

## ***Working together to progress EU policies for the benefit of allergic patients in Europe***

**High-Level EU Stakeholders Lunch - EAACI Congress - Vienna**  
Monday 13<sup>th</sup> June, 2016

### **Executive Summary**

The EAACI **High-Level EU Stakeholders Lunch** (June 13<sup>th</sup> 2016, Vienna Congress) brought together representatives from the EU Institutions, patient advocates, allergy national societies, industry, and EAACI leadership to jointly reflect on collaborations to advance EU policies for the benefit of allergic patients.

Keynote addresses included:

- Professor Antonella Muraro (President of EAACI) who reiterated that success in tackling the allergy crisis in Europe requires partnerships between all interested stakeholders and continuous collaborations in EU actions at policy level;
- MEP Sirpa Pietikäinen (Chair of the European Parliament Interest Group on allergy and asthma) who highlighted the need for comprehensive EU-wide programmes on allergy and asthma building on existing national and regional best practices;
- Stefan Schreck (European Commission) who reminded that the Commission sees a clear added-value in having all Member States working together on chronic diseases at EU level, and hence will continue supporting such policy dialogue, where allergy and asthma should naturally be included;
- Professor Sergio Bonini (EMA) who stressed the importance of developing facilitated pathways for marketing authorisations of allergen product and to distinguish between allergen products used for in vivo diagnostics and products for allergen immunotherapy;
- Michele Antonelli (European Biopharmaceutical Entreprises & Stallergenes Greer) who confirmed the industry's support to the development of precision medicine (PM) in allergy.

The moderated discussion was then the occasion for participants to hold fruitful discussions with the contribution of patient representatives from EAACI Patient Organisations Committee (Frans Timmermans) and EFA (Mikaela Odemyr).

The 2016 high-level event was a successful step in the further engagement of the EAACI network in a dialogue to foster partnerships and collaboration between EU policy-making bodies and interested stakeholders to address allergy and asthma as part of the EU health and research policy actions.

## Event Report

On Monday 13<sup>th</sup> June 2016, the President of EAACI, Professor Antonella Muraro convened the second edition of the EAACI High-Level EU Stakeholders Lunch during the EAACI annual congress in Vienna.

The event, *“Working together to progress EU policies for the benefit of allergic patients in Europe”*, brought together representatives from the EU Institutions, patient advocates, allergy national societies, industry, and EAACI leadership for joint reflection on how to further collaborate to advance EU policies for the benefit of allergic patients.

Core objectives of the meeting included:

- Fostering partnerships and collaboration between EU policy-making bodies and interested stakeholders to address allergy and asthma as part of the EU policy actions on chronic diseases
- Raising awareness on the growing prevalence of allergy and asthma in Europe and communicate the existing challenges to EU decision-makers.
- Incentivising greater research and innovation on allergy and asthma at EU level
- Promotion of prevention and healthy living as a cost-efficient approach to tackle the allergy burden

### **‘Working together to progress EU policies for the benefit of allergic patients in Europe’**

*Prof. Antonella Muraro , EAACI President*

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Professor Muraro welcomed all participants to the meeting emphasising the **importance of building partnerships and collaborations between all involved stakeholders** in order to successfully tackle the allergy pandemic in Europe.

The presentation documented the epidemiological, economic and societal burden of the allergy epidemic in Europe which currently affects 150 million EU citizens, with forecast to rise to half the entire EU population by 2025, making **allergy the most common chronic disease in Europe**. Allergy affects patients across the life cycle, starting early and often continuing lifelong, precluding sufferers to realise their full potential. Allergic diseases are largely underdiagnosed and sub-optimally managed which leads to an **economic toll on the EU economies**. The indirect costs of untreated allergy in Europe have been estimated between 55 and 151€ billion by year, and **142€ billion per year could be saved** if patients were diagnosed early and managed appropriately with available cost-effective treatments.

**Key areas where the EU has a role** to play of specific added-value include:

- Putting allergy and asthma at the **forefront of EU chronic diseases action**
- Supporting **pan-European prevention and health promotion programmes** in allergy and asthma
- Facilitating the **identification, collection and dissemination of good practises** in the prevention and management of allergy and asthma in Member States
- **Supporting European research and innovation programmes** to further develop precision medicine in allergy and asthma

- Encouraging a **holistic approach to health policy** inclusive of all relevant policy areas such as environmental, economy, research, education or food regulations.

Starting with the set-up of its **EU representation office in Brussels** in 2013 EAACI has been advocating at EU level for the unmet needs of allergy and asthma patients and healthcare professionals caring for these patients. This has allowed the Academy to build **strategic alliances** with aligned stakeholders (e.g. ECDA, Biomed Alliance) and to **engage with EU policymakers** via the European Parliament Interest Group on Allergy and Asthma, of which EAACI holds the secretariat together with EFA. EAACI's coordinated advocacy actions, in partnership with many allies, has led to the recognition of the Academy as a stakeholder that brings value in the development of EU chronic diseases and health research policy.

As many challenges and unmet needs remain, EAACI is even more convinced that the way forward is in the **power of partnerships**. Professor Muraro closed her introduction by calling on all stakeholders (healthcare professionals, patients, national professional societies academia, regulators, policymakers, industry ) **to continuously work together** to progress EU policies for the benefit of allergic patients in Europe.

#### **'Fighting allergy & asthma in Europe: perspectives from the European Parliament Interest Group on Allergy and Asthma'**

*MEP Sirpa Pietikäinen (EPP, Finland) , Chair of the European Parliament Interest Group on Allergy and Asthma*

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MEP Sirpa Pietikäinen addressed the audience through a video message. She began by highlighting the significant burden posed by allergy and asthma, diseases largely unknown to the public but with significant incidence in Europe. She stressed that the urgent health crisis requires coordinated policy efforts, further noting that this is a reason why the **European Parliament Interest Group on Allergy and Asthma** has been set in the aim to start mapping the needs and establish a roadmap for the future, jointly with the scientific community.

She pointed **at the need for a comprehensive EU-wide allergy and asthma programme**, for dedicating funds to research on the causes of the diseases, for investing in prevention measures and societal policies as well as to set ambitious targets for outdoor and indoor air quality.

She stressed her **belief in the capacity, commitment and determination of EAACI**, expressing her great satisfaction with working with "such an inspiring group as EAACI". She highlighted her will to work with EAACI to further push allergy as a health priority of one of the upcoming **EU Council Presidencies**.

She finally reflected on the opportunities Members of the European Parliament have, as politicians, to leverage actions and advocate at EU level, outlining that **by working together, allergy groups operating as focal points at national level and Members of the European Parliament, we have the capacity to pressure both national governments and the European Commission to implement effective change**.

She concluded by wishing a fruitful seminar to the audience and expressed her willingness to realise the next steps of her professional collaboration with EAACI.

## **'How EU policies on chronic diseases & multi-morbidity can contribute to tackling the allergy and asthma epidemic in Europe'**

*Mr. Stefan Schreck, Head of Unit - Health Programme and Chronic Diseases, DG Santé, European Commission*

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Mr. Schreck began by reminding the audience that EU Member States are responsible for the organization of their health systems, their public health and prevention programs etc. while with regards to health matters the European Commission can only complement MS policies with actions where the European added value can be demonstrated.

When it comes to EU added value, encouraging health in all policies is a top priority for the Commission. This is particularly relevant in the context of allergy and asthma diseases as they relate not only to health policies but also to environmental, food, research policies etc. The Commission aims to work **closely with all relevant policy sectors to efficiently address chronic diseases** in general, and allergy and asthma in particular. Collaborations between DG Santé and DG Environment take account of the link between various health conditions and the exposure of EU citizens to certain environmental agents. A close working relationship also exists with DG Research (RTD) with the overarching goal to help translate research results into effective practices at country level.

Mr. Schreck then explained that while MS are responsible for their national health policies, the EC sees a clear added-value in having all MS working together on **chronic diseases at EU level**, and hence will continue supporting such policy dialogue, where allergy and asthma should naturally be included.

Concurring with MEP Peitikäinen's video message, he emphasised that a key space where the Commission has an essential role to play is by helping **identifying and sharing good practices** in some Member States and to further encourage the spread of those practices across all European countries. Here the EC added-value will evolve towards the successful development of a good system to facilitate the **exchange of knowledge between countries**.

Professor Muraro commented that EAACI in its position of leading European medical society in the field of allergy has established the **EAACI National Societies Committee** that now includes 54 national allergy societies. The Committee is currently compiling a registry of best practices in the prevention, management and care of allergy at country level with the overarching goal to share this knowledge further and encourage implementation across countries.

Mr. Schreck reacted that the EC is looking into establishing a system that will collect all good practices in all diseases areas from all MS. Such a **system** could certainly include a **sub-chapter on allergy and asthma** and the work initiated by EAACI National Societies Committee was seen as highly valuable and awaited for with anticipation.

Finally, Mr. Schreck explained that more work needs to be done to further strengthen and develop the economic argument around preserving the health and well-being of EU citizens and how it **benefits not only patients individually but also European economies** at large. The EC continues to strengthen partnership and collaboration with the OECD in this regard.

## **'Future of allergy treatment and diagnosis: perspectives from the regulators'**

*Prof. Sergio Bonini, European Medicines Agency (EMA)*

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According to Professor Bonini, the **future of allergen products is unclear** and this uncertainty is likely to greatly influence the specialty of allergology and the optimal care of the allergic patients ahead.

Allergen products initially fell under Directive 89/342/EEC reaching market mostly as Named Patient Products (NPP), then Directive 2001/83/EC (amended in 2004) came into use and **Industrially manufactured Allergen products for both diagnostics and therapeutic use should undergo market authorisation**. However, the current reality is that these Directives have been implemented unharmoniously across MS. In some countries NPP legislations exist or are in a transient state, in others they do not.

The EMA has also published the guideline for *Quality of Extracts and for Clinical Development of Allergen Products* to aid manufacturers in gaining market authorization for allergen products, but the **requirements are complex**, the current EU pathway is expensive, slow in getting new therapies to patients, not to mention that the reimbursement procedures between countries also vary greatly and that additional EU regulations such as the EU Pharmacovigilance Regulation (EU)No.1235/2010 also apply and can create additional complexity.

The **challenges in the current regulatory context are many** and concern over 250 allergen medicinal products and over 3000 allergen products that are currently marketed as NPPs but which are not supposed to be NPPs from a regulatory standpoint as they are manufactured industrially.

There is a need to work on **facilitated pathways for MA of allergen products in the future and to distinguish between allergen products used for in vivo diagnostics and products for allergen immunotherapy**. Pharmacovigilance requirements should also be adapted/simplified and a harmonized situation across all MS needs should be sought.

The EMA and the European Commission are aware of the problems and several initiatives are in progress:

- A **Drafting Group has been created within the CMDh** (Coordination Group for Mutual Recognition and Decentralised Procedures - Human) to review the current situations of allergen products in EU MS and possibly find an agreement on harmonisation across EU.
- A **working group of the CHMP** (Committee for Medicinal Products for Human Use) has been assigned the task to identify topics to be addressed in view of revising the EMA guidelines for allergen products also looking at legislative actions if needed.

With both the EC and the EMA on board and aware of the allergen products problem progress is expected to occur in a short timeframe.

## **Future of precision medicine's development in Allergy: Perspectives from the industry**

*Mr. Michele Antonelli, European Biopharmaceutical Enterprises (EBE) - Stallergenes Greer, Executive Vice President, Europe and International*

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Speaking on behalf of EBE Mr. Antonelli started by highlighting the alignment of industry with all invited stakeholders **welcoming the precision medicine agenda in allergy**.

He emphasised the importance of allergy immunotherapy (AIT) as a patient-centric therapy meeting the definition of precision medicine. The pharmaceutical industry continuously strives to place allergy patients at the center of all they undertake by offering high quality products and services based on best evidence, promoting standardised and guidelines-informed clinical approaches and by tailoring treatments to individual needs and spectrum of allergies.

In the current context of precision medicine in allergy, **high-quality products** need to become the standard and demonstrate the following characteristics:

- Include **high quality allergen** raw materials,
- Contain the relevant allergen **activity**, from the naturally occurring sources such as e.g. pollen or cultivated in the laboratory on an optimal culture medium,
- Be **reproducible** from one batch to the other for allergen content and allergenicity
- Be supported by **evidence-based evaluation** of safety and efficacy (incl. well powered double blind placebo-controlled trials with determination of the optimal dose)
- Be registered with **safe and proven clinically effective dose**

The industry welcomes and supports the development of precision medicine in allergy and identifies **gaps where working in partnerships alongside all healthcare professionals, stakeholders and policymakers is of crucial importance**.

These include:

- The recognition of allergy as a **genuine disease with a significant burden**
- The **classification** of allergy in ICD-11
- A better **taxonomy** of patients eligible for AIT for better response and effective AIT solutions
- The need to improve **access to allergy care** in different Member States
- The need to **harmonise the regulatory system for AIT** in Europe
- Better **patient support programmes**.

EBE, through its dedicated working group on AIT, is **fully committed to the realization of precision medicine in allergy** at European level and look forward to working in partnerships with all stakeholders to foster innovation for the benefits of allergic patient in Europe.

## **Moderated Discussion: 'Fighting the Allergy Epidemic - How can we work together to progress EU policies to the benefit of allergic patients?'**

Moderators: Mr. Frans Timmermans - Chair EAACI Patient Organisations Committee; Ms. Mikaela Odemyr- EFA President

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The discussion was moderated by Ms. Mikaela Odemyr, the President of **EFA (European Federation of Allergy and Airways Diseases Patients' Associations)** and by Mr. Frans Timmermans, the Chair of **EAACI Patients Organisations Committee (POC)**.



The EAACI POC is composed of 29 patient organisations from EU countries and beyond, it plays a key role in all work streams of the Academy being part for instance of EAACI task force on AIT and Food Allergy and Anaphylaxis guidelines or collaborating with the EAACI National Societies' Committee. The POC was established in 2011 in recognition of the central role of the patients in promoting and developing **patient-centered healthcare for allergy and asthma**.

Professor Muraro opened the discussion asking Mr. Schreck if **an EU pilot project or a Joint Action** on 'the prevention and management of allergy' under the **EU Health Programme** could be an action of EU added-value that the EC would consider supporting given the size and costs related to allergy and asthma in Europe

Mr. Schreck reacted positively, indicating that under the Health Programme the EC funds Joint Actions on Chronic Diseases and that future actions may look at how to implement **best practices in chronic diseases**. Key will be to focus on best practices that are of **quality**, that can demonstrate **impact** and can make a **real change**.

In a follow-up comment, Professor Muraro told Mr. Schreck that EAACI was pleased of the revitalisation and expansion of the **EU Health Policy Forum** and its newly launched **IT platform** to facilitate exchange of views with the stakeholder community.

She suggested that allergy and asthma should be **discussed at one of the upcoming meeting of the Health Policy Forum**. She further asked whether the EC would support the launch of a **thematic network on 'the prevention and management of allergy and asthma'**?

Mr. Schreck replied encouraging EAACI leadership to meet with Mr. Artur Furtado - the **Deputy Head of Unit C4** - Health Determinants and Inequality, who is in charge of the EU Health Policy Forum and Platform.

Professor Hellings, EAACI Secretary General asked the moderators what should be the **role of patients in the realisation of precision medicine in allergy**, including treatment algorithms, clinical trials design, research priorities, public health programs. Mikaela Odemyr, EFA President, commented that she was delighted to see in this event the joint effort of all stakeholders to work in partnership. Through 20 years of experience being a mother of a child living with severe allergy, she is even more convinced that strong dialogue and **cooperation between all stakeholders group, including patients and carers** is crucial.

Mr. Timmermans then commented that patients have a central role to play as part of the 4Ps of precision medicine in allergy (provider, patient, public health, planning). He further added that patients are very well placed to voice the needs of **specific patients sub-groups** and hence contribute to **stratify and tailored strategy to the needs of each patient**. Healthcare professionals should also be educated to communicate with patients to allow for mutually beneficial partnerships.

Professor Anthony Frew (past President of EAACI) commented the video message of MEP Pietikäinen agreeing that the EU role in health is at supra-national level on questions such as air quality, food labelling, encouraging the dissemination of best practises etc. He also acknowledged that access to medicine and organisation of healthcare services happen at national level and are hence under the mandate of Member States and not of the EU as a whole but he asked Mr. Schreck if **health actions intended to deal with the epidemic at large** (e.g. pan national prevention programs) may be a place where the EU has a role to play.

In his answer Mr. Schreck commented that defining what actions have or do not have EU added-value can somewhat be challenging or theoretical. He then added that the European

Commission can come up with the best proposals for actions but if Member States are not interested in contributing to a joint effort, nothing will ever happen and that hence it is key to be in **dialogue with Member States' national and regional health authorities**. He further commented that in times of Euro-skepticism it is ever more important to explain why some actions coming from EU level may be useful and can be beneficial to citizens. Professor Muraro explained that EAACI fully understands this dynamic and that via its **National Societies Committee is also advocating for the recognition of the unmet needs of allergy at Member State level at the same time it is conducting its EU level work in Brussels**.

### **Conclusions and next steps**

*Prof. Antonella Muraro, EAACI President - Prof. Peter Hellings, EAACI Secretary General*

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Professor Muraro and Hellings concluded that they were pleased to see that the Academy is working with all stakeholders on key questions such as precision medicine, allergen immunotherapy, identification and dissemination of best practises in prevention and management of the diseases. They encouraged this culture change towards stronger communication and collaboration to be sustained and reiterated the strong commitment of the Academy to continue **advocating at European and national levels for the recognition of the unmet needs of the allergic patients as well as to continue lobbying for policy actions to fulfil its mission towards prevention and healthy living**.