



**EAACI**  
EUROPEAN ACADEMY OF ALLERGY  
AND CLINICAL IMMUNOLOGY

# A European Declaration on Immunotherapy

Combating allergy beyond  
symptoms





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Clemens von Pirquet,  
Viennese pediatrician who coined  
the term "allergy" in 1906.

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## Summary

**Allergy today is a public health concern of pandemic proportions**, affecting more than 150 million people in Europe only. Taking into account the epidemiological trends, the **European Academy of Allergy and Clinical Immunology (EAACI)** predicts that in less than 15 years more than half of the European population will suffer from some type of allergy.

Allergic patients do not only suffer from a **debilitating disease**, with a major impact on their quality of life, career progression, personal development and lifestyle choices, but also constitute a **significant burden on health economics** and macroeconomics due to billion days of lost productivity and absenteeism. Given that allergy triggers, including urbanisation, industrialisation, pollution and climate change, are not expected to change, **the only way forward is strengthening and optimising preventive and treatment strategies**.

A hallmark of allergy treatment is **allergen immunotherapy**, currently the only medical intervention that can potentially affect the natural course of the disease. Years of clinical trials, studies, and meta-analyses have convincingly shown that immunotherapy can achieve promising results for patients and the society, **improving** the allergic individuals' quality of life, **reducing** long-term costs and burden of allergies, and **changing** the course of the disease. Allergen immunotherapy does not only effectively alleviate allergy symptoms but has a **long-term effect** after conclusion of the treatment and can **prevent the progression of allergic diseases**.

Nevertheless, immunotherapy has not yet received adequate attention from European Institutions, including research funding bodies, even though this could be a most rewarding field in terms of return, translational value and European integration and a field in which Europe is recognised as a worldwide leader. Evaluation and surveillance of the full cost of allergic diseases is still lacking and impaired by the variety of health systems across Europe. Furthermore, the general population will greatly benefit from increased awareness and use of allergen immunotherapy and its potential.

**We call upon Europe's policy-makers to coordinate actions and improve individual and public health in allergy by:**

- Promoting immunotherapy awareness
- Updating national healthcare policies to support allergen immunotherapy
- Prioritising funding for immunotherapy research
- Monitoring the macroeconomic and health economic parameters of allergy
- Streamlining medical disciplines and specialties

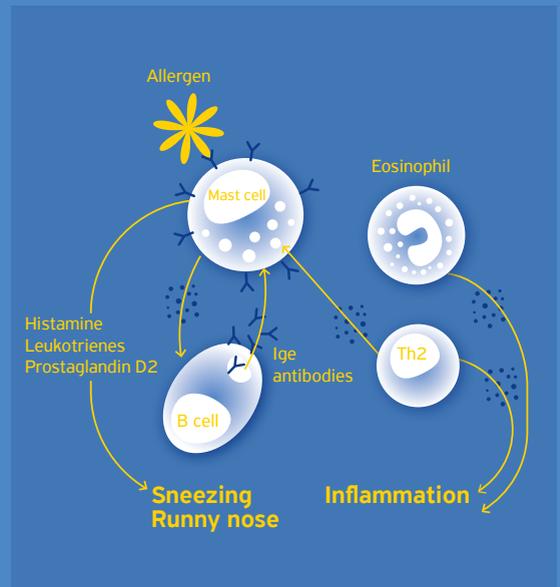
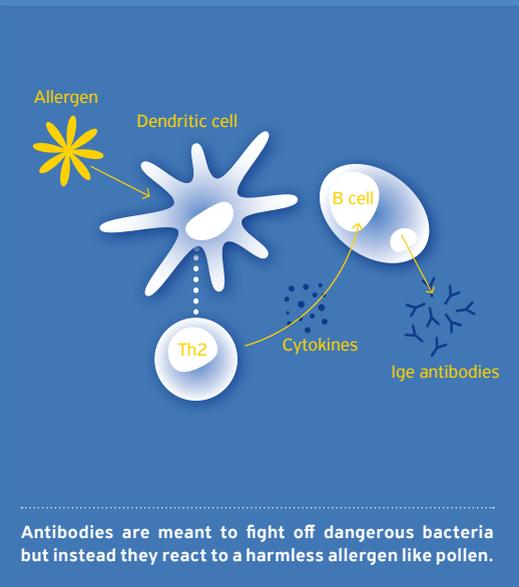
**The effective implementation of the above policies has the potential for a major positive impact on European Health & Well-Being in the next decade.**

### The Mechanisms of Allergy

An 'allergen', e.g. pollen, is wrongly recognised by the immune system, which produces IgE antibody against it (sensitisation phase). IgE sits on top of 'mast cells', that contain many highly active molecules (mediators). When the allergen re-enters the body, it is recognised by the IgE on top of the mast cells, making them 'explode', releasing their mediators and resulting in the symptoms of allergy.

**First exposure:** You build antibodies that will recognise the allergen in the future

**Next exposure:** Your antibodies recognise the allergen and trigger an allergic response.



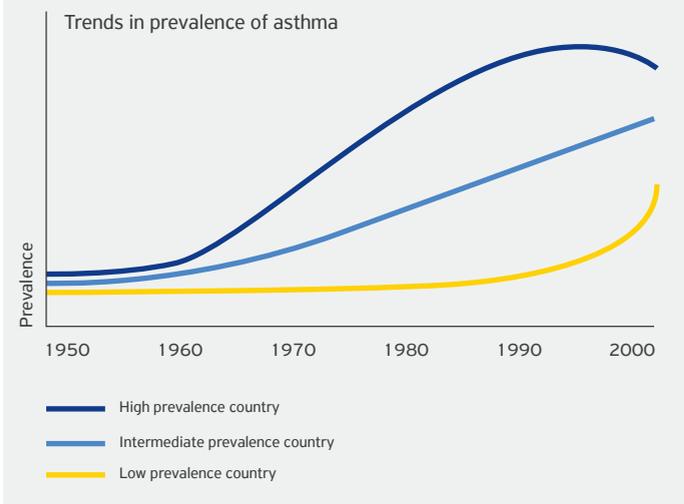
# Allergy Today: A Public Health Threat of Pandemic Proportions

At the beginning of the 20th century, allergy was viewed as a rare disease. Since then, several factors triggered an increase that has gradually become **dramatic** over the last four decades. It is currently estimated that up to **30% of Europeans suffer from allergic rhinitis or conjunctivitis, while up to 20% suffer from asthma and 15% from allergic skin conditions, while for many regions the prevalence is increasing**<sup>1</sup>. The burden peaks at the 20-40 year old age group with clinical symptoms of rhinitis reaching 45%. The worldwide numbers are equally worrying. Almost half a billion people suffer from rhinitis<sup>2,3</sup> and approximately 300 million from asthma<sup>4</sup>. Food allergies are also becoming more frequent and severe. Occupational allergies, drug allergies and allergies to the venom of stinging insects (often fatal) add further complexity and concerns. Finally, new types of allergic diseases and allergies against previously non-allergenic substances are being increasingly reported.

## The History of Allergy

Allergies were rare diseases before the 20th century. In 1906, when vaccination research was at the peak of attention, a pediatrician from Vienna, Clemens von Pirquet, noticed that patients who had received injections of horse serum or smallpox vaccine usually had quicker, more severe reactions to second injections. It was, in the mind of von Pirquet, an altered reaction, an *'allos ergon'*, (from Greek *'άλλος'*: different and *'έργον'*: action), who thus coined the term 'allergy'. Subsequently, the different forms of allergic reactions and diseases started to unravel and terms, such as anaphylaxis (1908), and atopy (1923) came up. Major diagnostic and therapeutic advances came early with the form of the skin tests and immunotherapy (1911). The key antibody of allergic reactions, IgE, was discovered in 1960. The realisation that allergy is a form of inflammation has guided advances in treatment; antihistamines (1930), corticosteroids (1950) and antileukotrienes (1990) are the main drugs still used today. Currently, better understanding of molecular mechanisms of allergy holds promise for revolutionising the field.

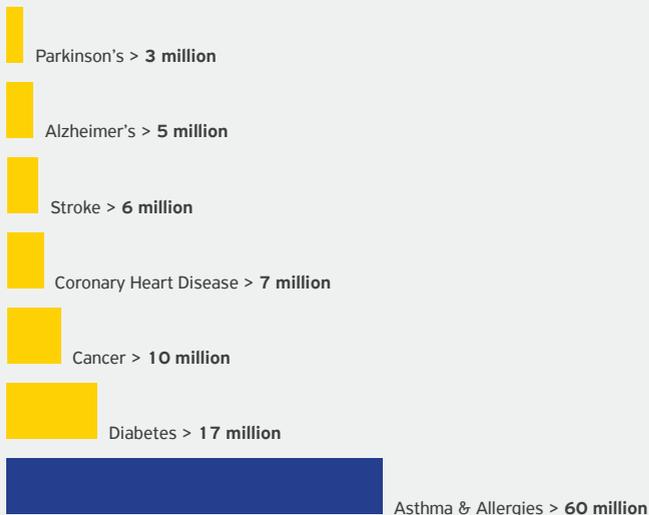
### The rapid increase of allergies during recent times



Source: WHO

A considerable proportion of allergic patients (15%-20%) live with a **severe debilitating disease** and under fear of death from a possible asthma attack or anaphylactic shock<sup>5</sup>. On the other hand, many patients still do not report their symptoms or are not properly diagnosed, indicating that the actual size of the problem is significantly larger. Taking into account the associated upwards trends shown by epidemiological studies, the European Academy of Allergy and Clinical Immunology (EAACI) predicts that **in less than 15 years, more than half of the European population will suffer from some type of allergy.**

### Allergies are the most frequent chronic diseases



## Asthma and allergies strike 1 out of 4 Europeans

### Definition of Allergy

Allergy is an exaggerated response of the human defense system against generally harmless substances.

### Facts about Allergies

- Allergies usually start in childhood and persist for many years, often for life. However, allergies can develop at any age.
- Allergies are the most frequent chronic diseases in children and young adults.
- Patients with one allergic disease have a high risk to develop more allergies.
- In children very often one allergic disease follows another (allergic march). Atopic eczema appears first, affecting more than 10% of babies in Europe.
- Allergies run in families, but most new cases appear in people without a previous family history of allergy.
- Asthma and allergic rhinitis very frequently co-exist in the same person; they are together called respiratory allergy.

The impact of allergies is detrimental both to individual sufferers and society as a whole. Patients face a relentless impairment in their quality of life, their sleep and mood, their competence at work or school and their overall personal development. Society now confronts increasing associated costs of a scale that will soon become impossible to deal with. With a current estimate of more than 150 million patients<sup>6</sup> and a prediction of **more than 250 million patients in Europe** in the next decade, allergies constitute a public health concern of pandemic proportions that **requires immediate action.**

**Impact of allergy and asthma on the European population**

**Question:** Do you have or have you ever had any of the following health problems?

**Option:** An Allergy

**Answers:** Yes

Sweden	34%	Czech Republic	18%	Hungary	14%
The Netherlands	31%	Malta	18%	Latvia	14%
Denmark	27%	Slovakia	18%	Poland	13%
Belgium	24%	Germany	17%	Italy	12%
France	24%	Austria	16%	Bulgaria	8%
Finland	23%	Cyprus	16%	Greece	8%
United Kingdom	23%	Romania	16%	Spain	7%
Estonia	22%	Croatia	15%	Ireland	7%
Luxemburg	21%	Portugal	15%		
Slovenia	19%	Lithuania	15%		

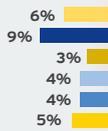


Source: Eurobarometer

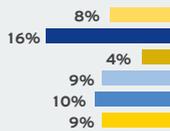
## Impact of asthma on school/work performance

Has asthma got in the way of...?

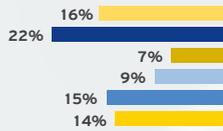
### Success at study



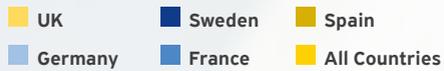
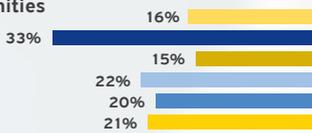
### Promotion at work



### Joining in at school/college



### Job opportunities



# The Impact of Allergy on the Quality of Life of Europeans

Allergic diseases at public health level have a **detrimental impact on the quality of life** of patients, as well as their families. People with allergy are at a **disadvantage** and their **personal development, career progression and lifestyle choices are affected**.

**Children** with allergy demonstrate difficulty in coping at school and develop associated learning difficulties and sleeping problems. As a result, it has been observed that sleepiness and mood swings frequently lead children to be isolated, perform less at school and even get bullied by their peers. Family life and personal relations are subsequently disturbed.

**Young adult patients** also face a significantly higher amount of problems in their work-place due to **increased sick days** and productivity reduction. Cognitive functions are impaired and can be especially detrimental to school, university or work performance. Many people with allergy report problems in their personal relationships<sup>5</sup>. Finally, several studies have shown that allergic individuals have a higher risk of developing **depression**<sup>9</sup>.

Climate change and the rise of global temperature should also be taken into account; one of their expected outcomes is the increase of pollen and aeroallergen levels, leading to a consequent increase in asthma exacerbations<sup>10</sup>.

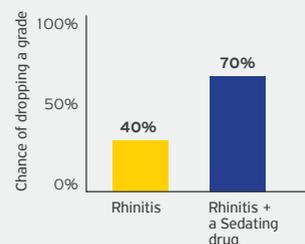
The impact of allergies on the quality of life of sufferers can be as high, or higher, than that of diseases that are perceived as more 'serious' (i.e. diabetes). Lately, physicians and scientists have been utilising a set of specific tools in order to evaluate the different domains of the quality of life of allergic patients. The findings stemming from this make us realise the extent of the issues and underline the urgent need for solutions. By focusing on quality of life as a key domain impacted by allergies and asthma, we will be able to give European patients **renewed access to optimism**. In addition, we should never overlook that a small yet significant proportion of allergic reactions may result in death; people at risk shall certainly be prioritised and protected.

## Quotes from Patients

*... My son has been suffering from allergy and asthma for 17 years now. Asthma is considered as more life threatening, but actually the food allergy is really a nightmare. He has been itching all his life, not sleeping, the family not sleeping either. Can anyone imagine themselves itching all their lives? (Mother of a 17 year old)*

*... Spring is the time when I start sneezing and coughing. I take so much medication that I lose count sometimes. I feel sleepy and tired at school and can't concentrate. I just want to be free of these symptoms. I sometimes feel embarrassed because my nose and my eyes are constantly red. (16 years old)*

**Rhinitis increases by 40% the chance of dropping a grade in summer examinations, while adding a sedating drug may further increase it to 70%<sup>24</sup>.**



## The Impact of Allergy on Health Economics and Macroeconomics

Allergic diseases occupy an increasingly larger share of the patient's daily time. The associated reduction in productivity and the rising number of sick days taken by patients represent one of the biggest negative outputs recorded **impacting national, business and health economies in Europe.**

Allergy incidents and their increase have an adverse effect on the European economy due to both direct costs (e.g. only for asthma: pharmaceutical cost stands at EUR 3.6 billion per year and health care services at EUR 4.3 billion per year)<sup>8</sup> and, perhaps even more, indirect costs. In total, 15% of the population receiving long-term treatment in Europe is due to allergies and asthma, making them the most common reasons for treatment among the young age group<sup>7</sup>. Among the direct medical costs, diagnostic tests, consultations and medication represent the primary components, while a major cost item is **hospitalisation**, usually associated with severe exacerbations of asthma or severe anaphylactic reactions.

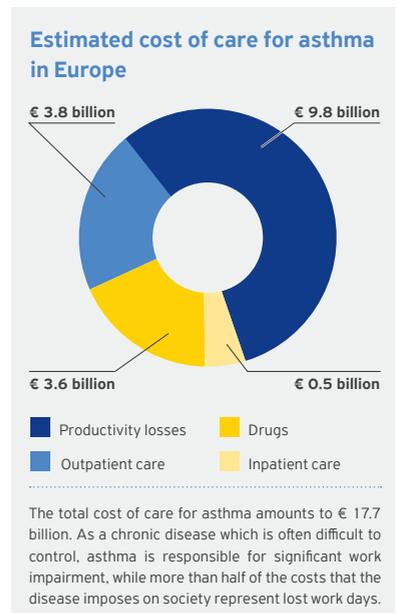
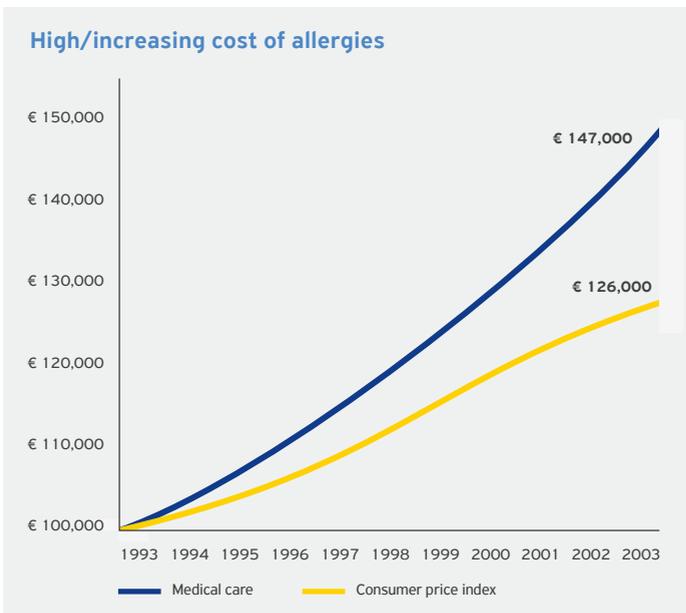
Moreover, performance deficits, loss of productivity and absenteeism are closely linked to allergy suffering and have a major effect on macro-



economics. Asthma and rhinitis are estimated to result in **more than a 100 million lost workdays and missed school days** each year in Europe (not only children absent from school on any given day, but also parents' productivity or absence from work)<sup>11</sup>.

Recently, it became apparent that in addition to absenteeism, hundreds of millions of euros are also lost by **presenteeism**, a condition in which people go to work, but are unable to perform to their capacity. The total cost of asthma alone is estimated at more than EUR 25 billion annually<sup>8</sup>. The cost of rhinitis is probably higher but, unfortunately, large scale socio-economic studies in Europe are lacking. Unpublished GA<sup>2</sup>LEN investigations calculate the current loss due to untreated Allergic Rhinitis-related presenteeism to be approximately a **EUR 100 billion annual cost** to employers. This is based on employment figures from European statistics but does not measure the loss to society due to presenteeism at schools or universities. Understanding and monitoring the costs of allergic diseases should be a priority: Health care systems that are not taking into account the rapid increase in prevalence, increase in severity and cost of allergies are in danger of collapsing from these conditions alone.

**If not properly controlled, the increasing cost of allergies may prove detrimental to public health economics in Europe.**



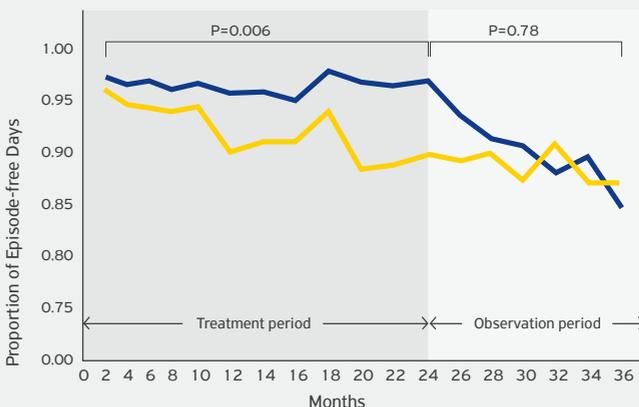
## The Unsustainability of Allergy's Current Symptomatic Treatments

Currently, allergies are treated in most cases by short-term symptom relieving or long-term anti-inflammatory drugs. The introduction of the latter, out of which corticosteroids are prominent, has reduced some of the serious outcomes of the disease. However, **important drawbacks** in regard to pharmacotherapy have also become evident: Firstly, the effectiveness of current medications in controlling allergy symptoms is **suboptimal**. Even under the well-controlled conditions of a clinical trial, and after optimising treatment, a considerable proportion of patients, sometimes even higher than 50%, will continue to have troublesome symptoms. Secondly, and most importantly, even after years of a continuous, effective treatment, **at the moment the daily use of medication stops, symptoms relapse**<sup>12</sup>. Finally, long-term use of drug treatment increases the possibility, but also the fear, of **adverse effects**. This is unacceptable for patients who respond with a characteristic lack of compliance with medical advice and frequently resort to non-proven –often expensive– methods with poor results, that are deepening, rather than solving, the problem.

With increasing costs of newer medications and increasing numbers of patients, this **continuous dependence on drugs is obviously unsustainable**. Both patients and physicians call for more effective symptom control, but also for treatments with long-term effects: **a cure of the disease** is what should be the target for researchers and public health decision-makers in the coming years.

### What do Patients need?

EFA, the European Federation of Allergy and Airways Diseases Patients Associations, has a vision of making Europe a place where people with allergy and asthma would receive the best quality of care and be actively involved in all decisions influencing their lives. People with allergy and asthma have the right to live symptom-free uncompromised lives, in a safe environment.



No long-term effectiveness of drug treatments. When researchers treated children with an inhaled corticosteroid, or placebo, for two continuous years, children receiving the steroid remained relatively without symptoms. However, as soon as the medication stopped, symptoms relapsed and one year later there was no difference from the children that received no medication (from *Guilbert TW et al. N Engl J Med 2006*<sup>12</sup>)

— Inhaled steroid  
— Placebo



# The Promise for a Cure and the Role of Allergen Immunotherapy

Current European lifestyles, including diet, urban living, industrialisation, exposure to pollutants, congregation and several more, are major triggers of symptoms in allergic patients and are not expected to change on a significant scale in the next few years. Therefore, the only way forward is **strengthening and optimising preventive and treatment strategies**. This has been clearly stated at the EU Sustainable Development Strategy; all European citizens should improve their subjective perception of quality of life, mental and physical health and have access to the best preventive measures<sup>13</sup>.

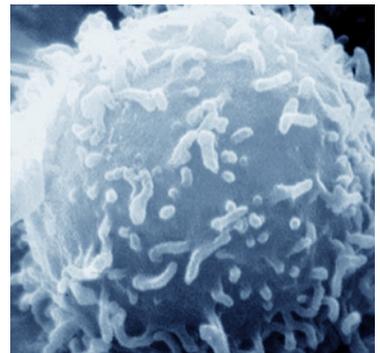
**Allergen immunotherapy is effective** in alleviating allergy symptoms to a similar (or even larger) extent as pharmacological treatments both for asthma and allergic rhinitis<sup>14,15</sup>. Unlike symptomatic medication, **the benefits of immunotherapy continue to be present several years after discontinuation of the treatment**<sup>16</sup>. Moreover, immunotherapy has shown to be able to prevent the progression of allergic diseases, as in the case of hay fever that may frequently lead to asthma<sup>17,18</sup>. Therefore, **immunotherapy is currently the only medical intervention that could potentially shift the global allergic diseases increase trajectory**.

Allergen Immunotherapy is a medical treatment used for almost a century<sup>19</sup>, offered mostly to the more severe or difficult patients, in whom use of medications is unsatisfactory, either because of lack of efficacy or because of unacceptable untoward effects. Currently, therefore, it is used only as a second-line treatment<sup>2,20</sup>.

Major technological advances in the quality and formulation of extracts used, new and more patient-friendly delivery systems and a deeper understanding of the mechanisms of allergic diseases have all led to the expectation of a **major breakthrough** in allergy treatment, in which immunotherapy should play a crucial role.

## What is Immunotherapy

'Allergen-specific immunotherapy' is a medical procedure, in which increasing amounts of a specific allergen are regularly administered to an allergic patient in order for his/her immune system to learn to tolerate it.



## How does Immunotherapy work

Immunotherapy stimulates a subset of lymphocytes, such as the one in the picture, called 'regulatory T-cells'. These cells are capable of leading the immunological balance towards tolerance of a specific allergen.





# What Can Allergen Immunotherapy Achieve

Immunotherapy holds promise for patients as well as society. When used properly, following specific diagnosis, and with good quality, well-characterised and clinically documented extracts it can change the life of allergic individuals.

## For Patients

Immunotherapy is effective in reducing symptoms of allergic rhinitis and/or asthma and improving the quality of life of allergy sufferers. It also results in reduced use of symptom relieving medications. Immunotherapy has long-lasting benefits, even after cessation of the treatment. In patients with allergy to insect venom, immunotherapy is able to prevent life-threatening reactions.

## For Doctors

Allergy specialists benefit from a therapeutic intervention that not only reduces symptoms in their patients, but also gives strong hope that the underlying allergy will be cured and/or stopped in its progression. Especially in children in whom the prospect of one allergy following the other (the allergic march) is ever present, it also offers a way for putting a break to this process, stopping the progression to more serious forms such as asthma.

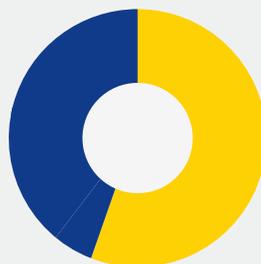
## For Public Health

Immunotherapy is currently the only treatment that offers the possibility of reducing long-term costs and burden of allergies, changing the natural course of the disease. Several pharmaco-economic studies have shown important benefits even from early time points, with steady increase with time. It is conceivable that further research may lead to preventive vaccination for allergies, as it is now the case for infectious diseases.

### Long-term effects of immunotherapy

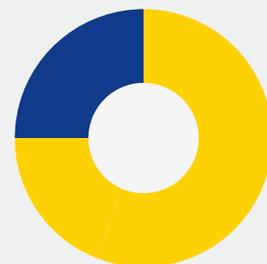
Children receiving immunotherapy for hay fever develop considerably less asthma 10 years later, in comparison with children that do not (control), supporting the effectiveness of immunotherapy in preventing progression of allergies to more severe forms. *Allergy 2007*<sup>21</sup>.

#### Control



■ No asthma ■ Asthma

#### Immunotherapy



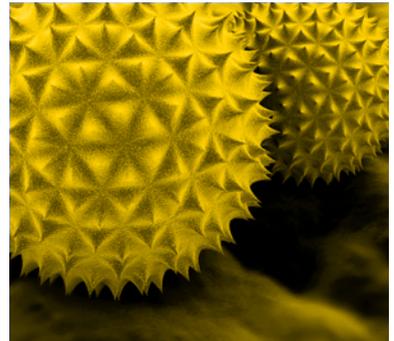
■ No asthma ■ Asthma

## Major Milestones

It has taken immunotherapy some time before reaching its current level of robustness. Several appropriately designed clinical trials have proven the **effectiveness of immunotherapy** in allergic rhinitis, asthma and venom allergy. Such trials have not been easy to design and perform for many reasons: extracts, populations, dosing schedules, disease localisation, and allergen exposure are among the factors that vary considerably and should be taken into account. Nevertheless, different **independent meta-analyses** of randomised blinded studies have consistently confirmed effectiveness. Furthermore, the **long-term effects**, after treatment cessation, have been repeatedly shown. Based on these findings, national and international **guidelines**, often using **Evidence-Based Medicine**, have been established in order to assist practicing physicians in selecting the appropriate patients and preparations and overall optimising treatment.

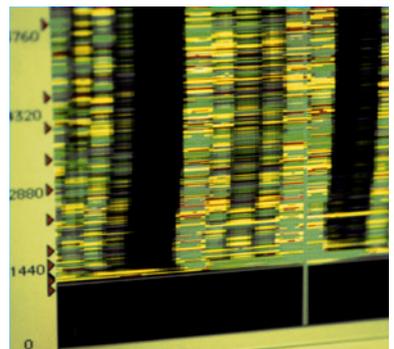
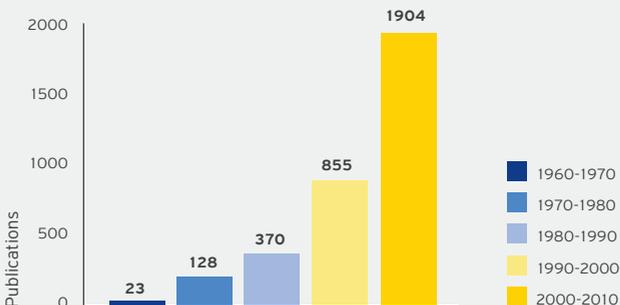
To this end, the continuous improvement of technologies that lead to high quality extracts and formulations have had a major beneficial impact on both safety and efficacy of immunotherapy medications. Moreover, the new delivery routes, such as sublingual immunotherapy, have further added to the armamentarium of allergy specialists, offering more convenient solutions and high safety.

Molecular allergology, the science that describes the detailed structure of the molecules that cause allergies, is expected to take the field to the **next step**, as the components of treatment will be defined to precision in quality and quantity.



Pollen grains under the microscope

### A rapid increase in immunotherapy publications in recent years reflects the development of the field



Molecular tools for allergy diagnosis and treatment

## Major Bottlenecks

Extensive further research is needed in immunotherapy at several levels:

- Even small changes in dose schedules may affect results both in efficacy and safety. The **potential schemes** are numerous and should be examined comprehensively.
- Although we are much closer than ever in understanding the **basic mechanisms** of immunotherapy, there are still open issues that would allow us to manipulate already established immune responses.
- New extract preparation and, even more, molecular components require **validation**. The complexity of component combinations requires novel bioinformatics approaches.

Immunotherapy has not received adequate attention from the European research funding bodies; however, this could be one of the most rewarding fields in terms of **return, translational value** and **European integration**. It is also a field in which Europe is recognised as **a leader worldwide**.

Studies exploring the full cost of allergic rhinitis and asthma are still lacking and impaired by the variety of health systems across Europe. The macro-economic impact of allergies and the long-term cost-effectiveness of immunotherapy need further detailed evaluation and attention.

**Awareness** of immunotherapy and its treatment potential is inadequate in the general population. In some cases immunotherapeutic approaches are mistakenly considered as identical to 'alternative', non-proven treatments.

## Call for Action

**Allergic diseases, including asthma, are the top smouldering risk of global healthcare.** The need to deploy effective treatment solutions such as immunotherapy to stop and potentially reverse allergy's impact on European health, well-being and macroeconomics is more urgent than ever before.

**We call upon Europe's policy-makers to coordinate actions and improve individual and public health in allergy by:**

### Promoting allergen immunotherapy awareness

1

Allergic rhinitis affects 600 million people worldwide, including 200 million with associated asthma. Half of all asthmatic adults and at least two thirds of asthmatic children are allergic. Millions of patients who see little or no improvement with symptomatic drug treatments, or wish to adopt a more curative approach to their illness can benefit from immunotherapy and should therefore be aware of the availability and benefits of such treatment. **Awareness campaigns**, and patient educational programs at pan-European or national levels, should be promoted in order to maximise the effects of the treatment on the population.

### Update national healthcare policies to support allergen immunotherapy

2

Allergic diseases negatively affect individual patients and society via impairment of quality of life, decreased work and school performance, increased absenteeism, and rising healthcare costs. Overall impact and cost are exacerbated by the lack of treatment or under-treatment. By **prioritising immunotherapy in health planning** and by designing healthcare policies that support immunotherapy treatments of allergy through **national health insurance subsidisation**, long-term effects at a national, social and individual level will be reduced. The prevention of allergic diseases can result not only in significant cost reduction, but also in a major improvement of the quality of life of Europeans<sup>25</sup>.

### Prioritise funding for immunotherapy research

3

After 100 years of clinical use of immunotherapy there has been tremendous progress in effectively diagnosing and treating specific allergies. However, in order to achieve optimum results several important details,

including dosing and timing schedules, duration and frequency of treatment, cost-effectiveness in different groups and for different allergens, need to be clarified. Furthermore, recent advances in molecular technology are ready to revolutionise immunotherapy treatments. However, immunotherapy has been rather neglected by European research funding schemes, while the majority of funding derives from the industry, thus focusing only on part of the treatment's full capacity.

3

### Monitor the macroeconomic and health economic parameters of allergy

There is a need for cost-benefit, cost-effectiveness and cost-utility analyses as allergic diseases are increasingly affecting large numbers of people with higher cost implications. This is an important part of the need to monitor allergies in general, taking into account the rapid changes in prevalence and their widespread implications. Treatments like immunotherapy that can combat both the symptoms and the long-term consequences can be more cost effective than routine health care by breaking the vicious circle of living with allergies and coping with prolonged periods of suffering and medical treatment<sup>22,23</sup>.

4

### Streamline medical disciplines and specialties

Health systems around Europe differ widely in regard to the provided services and range of health care professionals who address allergies. Immunotherapy is a highly specialised value-added treatment that can only be delivered by allergy specialists. However, the enormous number of allergic patients requires a wide range of health care professionals to be constantly trained and informed of new evidence as well as being equipped with appropriate tools to adequately respond to the expanding allergy incidents and patients needs.

5

**The effective implementation of the above policies will have a major positive impact in European Health & Well-Being in the next decade.**

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## Participating Organisations

### **EAACI - the European Academy of Allergy and Clinical Immunology**

is an association of clinicians, researchers and allied health professionals, dedicated to improving the health of people affected by allergic diseases. Established in 1956 and currently with over 6,500 individual members and 41 European National Societies, EAACI is the primary source of expertise in Europe for all aspects of allergy.



The **European Federation of Allergy and Airways Diseases Patients Associations (EFA)** is a European network of allergy, asthma and COPD patient organisations that was founded in 1991 in Stockholm, Sweden.

EFA was created to combine the forces of national patient associations on asthma and allergy for results at European level and to improve the health and quality of life of people in Europe with those diseases.



### **GA<sup>2</sup>LEN - the Global Allergy and Asthma European Network of Excellence**

is a consortium of more than 90 leading European partners and research centres specialising in allergic diseases. GA<sup>2</sup>LEN enhances the quality of research, integrates research and communicates the findings with the ultimate goal of reducing the burden of allergy and asthma for Europe's economy and society. Through its activities GA<sup>2</sup>LEN seeks to promote better health care and quality of life for more than 200 million Europeans with allergies.







Celebrating 100 Years of  
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