another type of product where there are potential problems of availability.'

In discussing the availability problems of the HAMPs and assessing the 'problem drivers' responsible for it (especially in the Case Study 6, page 105), the report presents and underlines following data:

- As far as the markets of HAMPs are concerned, the report considers HAMPs important, stating that the 'sales of such products remain significant and warrant an exploration of the problems of availability.' HAMPs are regarded as an indispensable part of the European pharmaceutical market and problems inhibiting their availability have to be resolved for a better functioning market.
- The report notes a number of remarks of the report centre about the current legal regulation for HAMPs (above all Directive 2001/83) and its provisions for the marketing authorization of HAMPs and the application of these provisions at European and national level. Here, the findings of the report are explicit: 'The lack of a coherent legal framework across the EU that would allow for products to be authorized is … seen as an important driver of availability problems'. And: 'purely regulatory problems drivers can mainly be linked to unavailability of…HAMPs. '
- The report also expands on the problem of the functioning of Art 16.2, Directive 2001/83. The report highlights the 'inconsistent application of Art 16.2 of the Directive' and concludes in regard to the simplified registration that its 'incomplete and ineffective implementation in Member States seems to result in relatively few products becoming registered as medicinal products', or, in other words: 'as a result in only a selection of

Member States where it *(Art 16.2.)* has been adopted have products been registered through this procedure'.

- The Matrix report also concludes that there are no clear and consistent EU registration procedures for HAMPs not covered by Art 14 (1) DR 2001/83.
- As far as the legal situation and marketing regulations in the MS of AMPs are concerned, the Matrix Insight report clearly states that the direct availability of AMPs is generally worse than in the case of HMPs.
- The general conclusion of the Matrix Insight report is that 'the current European pharmaceutical acquis could be reviewed to enhance availability of medicinal products.' In particular, it concludes that 'the implementation of existing EU provisions concerning these products (*HAMPs*) could be further improved.' This clearly highlights deficiencies in the European pharmaceutical market.

Taking this special concern of the Matrix Insight report about the lack of a coherent legal framework as the driver of availability problems in the HAMPs sector into account and looking at the availability of AMPs for patients and practitioners in Europe, the particular availability of these products are inhibited by the following factors:

- For nearly one hundred years in Europe AMPs have been utilised mainly by doctors (and only in a few MS by some non-medical practitioners) and are used in 22 European countries at present. But this 'well-established' use is not reflected in the legal recognition and codification of AM and AMPs at the national level in Europe.
- Only Germany and Switzerland provide a full legal recognition of Anthroposophic Medicine (AM) and safeguard the legal availability of AMPs (in Germany as Besondere Therapierichtung, System Sozialgesetzbuch V; in Switzerland as part of CAM under constitutional law).
- In Denmark, Finland, Sweden, Italy and the UK, AMPs are mentioned to varying degrees in national pharmaceutical regulations in connection with simplified registration procedures for homeopathic medicinal products.
- In Sweden the Anthroposophic Vidarkliniken has a special, time-limited permit from the Minister of Social Affairs to prescribe AMPs, but doctors are only allowed to practice AM within or in connection with the Vidarkliniken, making Sweden the only EU member state where professional law restricts physicians to use AM outside of one specific designated clinic.
- In Italy HAMPs are subject to a time extension before the transposition of European law rule. Italian Drug Agency (AIFA) and AM stakeholders have started a negotiation process for the availability of a limited number AMPs on the Italian pharmaceutical market.
- The majority of the EU member states in their pharmaceutical legislation neither mention AMPs directly nor in connection with the registration procedures for homeopathic medicinal products.
- The step-by-step development of the Community Code relating to medicinal products for human use is still characterized by a lack of adequate provisions for AMP. EU legislation provides neither a clear regulation of AMPs nor the necessary legal guidance for the competent national authorities. The Directive 2001/83 does not address AMPs in its stipulations in an appropriate way, mentioning AMPs only in the Whereas Nr 22 and regard it as sufficient to relegate AMPs into the legal provisions for HMPs.
- This lack of stipulations does not provide a "coherent legal framework" for AMPs, neither for the application of the existing registration-instruments like Simplified Registration,

Traditional Use and Well Established Use of the Directive 2001/83 in the process of marketing authorization of AMPs by competent authorities, nor does it justice, very generally, to the AMPs as a system in connecting these medicinal products only with HMPs. It should be noted that some AMPs are seen as a sub-division of HMPs, when manufacturing procedures of AMPs are similar to HMPs, but that has not brought about a registration pathway for all AMPs.

- The particular formulation of Art 16.2, Directive 2001/83, offering the national registration procedure some space for specific national rules, have stimulated the argument that CAM medicinal products and especially HAMPs rest within the competence of the MS and not with the European legal framework. This interpretation of Directive 2001/83 certainly falls short of the legal reality because it is the Community Code relating to medicinal products for human use which defines the registration process of medicinal process at national level. It hampers considerably a ‚coherent legal framework' for AMPs in the EU.
- Hence, producers, distributers, practitioners and patients have to cope with various and partly prohibitive provisions for the availability of AMPs in European countries. Their availability is fragmented to a surprisingly high degree in the different markets of these countries, which has, again, definite negative repercussions for the application of the AM therapeutic system for patients and practitioners as well as for the AM as an accepted and patient-demanded part of CAM and Integrative Medicine.

The Matrix Insight report offers an unbiased perspective to restart reconsideration of appropriate legal regulations for HMPs and AMPs ('traditional medicinal systems') as the EU Commission already stated on 29 September 2008 in Communication 584 to the Council and EP.

The Commission assumes that the availability of AMPs is not a problem because medicines can be ordered in advance from abroad. This does not fit with the status of AM as integrated health care in the national health systems. The specialists in the AM hospitals and the general practitioners in the national health systems need AMPs for emergency and acute situations for their patients.

IVAA together with the other AM stakeholder offers the EU Commission and other decision-making institutions at the European and national level their full cooperation to find and realize a better legal and regulatory solution for AMPs within the given current framework to overcome the described deficits in the European pharmaceutical market.

In summary:

• We urge discussions regarding possible solutions for a better legal basis for AMPs in the current Community Code for medicinal products for human use.

• We urge assessment of the political framework via which such a process could be realized without requiring major legal amendments to the present European medicines regulations.

• The IVAA is willing to provide good scientific standards for regulation of AMPs to enable this process.

5. Conclusion

As identified by the Matrix Insight report, non-authorisation of CAM medicinal products is a major driver of non-availability of these products to European citizens in many countries and work is needed to improve the national implementation procedures for them.

Authorisation procedures for medicinal products are a principal area of EU competence and we call upon the Commission and the European Parliament to improve the situation with regards to future access to CAM medicinal products across the EU. This would be an appropriate part of the European Commission's Regulatory Fitness and Performance programme REFIT, the aim of which is to make EU law simpler and to reduce regulatory costs, thus contributing to a clear, stable and predictable regulatory framework supporting growth and jobs. **Measures by the Commission and the European Parliament are now urgently needed to increase the availability of herbal, homeopathic and anthroposophic medicinal products across the EU.**