

Technology appraisal guidance Published: 27 March 2002

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Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> <u>impact of implementing NICE recommendations</u> wherever possible.

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1 Recommendations

- 1.1 It is recommended that in addition to therapeutic need (including chosen drug and dose), the following factors be taken into account when choosing inhaler devices for individual children with chronic asthma:
 - the ability of the child to develop and maintain an effective technique with the specific device
 - the suitability of a device for the child's and carer's lifestyles, considering factors such as portability and convenience
 - the child's preference for and willingness to use a particular device.
- 1.2 The general recommendations in 1.1 should be taken into account when considering the following specific guidance:
- 1.2.1 A press-and-breathe pressurised metered dose inhaler (pMDI) and suitable spacer device is recommended as the first-line choice for the delivery of inhaled corticosteroids as part of regular planned daily therapy, with the aim of maximising benefits of preventive therapy in attaining good asthma control, and minimising potential systemic absorption. Where clinicians believe that an individual child's adherence to the press-and-breathe pMDI and spacer combination is likely to be so poor as to undermine effective asthma control, other alternative devices (taking account of the factors outlined in 1.1 and evidence of equivalence of clinical effectiveness) should be considered, bearing in mind the need to minimise the risks of systemic absorption of corticosteroids.
- 1.2.2 In the case of other inhaled drugs, primarily bronchodilators, it is recommended that a wider range of devices be considered to take account of their more frequent spontaneous use, the greater need for portability, and the clear feedback that symptom response provides to the device user. In such circumstances the factors outlined in 1.1 are likely to be of greater importance in choosing a device.
- 1.3 Where more than one device satisfies the considerations outlined above in a particular child, it is recommended that the device with the lowest overall cost

(taking into account daily required dose and product price per dose) should be chosen.

- 1.4 On selection of an inhaler device, it is important that consideration is given to other aspects of asthma care that influence the effective delivery of inhaled therapy, including:
 - individual practical training in the use of the specific device
 - monitoring of effective inhaler technique and adherence to therapy
 - regular (i.e. no less than annual) review of inhaler needs, which may change over time with increasing age.

2 Clinical need and practice

- 2.1 Asthma is a chronic inflammatory disease affecting the lower airways, which manifests as reversible airway obstruction and mucosal inflammation, resulting in airway narrowing (bronchoconstriction). Children with asthma experience recurrent symptoms of cough, wheeze and breathlessness, and acute exacerbations/attacks. Symptoms can be caused by a variety of triggers principally infection, allergy, airborne chemicals, passive smoking, and exercise.
- 2.2 Acute episodes may be experienced by children with any level of chronic asthma. While symptoms vary in individual cases, acute episodes may have the following characteristics: mild episodes – cough, audible wheeze, normal speech between breaths, and peak expiratory flow rate and forced expiratory volume above 75% of predicted values; severe episodes – severe distress, cyanosis (bluish lips), reduced ability to speak (often limited to only a few words between breaths), and being chair or bed bound.
- 2.3 Childhood asthma is common studies suggest that the prevalence of diagnosed childhood asthma is between 10% and 23% in England. However, not all cases are diagnosed or treated, and it is estimated that in England and Wales 12% of boys and 10% of girls aged 5–15 years are treated for asthma. These treatment rates are higher than in any other age group and in the overall population (for which the treatment rate is 7%).
- A steady rise in the diagnosis of childhood asthma is reported in England and Wales, with increases from 7% to 13% in girls and from 10% to 17% in boys aged 5–14 years between 1990 and 1998.
- 2.5 Childhood asthma is a rare cause of death. However, the burden of the disease is considerable, in terms of physical and psychological morbidity (i.e. anxiety and stigma), reduced quality of life for children and their carers, and impact on schooling and social activities. Childhood asthma also presents an economic burden on health care resources.
- 2.6 The goals of asthma treatment are primarily the prevention of chronic symptoms, maintenance of near normal lung function and normal activity levels, and

prevention of recurrent acute episodes (which may lead to hospitalisation), in order to maximise quality of life and satisfaction with the care being provided. It is likely that currently many asthma sufferers are achieving sub-optimal control of symptoms because of inadequate or inappropriate use of preventive therapy.

- 2.7 A number of approaches to managing asthma are available, including nonpharmacological strategies (e.g. allergen and air pollutant avoidance), oral pharmacological therapy (e.g. corticosteroids, leukotriene receptor antagonists), and inhaled pharmacological therapy.
- 2.8 Inhaled therapy aims to reverse and prevent airway inflammation and constriction, in order to control acute symptoms and maximise respiratory flow. Where available as a therapeutic option, inhaled, rather than oral, administration is generally preferred, in order to reduce the total dose of drug required to produce a treatment effect, reduce the potential for systemic effects, and allow the drug to act in the lung as quickly as possible.

Two therapeutic approaches are used, often in combination.

- Bronchodilators (β₂-agonists, antimuscarinic bronchodilators) relieve symptoms of bronchoconstriction. Short-acting β₂-agonists deliver rapid relief, with a peak effect within 20 minutes. Long-acting β₂-agonists, which act for at least 12 hours, are used in conjunction with inhaled corticosteroids to treat children with more severe chronic asthma. Most children with chronic asthma are treated with inhaled bronchodilators.
- Anti-inflammatory agents (corticosteroids, cromoglicate and related compounds) act to prevent asthma symptoms. Three corticosteroid compounds are available: budesonide, beclometasone dipropionate, and fluticasone propionate. Sodium cromoglicate and nedocromil sodium are nonsteroidal alternatives. Children with moderate or severe chronic asthma usually require inhaled anti-inflammatory treatment as well as bronchodilators.
- 2.9 A guideline on the management of asthma in adults and children were issued by the British Thoracic Society (BTS) in 1997. These guidelines are the most commonly used in the UK, but are not explicitly evidence-based. They outline a five-step approach to managing asthma in adults and schoolchildren, usually

starting with inhaled short-acting β_2 -agonists, and introducing anti-inflammatory therapy, long-acting β_2 -agonists and antimuscarinic bronchodilators if symptom control is not achieved. General guiding principles are set out regarding the appropriate selection of devices, though specific device recommendations are not made. The guideline is currently being updated in conjunction with the Scottish Intercollegiate Guidelines Network (SIGN).

2.10 The vast majority of chronic asthma care takes place in a primary care setting, often involving practice nurses. The aim is to maximise self-management of the disease. If symptom control is not achieved, drugs, doses, device suitability, inhaler technique and adherence should be reviewed. Doses of inhaled steroids and other drugs should be regularly monitored and slowly stepped down to the minimum dose required to maintain good control of symptoms.

3 The technologies

- 3.1 Three main types of inhaler device are available: 'press-and-breathe' pressurised metered dose inhalers (pMDIs), breath-actuated pressurised metered dose aerosol inhalers, and dry powder inhalers (DPIs). In addition, press-and-breathe pMDIs can be used in conjunction with spacer systems, and pMDIs use either chlorofluorocarbon (CFC) or CFC-free, hydrofluoroalkane (HFA) propellants.
- 3.2 Over 70 individual inhaler products (including different drugs and doses), together with at least five further spacer device attachments, are licensed in the UK for use by children aged 5–15 years. Innovation is continuing and new devices are emerging into the market. The majority of research on asthma therapy concentrates on the effect of drugs rather than that of the delivery device. Consequently there is a shortage of independent and evidence-based information for clinicians and patients choosing devices.

Press-and-breathe pMDIs

- 3.3 Around 60% of childhood asthma inhaler medication is delivered by press-andbreathe pMDIs. These comprise a small plastic construction carrying a metal aerosol canister, often containing 200 doses. Both branded and generic pressand-breathe pMDIs are available. The inhaler is prepared by shaking. Users should remove the mouthpiece cap, breathe out, then take a slow deep breath through the mouth, actuating the device (i.e. pressing the canister) as inhalation begins, and then hold their breath.
- 3.4 Individuals may experience a number of problems with press-and-breathe pMDIs that can affect adherence to therapy and adequacy of delivery of drug to the lungs, and therefore effectiveness. It is estimated that at least 50% of press-andbreathe pMDI users have less than optimal technique. Problems include difficulty in co-ordinating device actuation and inhalation, oropharyngeal deposition of the drug, and, in the case of CFC devices, the 'cold freon effect', when the temperature of the propellant causes some individuals briefly to stop inhaling.

Spacer systems

- 3.5 The use of various spacer systems, which attach directly to the inhaler device, is one approach to alleviating some of the problems associated with pMDI use.
- 3.6 Two general types of spacer are available:
 - Detachable chambers (small, medium or large volume): this type of spacer is attached to a press-and-breathe pMDI when required, and acts as a holding chamber for the aerosol and drug, allowing a number of breaths to be taken. Most spacers of this type incorporate a valve system, and inhalation techniques need to be taught. Five such spacers are currently available on NHS prescription.
 - Small-volume extended mouthpiece spacers: these provide increased distance between the point of aerosol release and the oropharyngeal area. They are available for use with some press-and-breathe and breath-actuated pMDIs.
- 3.7 Many spacers are designed in conjunction with specific press-and-breathe pMDIs. However, some are designed to allow attachment to a wider range of press-and-breathe pMDIs, and in these cases there may be some uncertainty about their performance with different inhalers compared with those spacers designed for use with an individual inhaler.
- 3.8 Detachable plastic spacers are prone to developing an electrostatic charge, which causes adhesion of the drug to their surface, so reducing delivery. Careful washing and air-drying (i.e. leaving to dry) of spacers at appropriate intervals reduces this problem. A metal spacer, which aims to avoid problems with electrostatic charge, has also been developed.
- 3.9 Other shortcomings associated with spacers are portability and inconvenience, and feelings of stigma, which children may experience with their use.

Breath-actuated pMDIs

3.10 Breath-actuated pMDIs also deliver a pressurised aerosol metered dose of drug, but are automatically actuated when the user inhales through the mouthpiece. Automatic actuation removes the difficulty of actuation-inhalation co-ordination that is associated with press-and-breathe pMDIs. However, the sound of some devices and the different sensation of automatic actuation may hamper use in some children. Oropharyngeal deposition can be a problem in breath-actuated pMDIs. Two breath-actuated pMDIs are currently available.

Dry powder inhalers (DPIs)

- 3.11 DPIs deliver the micronised drug, and generally a carrier powder, using the individual's own inspiratory flow. This is another approach to overcoming the problem of actuation–inhalation co-ordination associated with pMDIs. Many newer DPIs also incorporate approaches to counting doses used or the amount of drug remaining, which can be used to aid monitoring of adherence to treatment.
- 3.12 Some children (generally younger ones) may not reliably generate inspiratory flows that are high enough for effective delivery. These problems may present difficulty during acute exacerbations, and a press-and-breathe pMDI and spacer may be required for back-up.
- 3.13 There is greater variation in the design of DPIs than in other device types. A child may find one DPI device easier to use than another, or express a preference because of the appearance of a particular device. Seven DPIs are currently available for children.

Choosing suitable devices

3.14 The benefit gained from inhaled therapy is a unique combination of the drug, device and the individual (i.e. physical, cognitive, psychological and lifestyle characteristics). Consequently the following factors require consideration when choosing a device.

- Inhaler technique Poor technique, resulting either from poor training or from choosing a device poorly suited to the child, can significantly reduce the amount of drug delivered to the lungs and result in poor asthma control. Some children, especially the younger ones in the age range being considered, may have difficulty with actuation–inhalation co-ordination with a press-and-breathe pMDI, while others may have inconsistent inspiratory flow, which causes problems in using a DPI, or find the automatic actuation of some breath-actuated devices off-putting.
- Adherence to treatment Even where good technique is possible, children may not use their devices appropriately. Device use may be influenced by a range of factors, including convenience, ease of device use, portability, the stigma of having asthma, and personal or peer preference for a specific device. The relative importance of these factors changes as children get older and so the choice of device should be reviewed frequently.
- Availability of drugs Some drugs are only available in particular devices.

4 Evidence

4.1 The systematic review included evidence on clinical effectiveness, ease of use, preference, compliance, and cost effectiveness.

Clinical effectiveness

- 4.2 Because of the specificity of device and drug effect, evidence for one drug in one device cannot be generalised to other drugs. Therefore, only research comparing the same drug (e.g. salbutamol vs salbutamol) at an equivalent dose level in different devices was considered. Studies including children aged 5–15 years were included in the review. Since the appraisal concerns device choice, rather than whether to treat using inhaler devices, placebo comparisons were not included. All studies included in the consideration of clinical effectiveness were randomised controlled trials (RCTs).
- 4.3 Evidence in this area is generally limited in quantity and quality. Only one relevant study comparing a breath-actuated device with other devices was found, and few studies considered devices delivering cromoglicates, long-acting B₂-agonists, or drugs in combination. Many of the available studies included fewer than 50 children, and were under-powered. The review found that studies claiming to demonstrate equivalence were often unable to do so, and that some studies used inappropriate dose comparators.
- 4.4 Three in vitro studies of drug delivery were identified, but these do not provide a sufficiently reliable basis for generalisation to device performance in children with asthma in clinical practice.

Delivery of bronchodilators

4.5 Twenty-three studies in the systematic review examined different devices in the delivery of bronchodilators.

Seven studies compared press-and-breathe pMDIs with and without spacers. In the main these included children, and all had fewer than 50 participants. Two of the studies found a significant difference in lung function favouring the pMDI and spacer combination. These were randomised cross-over studies, involving a total of 30 children aged between 5 and 14 years, that compared the delivery of terbutaline from a pMDI with delivery from a pMDI plus 750 ml collapsible spacer.

Thirteen studies compared press-and-breathe pMDIs (with or without spacer) with DPIs, and none demonstrated a statistically significant difference in lung function. Some of the studies used inappropriate dosing schedules, which may have biased their findings. Some studies included a high proportion of adults.

Three studies comparing different DPIs were included. They found no significant difference in lung function or symptoms, and all were small or included few children.

Delivery of anti-inflammatory drugs

4.6 Eight studies examined different devices for the delivery of corticosteroids. One used a filter method to compare a press-and-breathe pMDI in combination with one of two alternative spacers. It found significantly higher deposition of drug on the filters attached to a 250 ml metal spacer compared with a 750 ml plastic spacer. However, the study included only 16 children (aged 5 to 8 years), and found no difference in symptom scores between the two treatment groups.

Five studies compared press-and-breathe pMDIs (with or without spacers) with DPIs. One large well-designed study reported equivalence of a pMDI with spacer and a DPI at half of the drug dose used in the pMDI. However, the authors of a systematic review concluded that this finding did not represent evidence of advantage of the DPI over the press-and-breathe pMDI and large-volume spacer as the device of choice for the delivery of corticosteroids in childhood asthma. In addition, a filter collection study comparing a press-and-breathe pMDI plus spacer with a DPI in children aged 5–15 years reported significantly higher deposition in the DPI group, though no differences in lung function were reported. The remaining studies were of poor quality or were likely to have included few children.

Two adequately powered studies compared different DPIs, though neither reported a difference in effectiveness between devices.

One study compared a press-and-breathe pMDI with a breath-actuated pMDI for cromoglicate. No differences were found in lung function, but the study was under-powered.

CFC-free devices

4.7 The studies included in the review reported no evidence of difference in the effectiveness of devices using CFC-containing or CFC-free propellants in pMDIs. However, it is important to note that there are some reports of higher drug deposition of corticosteroids from HFA devices. Consequently it is possible that required doses may be different when transferring children from CFC to HFA inhalers.

Other influences on effectiveness

- 4.8 Thirty-one studies on ease of use, preference or compliance were included in the systematic review. However their quality was generally poor, and many devices have not been studied. Many of the studies did not involve direct device comparison, had fewer than 100 participants, included adults, or did not examine the actual impact of these factors on disease outcomes. Only 11 of the studies were RCTs.
- 4.9 A number of studies found that good individual (verbal) instruction was the key to correct inhaler technique, and two suggested that above age 5 or 6 years, this was the case regardless of the device. Studies on ease of use, adherence and preference are, however, of questionable value as the empirical value of these factors remains uncertain. Conclusions drawn from this body of research are likely to involve 'double counting', in that the effects of ease of use and preference may also contribute to compliance.

Cost effectiveness

- 4.10 No robust cost-effectiveness or utility studies examining use of inhalers in children aged 5–15 years with asthma were identified by the systematic review.
- 4.11 There are substantial differences in the acquisition costs of inhaler devices within the same drug dose range. For instance, in the delivery of one puff of salbutamol (β_2 -agonist) a day, the lowest annual inhaler costs per device type are: pressand-breathe pMDI, £3.14; breath-actuated pMDI, £10.99; and DPI, £11.53. The highest cost for a DPI delivering salbutamol at this dose is £30.42.

Similarly, in the delivery of a 200ug dose of beclometasone (corticosteroid) a day, the lowest annual inhaler costs per device type are: press-and-breathe pMDI, £28.73; breath-actuated pMDI £28.73; and DPI £38.51. The highest cost for a DPI delivering beclometasone at this dose is £69.06. The annual costs of suitable spacer devices available on NHS prescription range from £4.28 to £8.56.

- 4.12 One study reported that the overall annual average cost of care for people with asthma who have not experienced an asthma attack in the past year was £108, compared with £381 for people who have had at least one attack over the same period. Higher costs in primary care contacts, hospital admissions and visits, and medication all contributed to the overall difference.
- 4.13 An economic analysis considering differences in overall costs between devices found that only small improvements in asthma outcomes were needed for a device to be considered cost-effective compared with the cheapest available alternative for the delivery of the same drug at the same dose. Consequently if, after taking account of the factors specified in section 1.1, a clinician considers that a particular device would be more likely to achieve good asthma control in a particular child than cheaper ones available, then that device should be chosen.

Consideration

4.14 The available evidence generally fails to distinguish adequately between devices to suggest significant advantage in clinical effectiveness for one single delivery system.

However, a limited amount of evidence supports the use of press-and-breathe pMDIs with large-volume spacers compared to press-and-breathe pMDIs alone in the delivery of bronchodilators, whilst one study reported equivalence of a press-and-breathe pMDI and large-volume spacer with a DPI at half the dose used in the pMDI in the delivery of a corticosteroid.

On balancing these findings, clinical opinion and pharmacological considerations, the appraisal committee concluded that press-and-breathe pMDIs and spacer devices have an important role to play in the delivery of corticosteroids in aiming to achieve optimal asthma control. Despite this, it was acknowledged that the effectiveness of any device depends on the willingness and ability of a child to use it and to adhere to an effective regimen. The aim should be to identify the most clinically appropriate device that the individual child will use, bearing in mind the need to minimise the systemic absorption of inhaled corticosteroids.

- 4.15 Economic analysis suggests that no device should be excluded on grounds of cost effectiveness; however, when more than one device is felt to satisfy the considerations set out in 4.14 in an individual child, the device with the lowest overall cost (i.e. considering daily required dose and product price per dose) should be chosen.
- 4.16 As there is limited evidence on the effectiveness of alternative spacers for a given inhaler, if a choice is available, the decision should be guided by information in the inhaler's Summary of Product Characteristics.

5 Implications for the NHS

- 5.1 Overall budget impact is very sensitive to device prescribing patterns, since acquisition costs of inhalers delivering the same class of drug at the same dose vary substantially (as outlined in 4.11). However, with the exception of spacer devices, it is difficult to predict the impact of the guidance set out in section 1 on local inhaler prescribing patterns and costs. Consequently, an estimate of current inhaler prescribing patterns in primary care is set out below for England and Wales. These prescribing rates and costs can be used together with local information on inhaler use to calculate the likely local cost impact of the guidance. Estimates of the cost impact of the guidance as regards spacer devices are detailed in 5.5.
- 5.2 Analysis of inhaler device prescribing in a large sample of older children treated in primary care shows that press-and-breathe pMDIs account for 60% of prescribed items, breath-actuated pMDIs account for 17%, and DPIs account for 23%.
- 5.3 Applying the estimates in 5.2 to England and Wales as a whole suggests that the approximate current annual acquisition costs for devices prescribed to children aged 5–15 years in primary care are as follows: £11.2 million (£1499 per 1000 total population aged 5–15 years) for press-and-breathe pMDIs, £4.2 million (£562 per 1000) for breath-actuated pMDIs, and £21.7 million (£2898 per 1000) for DPIs.
- 5.4 In addition, the analysis shows that in primary care, only 20% of children aged 5–15 prescribed a press-and-breathe pMDI delivering corticosteroids are currently prescribed a spacer attachment. The estimated total annual acquisition cost for spacer attachments is currently £233,000 (£31 per 1000) in England and Wales as a whole.
- 5.5 If all children prescribed a press-and-breathe pMDI delivering corticosteroids in primary care were to be prescribed one spacer attachment per year, it is estimated that the total annual acquisition cost in England and Wales would increase to £1.2 million (£156 per 1000). Manufacturers generally recommend two spacers per year.
- 5.6 In addition to any anticipated changes in device acquisition costs, it is also

important that planning recognises the wider resource implications of implementing the guidance, including those set out in 1.4 and 7.3.

6 Further research

- 6.1 Given the scarcity of robust research comparing inhaler devices (including spacers) in older children, decision-making is likely to be substantially improved by adequately powered RCT equivalence studies. Ideally, these would include:
 - treatment of a full spectrum of chronic asthma severity in generalisable clinical settings
 - qualitative assessment of children's experience of devices and factors influencing adherence
 - examination of clinically relevant outcome measures (e.g. symptoms, activities, time away from school) rather than short-term measures of lung function
 - examination of differences in resource use
 - epidemiological investigation of the determinants (e.g. social factors) of adherence, effectiveness and cost effectiveness of treatment.
- 6.2 The Institute acknowledges that such studies would require large numbers of participants and present a significant challenge to manufacturers and other researchers. A parallel or alternative approach would be to undertake epidemiological and qualitative research on the factors influencing adherence and competence.
- 6.3 Given that none of the currently available inhaler devices are completely satisfactory for children, manufacturers should consider research into novel inhalers that can be used effectively with greater ease by children.

7 Implementation

- 7.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication.
- 7.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final draft guidance.
- 7.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a child aged 5 to 15 has chronic asthma and the doctor responsible for their care thinks that inhaler devices are the right treatment, they should be available for use, in line with NICE's recommendations.

8 Appraisal committee members

The appraisal committee is a statutory committee whose members sit for 3 years. Two meetings are held per month and the majority of members attend one or the other. Declared interests may also exclude a member from individual technology appraisals. The committee are <u>supplemented by technology specific experts</u>.

Dr Jane Adam Radiologist, St George's Hospital, London

Dr Sunil Angris General Practitioner, Waterhouses Medical Practice

Professor David Barnett (Chair) Professor of Clinical Pharmacology, University of Leicester

Professor Carol Black Consultant Physician, Royal Free Hospital & UCL, London

Professor John Brazier Health Economist, University of Sheffield

Professor Bruce Campbell Consultant Surgeon, Royal Devon & Exeter Hospital

Professor Mike Campbell Statistician, Institute of General Practice & Primary Care, Sheffield

Dr Karl Claxton Health Economist, University of York

Professor Jack Dowie Health Economist, London School of Hygiene & Tropical Medicine, London

Mr Chris Evennett Chief Executive, Mid-Hampshire Primary Care Trust

Dr Paul Ewings

Statistician, Taunton & Somerset NHS Trust

Sally Gooch Director of Nursing, Mid-Essex Hospital Services Trust

Liz Heyer Chief Executive, Barnet & Chase Farm Hospitals NHS Trust

Ruth Lesirge Lay Representative; Director, Mental Health Foundation

Dr George Levvy

Lay Representative; Chief Executive, Motor Neurone Disease Association

Dr Gill Morgan

CEO, North & East Devon Health Authority

Professor Miranda Mugford Health Economist, University of East Anglia

Siân Richards General Manager, Cardiff Local Health Group

Professor Philip Routledge Professor of Clinical Pharmacology, University of Wales

Dr Rhiannon Rowsell Pharmaceutical Physician, AstraZeneca UK Ltd

Dr Stephen Saltissi Consultant Cardiologist, Royal Liverpool University Hospital

Professor Andrew Stevens Professor of Public Health, University of Birmingham

Professor Ray Tallis

Consultant Physician, Hope Hospital, Salford

Professor Mary Watkins

Head of Institute of Health Studies, University of Plymouth

Dr Norman Waugh

Public Health Consultant, University of Southampton

Dr Trisha Greenhalgh

Director, Open Learning Unit, Primary Care and Population Sciences, University College London

9 Sources of evidence

The following documentation and opinion was made available to the appraisals committee.

a. Assessment report prepared by School of Health Related Research (ScHARR), University of Sheffield, (Clinical and Cost Effectiveness of Inhaler Devices used in the Routine Management of Chronic Asthma in Older Children, August 2001).

b. Manufacturer/sponsor submissions:

- 3M Health Care Ltd
- AstraZeneca UK Ltd
- Aventis Pharma Ltd
- Boehringer Ingelheim
- Celltech Pharmaceuticals Ltd
- GlaxoSmithKline
- Norton Healthcare
- Trinity Pharmaceuticals
- Yamanouchi Pharma Ltd

c. Professional/specialist group, patient/carer group and trade association submissions:

- British Lung Foundation
- Royal College of Paediatrics and Child Health
- The General Practice Airways Group (GPIAG)
- British Thoracic Society
- National Asthma Campaign
- d. External expert and patient advocate attendance:

- Dr Mark Levy, Representative from GPIAG and Senior Lecturer (Clinical) Part Time, Dept of General Practice & Primary Care, Aberdeen University
- Trisha Weller, Head of Quality Assurance, National Asthma & Respiratory Training Centre
- Dr Mark Everard, Consultant in Paediatric Respiratory Medicine, Sheffield Children's Hospital
- Marsha Williams, Campaigns Manager, National Asthma Campaign
- Jack Barnes, Director of Research & Policy, National Asthma Campaign
- Dr Andrew Bush, on behalf of the British Lung Foundation, Reader in Paediatric Respirology, Royal Brompton Hospital

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