

# **SUMMIT FOR CHANGE IN ASTHMA MANAGEMENT**

## **The Brussels Declaration**

**MAY 2007  
1<sup>st</sup> EDITION**

**[www.summitforchange.eu](http://www.summitforchange.eu)**



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## **Introduction**

The "Summit for Change in Asthma Management" meeting held in the European Parliament on the 18th and 19th of October 2006 has resulted in a strong and wide-ranging Declaration supported by participating politicians, clinicians, regulatory experts and patient representatives.

We have identified ten points for change that we believe must be addressed to reflect the current understanding of asthma and its impact on the individual and society. We also addressed the management of asthma from a political and policy aspect, as well as the approach needed by clinicians dealing with the everyday patient. The needs and perspectives of the people with asthma, their families and care givers are a central focus within this Declaration.

Liz Lynne and I feel strongly that all groups represented in this summit have a responsibility to contribute to the changes described in the Declaration. We also recognise that a fundamental impetus for change must be reflected in the EMEA Regulatory Guidance Note on asthma. This must go through its normal discussion and development but we urge colleagues to review the current recommendations and submit areas for change that will be needed. On our Summit for Change website we have posted some perspectives of the changes that are required, but we welcome further input and comment.

The ten key points identified in the Declaration will only make a difference if they produce real change in action with all colleagues involved in the care of people with asthma, as well as the organisations that represent their needs.

The Summit is only the start and we look forward to supporting all efforts that achieve the objectives of this Declaration.

Professor Stephen Holgate

Liz Lynne

## **SUMMIT FOR CHANGE IN ASTHMA MANAGEMENT**

### **The Brussels Declaration**

#### **10 Points for Action**

#### **Significant public health issue**

1. All stakeholders must recognise asthma as a serious public health issue and consequently make asthma care a political priority.

#### **Decision support**

2. Policy makers and Professional Bodies, including European Patients' Associations must respond now to the developing understanding of asthma including recognition as a respiratory manifestation of systemic inflammatory processes.
3. The medical community, guided by its Professional Bodies, must ensure that it rapidly responds to the latest scientific understanding of asthma, recognising that asthma presents differently for adults, children and infants and different ethnic groups and management cannot necessarily be extrapolated from one group to the other. Studies and recommendations must recognise this.
4. There should be an immediate update of the EMEA Regulatory Guidance Note on asthma which is essential to ensure that asthma treatment and diagnosis responds to the latest scientific knowledge, clinical and real world experience, and that relevant national organisations, including patient groups and organisations, should be involved in a process for an ongoing and timely update of asthma management guidelines for both adults and children, backed by support for clinicians and patient organisations to help them integrate these guidelines into practice.

#### **New research contribution**

5. Guidelines should continue to use the results of traditional randomised clinical trials where these add to our understanding; however, in addition, they should seek evidence from other studies such as health economic and health outcomes studies that focus on a broader range of end points and patients that reflect 'real-world' patient care and family life including studies that particularly address the child/infant.

6. Funders at national and EU level must consider funding new studies that help to answer questions about the impact of co-morbidities on asthma, how to promote adherence to optimal treatment by both professionals and patients and advance patient-centred care, effective prevention strategies and prevalence studies.

### **Delivery of care**

7. Policy makers, politicians, clinicians and third parties (including those representing patients' perspectives and opinions) must explore variation in asthma care across Europe and distinguish between normal variation due to differences in healthcare systems and cultures, and variation that can be reduced through policies that improve organisation of care and clinical practice and create a more informed and engaged public who are aware of the needs of patients with asthma and allergies.

### **Organisation of care**

8. National policies should incentivise the organisation of care so that people with asthma can actively participate in and make choices about their care. The EU and national agencies must improve their ongoing pharmacovigilance processes and medical utilisations in asthma to ensure that medications are used appropriately and that potential safety issues in terms of medicines and their usage are quickly and clearly identified, communicated and monitored.

### **Prevention**

9. The EU and national governments must liaise with other agencies to understand and reduce the impact of environmental factors on asthma such as smoking, air pollution, hazards in schools, day care, the work place and home, as well as other environmental triggers.

### **Engagement of other agencies – achieving these targets**

10. National policies should set targets for healthcare providers to keep registries, reduce hospitalisations, emergency healthcare use, days off work and days off school experienced by people with asthma and encourage use of tools/instruments to assess asthma control and reasons for poor control where it exists in the individual.

## The Brussels Declaration

Case for Action	European Actions	European National Actions	Third Party Actions
<b>1. All stakeholders must recognise asthma as a serious public health issue and consequently make asthma care a political priority.</b>			
<p>Worldwide incidence of asthma is thought to have doubled in the past ten years with over 180,000 people now estimated to die from asthma annually.<sup>1</sup> The financial burden of asthma in the EU amounts to nearly €17.7bn and productivity lost to poor asthma management is estimated at €9.8bn per annum.<sup>2</sup></p> <p>In light of these facts, it is imperative to acknowledge asthma as a serious threat to public health and make the correct diagnosis and treatment of asthma a political priority. Asthma must be recognised as a public health issue in order to achieve the correct political priority.</p> <p>Whereas the EU has no competence with regards to treatment, there are various programmes and initiatives at EU level (Public Health, Research, Environment, Enterprise, Social Affairs) which need to be assessed in order to promote a horizontally coherent approach to asthma at EU level.</p>	<p>We call on the EU to take actions that recognise asthma as a public health issue</p> <ul style="list-style-type: none"> <li>• A European Parliament Declaration on asthma, based on core elements of the Brussels Declaration</li> <li>• A review of the 2004 Council Recommendation on Paediatric Asthma</li> <li>• A Council Recommendation on Asthma.</li> </ul> <p>European healthcare professional and patient bodies must continually reinforce the need for asthma treatment and diagnosis to be a political priority.</p>	<p>Member States to also recognise asthma as a public health issue by taking active steps to</p> <ul style="list-style-type: none"> <li>• Develop integrated asthma-management programmes</li> <li>• Involve representatives of key stakeholders (healthcare professionals, insurers, patients, academics, pharmacists) with a view to improving national asthma management.</li> </ul> <p>There must also be direct governmental support for primary care uptake of guidelines that</p> <ul style="list-style-type: none"> <li>• Recognise asthma as a respiratory manifestation of systemic inflammatory processes</li> <li>• Recognise that the measurement of asthma should focus on outcomes and not just FEV<sub>1</sub></li> <li>• Ensure medications are utilised appropriately once approved</li> <li>• Ensure implementation.</li> </ul> <p>In the next six months, Member State actions should be separately identified and actioned.</p>	<p>In the next six months, third parties at international and national level to</p> <ul style="list-style-type: none"> <li>• Assist EU and national policy-makers in developing comprehensive public health responses to this asthma threat</li> <li>• List and identify the initiatives which they do have to drive change.</li> </ul> <p>These third parties are participants in the Brussels Summit and are identified elsewhere.</p>

<sup>1</sup> WHO Factsheet Nr. 206 (<http://www.who.int/mediacentre/factsheets/fs206/en/>)

<sup>2</sup> 2003 White Book of the European Respiratory Society (ERS). (<http://dev.ersnet.org/268-white-book.htm>)

Case for Action	European Actions	European National Actions	Third Party Actions
<b>2. Policy makers and Professional Bodies, including European Patients' Associations must respond now to the developing understanding of asthma including recognition as a respiratory manifestation of systemic inflammatory processes.</b>			
<p>Historic models of asthma have focused on both asthma severity and airway reversibility as concepts that have driven drug usage and reimbursement, clinical study requirements, guideline recommendations and primary care practice with patients in everyday life.</p> <p>Asthma must now be recognised as a respiratory manifestation of systemic inflammatory processes as well as a local lung disease which critically has other effects in the body and direct impact on a 'normal life' producing symptoms such as sleep disturbance, work productivity, school attendance, physical activity, etc.</p> <p>New GINA guidelines (November 2006)<sup>3</sup> have demonstrated a complete shift in therapeutic focus to asthma control as being the priority and a classification based predominantly on asthma severity as no longer being useful.</p> <p>It is clear that asthma management in the adult cannot be extrapolated to the child and this recognition must be incorporated into this new understanding of asthma. Furthermore, triggers more specific to paediatric asthma should be taken into consideration, such as viral infections, allergens, exercise, etc.</p>	<p>Relevant individuals and bodies internally review their roles and responsibilities in order to</p> <ul style="list-style-type: none"> <li>• Prepare and take action to change requirements to recognise asthma as a respiratory manifestation of systemic inflammatory processes and to reflect asthma control (rather than severity) as the focus of effective management (aligning with new GINA guidelines)</li> <li>• Produce a review and summary of the changes and reassessment that will be needed</li> <li>• Produce a timeline for implementing the changes to reflect the new medical understanding of asthma</li> <li>• Ensure a clear and separate approach to requirements for the management of asthma in children (both school age and pre-school/infant), including age-specific clinical trials and those which consider paediatric triggers for asthma as well as relevant outcomes.</li> </ul> <p>European professional and patient bodies must continually reinforce the need to review the model/current understanding of asthma in all policy settings.</p>	<p>Following EU review and reassessment, relevant individuals and national bodies internally review their roles and responsibilities in order to</p> <ul style="list-style-type: none"> <li>• Implement action to change requirements to recognise asthma as a respiratory manifestation of systemic inflammatory processes and to reflect asthma control (rather than severity) as the focus of effective management (aligning with new GINA guidelines)</li> <li>• Endorse the EU review and summary of the changes and reassessment that will be needed and evaluate relevance locally</li> <li>• Ensure all reimbursement policies reflect the need for control of asthma and not only relief of airway constriction</li> <li>• Produce a timeline for implementing the changes to reflect the new medical understanding of asthma</li> <li>• Ensure a clear and separate approach to requirements for the management of asthma in children (both school age and pre-school/infant), including age-specific clinical trials and those which consider paediatric triggers for asthma</li> <li>• Recognise that children are not small adults and therefore the evidence base for treatment cannot be extrapolated from adult data</li> <li>• Recognise that treatment for children</li> </ul>	<p>Healthcare journalists and writers specialising in this area to take responsibility to reflect and communicate the changed emphasis in asthma management.</p>

<sup>3</sup> GINA Global Strategy for Asthma Management and Prevention 2006. (<http://www.ginasthma.com/download.asp?intId=217>)

Case for Action	European Actions	European National Actions	Third Party Actions
<p>It is recognised that asthma is significantly worsened (in adults and children) through the presence of unrecognised and untreated co-morbidities such as allergic rhinitis and other allergies, viral infections, etc.</p>		<p>must be documented in children.</p>	

Case for Action	European Actions	European National Actions	Third Party Actions
<p><b>3. The medical community, guided by its Professional Bodies, must ensure that it rapidly responds to the latest scientific understanding of asthma, recognising that asthma presents differently for adults, children and infants and different ethnic groups and management cannot necessarily be extrapolated from one group to the other. Studies and recommendations must recognise this.</b></p>			
<p>All specialists and bodies working for the improvement of asthma diagnosis and management in Europe must take action to ensure all professional and patient understanding of asthma fully and rapidly reflects modern knowledge of adult and paediatric patient needs, including</p> <ul style="list-style-type: none"> <li>• Greater flexibility of choice of medication</li> <li>• The systemic inflammatory processes in the disease</li> <li>• Therapeutic interventions specific for children (by age group) and that take into account child specific issues including childhood triggers, more intermittent pattern of the disease and difficulty of administration</li> <li>• Ongoing pharmacovigilance systems to ensure the optimal and safe use of medications from healthcare providers.</li> </ul>	<p>European professional and patient bodies must continually support best practice in understanding and management of asthma and link with groups such as</p> <ul style="list-style-type: none"> <li>• International primary care groups, paediatric groups and specialist respiratory groups, e.g. IPCRG, ERS, EAACI, GA<sup>2</sup>LEN, ARIA, WHO, GARD</li> <li>• Media</li> <li>• Health writers</li> <li>• National patient groups</li> <li>• National policy bodies</li> <li>• Healthcare reimbursement bodies</li> <li>• Respiratory Nurses.</li> </ul>	<p>National professional and patient bodies must continually support best practice in understanding and management of asthma and link with groups such as</p> <ul style="list-style-type: none"> <li>• National primary care groups, paediatric groups and specialist respiratory groups, e.g. IPCRG, ERS, EAACI, GA<sup>2</sup>LEN, ARIA, WHO, GARD</li> <li>• Media</li> <li>• Health writers</li> <li>• National patient groups</li> <li>• National policy bodies</li> <li>• Healthcare reimbursement and evaluation bodies</li> <li>• Respiratory nurses.</li> </ul>	<p>Ensure national healthcare education groups adapt educational materials to reflect asthma as a respiratory manifestation of systemic inflammation.</p> <p>Pharmaceutical industry and other healthcare suppliers to support the new emphasis on education for people with asthma, including the use of media channels with appropriate national oversight.</p> <p>Patient groups to communicate and educate members (patients) on the new understanding of asthma and the choices available to maximise control, improve quality of life and address issues such as difficulty of administration.</p>

Case for Action	European Actions	European National Actions	Third Party Actions
<p><b>4. There should be an immediate update of the EMEA Regulatory Guidance Note on asthma. This is essential to ensure that asthma treatment and diagnosis responds to the latest scientific knowledge, clinical and real world experience, and that relevant national organisations, including patient groups and organisations, should have a process for an ongoing and timely update of asthma management guidelines for both adults and children, backed by support for clinicians to help them integrate these guidelines into practice.</b></p>			
<p>Clinical and regulatory guidelines have significant influence on the diagnosis, treatment and management of asthma. It is therefore essential that</p> <ul style="list-style-type: none"> <li>Guidelines are regularly reviewed to reflect latest scientific findings from a broad range of evidence, including traditional randomised clinical trials as well as health outcome measures which reflect evidence on the heterogeneous asthma population managed in clinical practice</li> <li>Revisions and updates on guidelines are effectively communicated to relevant stakeholders.</li> </ul> <p>This way, their implementation for the benefit of patients can be ensured.</p> <p>The new GINA guidelines, moving from a historic perspective of asthma severity to one of asthma control, are an excellent example of the current change needed in asthma guidelines.</p> <p>Specific new guidance, however, is required for paediatric asthma, recognising the different nature of the disease, issues specific to the child (e.g. triggers and ease of administration) and the need for specific guidelines for school aged and pre-school / infant children.</p>	<p>EMEA/CHMP to initiate an immediate revision of the current EMEA Guidance Note on asthma, taking into consideration new clinical and health outcomes data, the advice from relevant stakeholders in the field, specifically noting changes to GINA guidelines to enable greater patient choice.</p> <p>Ensure the issue of paediatric asthma is clearly addressed within the Guidance Note and support specific initiatives that aim to address the real absence of paediatric guidelines.</p> <p>Establish a yearly, open review of the Guidance Note, to ensure treatment choices appropriately reflect the latest scientific knowledge, clinical and real-world evidence.</p>	<p>National experts seconded to the EMEA to promote a rapid revision of the Guidance Note.</p> <p>National Medicines Authorities to take account of the provisions set out in the revised EMEA Guidance Note.</p> <p>Work with healthcare professional organisations to specifically address the absence of paediatric guidelines.</p> <p>Member States to ensure that relevant stakeholders (representatives of healthcare professionals, health insurers, patients, pharmacists, etc.) are informed of latest scientific knowledge reflected in updated guidelines. GINA members to assist in this information exchange.</p>	<p>Relevant stakeholders in the field (representatives of patient and professional associations, scientific research centres) to enter in a dialogue with the EMEA's scientific advice groups on the update of the EMEA Guidance Note on asthma.</p> <p>Critically assess existing guidelines against real-life scenarios (including paediatrics) with a view to further improvements.</p> <p>Regularly inform healthcare professionals and patients about recent scientific findings reflected in guidelines.</p>

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<p><b>5. Guidelines should continue to use the results of traditional randomised clinical trials where these add to our understanding; however, in addition, they should seek evidence from other studies both clinical and health economic, that focus on a broader range of end points that reflect ‘realworld’ patient care and family life including studies that particularly address the child/infant. When guidelines are produced and updated, a patient representative should be involved in that process as a basic requirement.</b></p>			
<p>All parties to recognise the need to support health outcomes studies that guide the management of asthma in a majority of patients and not just in small specific groups included in randomised controlled clinical trials. New end points will need to be used to provide a wider insight to achieving control in asthma.</p> <p>Studies should be conducted in rigorous but close to clinical practice conditions reflecting the primary care management of asthma for most patients and the patient populations should reflect the general population with asthma, e.g. different phenotypes, smokers, etc.</p> <p>The simple historical focus on airway reversibility is now recognised as being too limited and does not reflect the impact of asthma in the majority of people in everyday life.</p> <p>Measurement of control requires a multi-factorial view that takes into account more than airway function and also recognises the effect of co-morbidities, such as allergies, and the ability of the patient to properly administer medication. This is especially important when a comparator treatment or device is used in a study.</p>	<p>EU/EC bodies to reflect the new understanding of the need for asthma control and recognition of additional markers and end points to measure clinical control, in line with updated scientific understanding and GINA guidelines.</p> <p>This requires</p> <ul style="list-style-type: none"> <li>• Focus on ethnicity: development of best practice in asthma management within ethnic ecologies</li> <li>• Greater variations of patients in clinical trials (including specific paediatric studies)</li> <li>• New understandings of effectiveness (health outcomes) and efficacy studies</li> <li>• Inclusion of additional end points for the evaluation of efficacy, beyond lung function, which often does not correlate with other clinical control measures</li> <li>• Inclusion of outcomes and observational research data (so called ‘real world’ studies) in the primary care setting.</li> </ul>	<p>National regulatory bodies to reflect the new understanding of the need for asthma control and recognition of additional markers and end points to measure clinical control, in line with updated scientific understanding and GINA guidelines.</p> <p>This requires</p> <ul style="list-style-type: none"> <li>• Greater variations of patients in clinical trials (including paediatric)</li> <li>• New understandings of effectiveness and efficacy studies</li> <li>• Inclusion of additional end points for the evaluation of efficacy beyond lung function, which often does not correlate with other clinical control measures</li> <li>• Inclusion of outcomes and observational research data (so called ‘real world’ studies) in the primary care setting.</li> </ul>	<p>Local guideline committees embrace and support the changed emphasis to focus on asthma as a systemic inflammatory disease and the need to focus on asthma control.</p> <p>National policy and payors to now make choices based on achieving asthma control, rather than the historical perspective, and respond to the new clinical end points.</p>

Case for Action	European Actions	European National Actions	Third Party Actions
<b>6. Funders at national and EU level must consider funding new studies that help to answer questions about the impact of co-morbidities on asthma and how to promote adherence to optimal treatment by both professionals and patients and their parents in the case of childhood asthma.</b>			
<p>All funders to recognise the need to support health outcomes studies that guide the management of asthma in a majority of patients and not just in small specific groups included in randomised controlled clinical trials. Funders to support studies utilising new end points in order to provide a wider insight to co-morbidities and achieving control in asthma.</p> <p>Studies need to be conducted in the primary care setting and the patient populations should reflect the general population with asthma, e.g. different phenotypes, smokers, etc.</p>	<p>European funders to reflect the new understanding of the need for asthma control and recognition of additional markers and end points to measure clinical control, in line with updated scientific understanding and GINA &amp; ARIA guidelines.</p> <p>This requires</p> <ul style="list-style-type: none"> <li>• Focus on studies that evaluate the impact of co-morbidities</li> <li>• Focus on strategies that promote adherence to optimal treatment by both professionals and patients</li> <li>• Develop all studies to reflect the ‘real world’ situation.</li> </ul>	<p>National funders to reflect the new understanding of the need for asthma control and recognition of additional markers and end points to measure clinical control, in line with updated scientific understanding and GINA &amp; ARIA guidelines.</p> <p>This requires</p> <ul style="list-style-type: none"> <li>• Focus on studies that evaluate the impact of co-morbidities</li> <li>• Focus on strategies that promote adherence to optimal treatment by both professionals and patients</li> <li>• Develop all studies to reflect the ‘real world’ situation.</li> </ul>	<p>Professional and patient groups to focus on outcomes and results of studies in order to educate patients and reach wider general public.</p>

Case for Action	European Actions	European National Actions	Third Party Actions
<p><b>7. Policy makers, politicians, clinicians and third parties (including those representing patients' perspectives and opinions) must explore variation in asthma care across Europe and distinguish between normal variation due to differences in healthcare systems and cultures, and variation that can be reduced through policies that improve organisation of care and clinical practice and create a more informed and engaged public who are aware of the needs of patients with asthma and allergies.</b></p>			
<p>Develop a consensus on current best practice in asthma diagnosis and the assessment of control for patients. Recognise the need for greater flexibility and physician/patient choice in asthma management, which allows selection of treatment to be based on patient needs and practical issues.</p> <p>Across countries, there are dramatic variations in asthma care, most of which happens in the primary care setting and there is a dramatic need for the transfer of best practice to produce an equally dramatic improvement in asthma care and ensure appropriate use of medications.</p> <p>The nature of asthma contributes to the broad impact on the life of the individual with asthma and therefore there is also a need for a more holistic approach to management that extends beyond drug therapy.</p>	<p>The Commission should encourage Member States to</p> <ul style="list-style-type: none"> <li>• Adapt best practice solutions in asthma (e.g. the Finnish Asthma Programme) to their own healthcare system</li> <li>• Address the dramatic variations in asthma care across the EU</li> <li>• Establish a network of all relevant stakeholders under the auspices of DG SANCO.</li> </ul> <p>Healthcare bodies to take responsibility for driving best practice in asthma diagnosis and control to other international and national groups.</p>	<p>Member states to</p> <ul style="list-style-type: none"> <li>• Learn from comprehensive public health responses to asthma in other Member States (e.g. the Finnish Asthma Programme)</li> <li>• Foster exchange of best practice in asthma internally in order to tackle existing inequalities in primary care</li> <li>• Communicate the new best practices that recognise the difference of infants and paediatrics.</li> </ul>	<p>Professional and patient groups to</p> <ul style="list-style-type: none"> <li>• Help develop specific criteria for diagnosis</li> <li>• Define best practice in asthma for different groups (e.g. children vs. adults)</li> <li>• Educate key media to understand and support best practice</li> <li>• Emphasise need for a more holistic approach to asthma management that extends beyond drug therapy, particularly vis-à-vis guideline groups such as GINA</li> <li>• Ensure medical school training has responded to new understanding of best practice.</li> </ul>

Case for Action	European Actions	European National Actions	Third Party Actions
<p><b>8. National policies should incentivise the organisation of care so that people with asthma, their families and care givers can actively participate in and make choices about their care. The EU and national agencies must improve their ongoing pharmacovigilance processes and medical utilisations in asthma to ensure that medications are used appropriately and cost-effectively and that potential safety issues are quickly and clearly identified, communicated and monitored.</b></p>			
<p>Healthcare outcomes will not improve unless patients are listened to and participate at an individual and collective level. Breakthroughs in improvement have been achieved when patients are involved in the decisions about their care and are supported in self-management. Services are only positively transformed when they use patients' experience and ideas.</p> <p>In this context, strategies need to be developed that maximise adherence to treatment to encourage people to have more choices in their healthcare to achieve the best possible control of their asthma.</p> <p>Develop criteria to improve pharmacovigilance and appropriate drug utilisation in asthma. This is needed to fully recognise and respond to changing asthma management needs that protect the individual and allow the new approach to asthma, which focuses on 'normal' life.</p> <p>Particular attention must be made to pharmacovigilance and the child as paediatric asthma has different and specific pharmacovigilance requirements.</p>	<p>The European Institutions need to ensure the adequate involvement of patient organisations in the development of relevant policy initiatives.</p> <p>The proposed update to the European legislation on pharmacovigilance should embrace active participation of patients including patient reporting of adverse drug reactions.</p> <p>The European Commission's Pharmaceutical Forum should work towards facilitating the public availability of quality information for patients to enable guided self-management of asthma.</p> <p>The European Commission's Directorate General for Research needs to ensure that EU-funded research on asthma, such as research into air quality under FP7, adequately takes into account the different sub-groups of asthma patients (i.e. those who smoke, those with/without allergic asthma, children with asthma, etc.).</p> <p>EU/EC link with major professional bodies to</p> <ul style="list-style-type: none"> <li>• Develop and validate criteria, which evolve with scientific understanding</li> <li>• Communicate and disseminate criteria to Member States</li> <li>• Assess the effectiveness of criteria, on</li> </ul>	<p>Involve patients from the beginning in developing relevant policy initiatives and guidelines.</p> <p>Encourage healthcare providers to involve patients in service redesign.</p> <p>Support behaviour studies that further understanding of why asthma patients do not adhere to suggested treatment and show how greater choice and empowerment can help patients to identify and adhere to optimal improvement and so enhance their health.</p> <p>Public health guidance should be issued with the aim of raising patient expectations about asthma management (e.g. optimal quality of life) and perception of their own asthma.</p> <p>National Member States to</p> <ul style="list-style-type: none"> <li>• Ensure national pharmacovigilance matches new criteria</li> <li>• Validate nationally.</li> </ul>	<p>Effectively represent patients' perspective and concerns at EU and national levels.</p> <p>Empower patients to self-help (e.g. UK mental health model).</p> <p>Empower patients to have best possible control of their asthma (concordance model).</p> <p>Encourage patients and their families to better adhere to asthma treatment and follow-up.</p> <p>Professional groups to ensure patient groups/representative are involved in guideline development and implementation.</p> <p>Link relevant key stakeholders to specific initiatives, such as the Pharmacovigilance Working Party on Paediatrics.</p>

Case for Action	European Actions	European National Actions	Third Party Actions
	<p>an ongoing basis.</p> <p>Stakeholders to initiate discussions ahead of the adoption of a proposal for a European Commission Strategy on Pharmacovigilance.</p> <p>Stakeholders to provide expertise with regard to the formulation of a new legal proposal for an EU strategy on pharmacovigilance.</p>		

Case for Action	European Actions	European National Actions	Third Party Actions
<b>9. The EU and national governments must liaise with other agencies to understand and reduce the impact of environmental factors on asthma such as smoking, air pollution, hazards in schools, day care, the work place and home, as well as other environmental triggers.</b>			
<p>The environment can be responsible for both sensitising and aggravating the existing condition.</p> <p>For this reason greater emphasis needs to be on tackling environmental factors (e.g. outdoor and indoor air quality, allergens and housing).</p> <p>The issue of smoking must also be addressed as tobacco smoking makes asthma more difficult to control, results in more frequent exacerbations and hospital administrations, produces a more rapid decline in lung function and increases risk of death.</p> <p>There is urgent need to develop comprehensive, innovative strategies for the prevention of allergy and asthma, particularly, as allergies are typically co-morbid with asthma.</p>	<p>EU/EC to</p> <ul style="list-style-type: none"> <li>• Promote research into asthma, allergies as well as indoor and outdoor air quality under FP7</li> <li>• Take action to reduce environmental risk factors for asthma and respiratory allergies as part of the European Environment and Health Action Plan 2004-2010</li> <li>• Take action to reduce environmental risk factors at the workplace and in school</li> <li>• Ban smoking in public and work places EU wide</li> <li>• Agree on outdoor pollution standards according to WHO guidelines<sup>4</sup></li> <li>• Support Europe-wide smoking prevention and cessation activities and clinical studies that consider smokers as a specific patient population, to reduce harmful impact of environmental tobacco smoke.</li> </ul>	<p>Member States to</p> <ul style="list-style-type: none"> <li>• Develop national horizontal strategies for the prevention of allergy and asthma to ensure the issue is adequately reflected in relevant policy initiatives</li> <li>• Support studies that enable a better understanding of the effects of the environment on asthma across different ages</li> <li>• Implement ban on smoking in public and workplaces</li> <li>• Launch programmes to reduce outdoor and indoor air pollution.</li> </ul>	<p>Professional and other primary care and healthcare and wellbeing groups to</p> <ul style="list-style-type: none"> <li>• Develop and disseminate innovative ways of prevention</li> <li>• Develop specific prevention strategies for children and mothers.</li> </ul> <p>Media and other bodies responsible for communicating with the general public to</p> <ul style="list-style-type: none"> <li>• Advise on simple prevention measures</li> <li>• Report on environmental benefits and challenges</li> <li>• Support smoking prevention and cessation initiatives.</li> </ul>

<sup>4</sup> WHO Air Quality Guidelines Global Update 2005. (<http://www.euro.who.int/Document/E87950.pdf>)

Case for Action	European Actions	European National Actions	Third Party Actions
<p><b>10.</b> National policies should set targets for healthcare providers to keep registries, reduce hospitalisations, emergency healthcare use, days off work and days off school experienced by people with asthma and encourage use of tools/instruments to assess asthma control in the individual, i.e. small children, teenagers, adults and parents of children with asthma.</p>			
<p>Change is needed at both European and national levels to ensure that systems and processes monitor and report on the improvements being achieved as a measure of improving asthma control.</p> <p>These systems need to be sensitive to the major areas of impact of asthma on 'normal' living.</p> <p>This additional recording includes major events such hospitalisations and emergency room interventions. Measures now must reflect impact on schooling and factors such as changes in personal and family ability to develop normally.</p> <p>Tools and instruments to measure and guide improvements in asthma management should be encouraged to be used by patients and the care system as a core of ongoing improvement.</p>	<p>EU/EC to</p> <ul style="list-style-type: none"> <li>• Support initiatives that promote pan-European monitoring and measurement of asthma control</li> <li>• Set annual targets for improvements in asthma control across the EU.</li> </ul>	<p>Member states to</p> <ul style="list-style-type: none"> <li>• Support initiatives that promote national monitoring and measurement of asthma control</li> <li>• Set annual targets for national improvements in asthma control.</li> </ul>	<p>Professional groups to play an active role in educating healthcare professionals about asthma control measures and monitoring systems.</p>