



Department
of Health

Amendments to the Human Medicines Regulations 2012 to allow the supply of salbutamol inhalers to schools

Response to the consultation MLX 385

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Amendments to the Human Medicines Regulations 2012 to allow supply of salbutamol inhalers to schools

Response to the consultation MLX 385

Prepared by the Disabled and Ill Child Services Team, Department of Health

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1. Introduction

This document summarises responses received to the UK-wide public consultation (in accordance with section 129(6) of the Medicines Act 1968) in May 2014 on proposed changes to the Human Medicines Regulations 2012, to allow the supply of salbutamol asthma inhalers to schools for emergency use.

Under the Human Medicines Regulations 2012, asthma inhalers are prescription-only medicines and schools cannot hold their own stock of inhalers for use in emergencies.

Approximately 20 children of school age in England and Wales die every year from asthma and most deaths occur before the child reaches hospital. A survey from Asthma UK found that 64% of children with asthma have at some point been unable to access a working reliever inhaler in school, the inhaler having been forgotten, lost or broken or run out. 62% of children with asthma have had an asthma attack while at school.

In 2012, Asthma UK made enquiries as to whether the law could be changed to allow schools to keep a spare reliever inhaler for use in an emergency. The Department of Health (DH) then consulted with the Department for Education (DfE) and interviewed teachers and parents to ascertain their feelings on the subject. Staff and parents were almost unanimously in favour of schools being allowed to hold an inhaler for emergency use. Some schools had already implemented protocols for holding and using inhalers in an emergency, although not permitted by the legislation.

The MHRA subsequently presented an evaluation of risks and benefits of schools holding a salbutamol inhaler for emergency use to the Commission on Human Medicines (CHM). The CHM recommended that the legislation should be amended.

As part of the consultation, DH published its draft guidance for schools on the use of emergency inhalers, which had been developed with some partner organisations and clinicians. The consultation letter and original draft guidance can be found at: <https://www.gov.uk/government/consultations/proposals-to-allow-the-supply-of-salbutamol-asthma-inhalers-in-schools-for-emergency-use-mlx385>

The consultation response template, which includes specific questions for respondents, is given in Annex B.

Over 4000 responses to the consultation were received, from parents, people with asthma, paediatric and respiratory clinicians, school nurses, GPs, pharmacists and key organisations (which are listed below in Annex A). Asthma UK provided signatories to a petition supporting the proposals. In the following summary, the names of individuals have not been given; however, direct quotations have been made where respondents have indicated willingness for their comments to be made available.

2. Summary of responses

The following summary is organised by the topics set out in the consultation response template (Annex B).

A. Support for the proposals

There was consistent support for the proposals. Only two respondents directly opposed the proposal to allow schools to hold salbutamol inhalers for emergencies, on the grounds that it would deter families from ensuring that children brought their own inhaler to school.

Many respondents made important points in relation to safe practice by schools in their management of the inhaler (covered below) and commented on the draft guidance, and we have incorporated changes in the guidance for schools, which will be published shortly.

B. The relevance and impact of the criteria

This section asked questions on current practice, the likely intentions of respondents – particularly schools – and key issues relevant to implementation. The questions to which comments refer are underlined (some general comments have also been included under a relevant heading). Direct quotations are italicised.

i) Does the school you refer to have a spare salbutamol inhaler for emergency use? If yes, through what mechanism?

A number of schools had developed asthma policies which included the holding of emergency inhalers, including in North Staffordshire, Dudley and Norfolk, all of which had now ended on legal advice. More widespread was the practice of children with asthma being prescribed spare inhalers for emergencies which could be kept suitably labelled at school.

We have in the past had this service in North Staffordshire schools, managed by a paediatrician and children's specialist asthma nurse and found it to be extremely valuable....

Health centre, Stoke-on Trent

ii) Do you think this proposal would allow schools to access/receive salbutamol asthma inhalers? What could be the implementation issues?

The consensus was that the proposals were suitable for allowing schools to access salbutamol inhalers, provided schools had a reasonable asthma policy, in line with guidance, and teachers were properly trained and supported. Implementation issues are considered below under question iv.

iii) If the school you are referring to became eligible for access to salbutamol asthma inhalers, would it consider holding a spare inhaler in its premises and completing training to administer it safely?

Again, there was overwhelming agreement that schools would make full use of this power, and would seek to ensure staff had suitable training and support; there were divergent views on how much training might be needed by staff, and who might provide this, with some respondents highlighting the existing pressures already placed on school nurses; however, a number of respondents recognised that asthma clinics were likely to be receptive to supporting schools in providing simple guidance and training on effective use of the inhaler. Some highlighted that very little was needed by way of training in the correct use of an inhaler.

iii) If you answered question iii) with yes, can you please indicate how many salbutamol asthma inhalers and compatible spacers you are expecting to request/buy and use in a twelve month period under this proposal?

Some respondents felt this was a tricky question to answer, as it is dependent on the size of the school and the number of sites it comprises, and the number of children known to have asthma, and past experiences of children who had not been able to access their inhaler. However there was broad agreement from respondents that only a small number of inhalers were likely to be needed annually. It was noted that provision should be made for separate inhalers for infants and junior schools in a single-site primary school, and that there should be more than one inhaler available if necessary for larger schools (and suggestions here were in the range of 3 to 6).

Usage could be quantified where there had been a formal programme of inhalers provided to schools, as for example, in Dudley.

In Dudley there are 109 schools and the emergency inhaler was used between 300 and 350 times a year. This suggests each school had to use the inhaler an average of 3 times a year. This means they would need to buy one inhaler and five spacers a year (as the spacers are single use there should always be another available).

Asthma UK

It was also reported that in Dudley, following introduction of emergency inhalers in schools, use of the inhaler reduced on average in years 2 and 3 of the scheme, which suggests that the introduction of emergency inhalers has the potential to support improved asthma management in children.

iv) Can you identify any practical problems if schools are allowed to supply salbutamol asthma inhalers for emergency use?

A wide range of potential issues were identified, with many valuable suggestions for improving the guidance for schools. Significant issues are listed below, with comments within square brackets.

- A need to distinguish where children did not have asthma, but may be subject to another condition, which have similar symptoms. [A child's health plan should indicate this, and the child would also not be included on the school's asthma register].
- Infection control [which is addressed by the guidance recommendation that spacers are single use].

- Spacers can be different sizes [addressed by the guidance advice that the school seek advice from its supplier].
- Inhalers expiring [the guidance indicates the need for regular checks].
- Ensuring that staff are trained correctly and able to identify signs of an acute asthma attack [the guidance includes advice on recognising symptoms, and training].
- The spare inhaler(s) must be kept in places where they can be quickly accessed. Larger settings will need to have spare inhalers strategically placed with all staff aware of their location [addressed by the guidance].
- Ensuring sufficient numbers of staff are trained so that there isn't a delay in treating a patient until someone who has been trained is available.

The name the child uses for his inhaler should be recorded (my son used the word puffer, which was not understood by the teacher). Older children should be taught to use a word that is agreed with the responsible member of staff.

Parent

It is not easy to use an inhaler, and while spacers do eliminate one problem, they do not replace initial training on technique and regular monitoring of that technique that is necessary to gain maximum benefit (or even any benefit) from a Salbutamol MDI. I am a pharmacist and in my practice I almost daily monitor technique. By far the majority of asthmatics do not use their inhalers correctly. See <http://www.cumbria.nhs.uk/ProfessionalZone/MedicinesManagement/EnhancedServices/common-mistakes-inhaler-technique-Dec-12.pdf>.

Pharmacist

v) Are you aware of any risks associated with the use of salbutamol asthma inhalers?

Most respondents felt that there was no intrinsic risk from the use of salbutamol itself provided it was used by children who had asthma and who had been prescribed an inhaler (this was also essential to prevent a child being given an inhaler when their symptoms denoted a different condition).

Salbutamol is a very safe medicine. It has been in use since the 1960s and is the mainstay of symptom relief in asthma, so its effects are well understood. It has few side effects and is unlikely to pose any significant risk if given unnecessarily to a child with asthma. The clearest theoretical risk - that of cross-infection through use of a shared device - would be effectively mitigated by the proposal for the inhaler to be used with a spacer device which is replaced after each use. We are, however, unaware of any case of illness following cross-infection being reported.

Asthma UK

Asthma UK also highlighted that published evaluations of school policies which included the introduction of emergency inhalers and spacers in schools had reported no adverse events.

Some respondents highlighted the potential side effects, as given in the patient information leaflet, and the British National Formulary, but concluded that the risks were slight compared to the risk of an inhaler not being available when a child suffered an asthma attack.

Two key risks were highlighted potentially arising from the policy of allowing schools to hold emergency inhalers: that of cross infection from multiple use of a single inhaler, and the risk that parents might be less vigilant in ensuring their child took their prescribed inhaler to school. The proposed guidance for schools will make clear that the spacer must not be reused, and that the inhaler needs to be cleaned before reuse, and, following a respondent's suggestion, the model letter seeking consent from parents to the use of the emergency inhaler if needed by their child will also include a commitment from the parents to ensure their child brings their own inhaler to school.

A broader issue was raised of the need for awareness amongst staff of the nature of an emergency, and that the use of the inhaler should not delay the calling of an ambulance where a child was seriously ill. It was also highlighted that an initial response to medication could provide a false reassurance to staff that a child had improved, when they had in fact undergone a physical deterioration, although this could, of course, also apply where a child had used their own inhaler.

Salbutamol is a first measure, not a definitive treatment of serious acute asthma, so we need to ensure that the use of an inhaler does not delay the child from being assessed and treated will someone waits to see if it works.

Dispensing Doctors Association

The guidance for schools should be able to mitigate this by ensuring awareness of the need for vigilance, and the importance of calling an ambulance if in any doubt as to a child's condition.

vi) Do you think this could encourage parents to not make sure that their children have asthma inhalers when they go to school?

Most respondents did not feel that allowing a school to hold an emergency asthma inhaler would discourage parents from making sure their children brought their own inhaler to school (the only exception were the two respondents which, as mentioned, did not support the proposed change on these grounds). There was, however, agreement amongst respondents who commented on this that the school should do as much as possible to ensure that parents continued to recognise that the emergency inhaler was just that – an option in an emergency. As mentioned above, one way to reinforce this could be via the letter seeking consent from parents and other opportunities – such as health plans, and other parental communications - should be similarly utilised.

Teaching unions highlighted that schools might need to tackle families of children who were persistently without their own inhaler. Some respondents suggested that availability of the emergency inhaler might provide a basis for this, in allowing a discussion, when following up on the use of the emergency inhaler, about the need for the child to have their inhaler at school at all times. In Dudley it was reported that, if a child had needed to use the emergency inhaler at school, the parent was informed and the reason why the child was unable to use their own inhaler was addressed, resulting in improved asthma management for the child.

While there is a risk that it may reduce the pressure on parents to provide the inhalers, there are currently those pupils for whom parents are less likely to provide inhalers with the current system for whom this would be greatly beneficial. I feel this outweighs the concern expressed above. Having the emergency inhaler in school

shouldn't change the current responsibility on parents and this can be clearly document on agreements and in school policies.

An asthma nurse

vii) If you currently work in a school, how often have you seen a child suffering an acute asthma attack, not in possession of their own asthma inhaler, in the past 12 months?

Parents and school nurses reported examples of children having an asthma attack when their own inhaler was not available. There was anecdotal evidence from a teaching union that this was a frequent problem in schools.

A number of school and college leaders have reported distressing cases of the sudden death of young people from asthma attacks. If even a proportion of these would have been prevented by this proposal, which seems to have little downside, then it will be very welcome in similar cases in future.

The Association of School and College Leaders

viii) Do you think this proposal increases the liability of schools?

Most respondents felt that the proposal would not increase the liability of schools, if they acted responsibly and in line with the guidance. This is perhaps the key issue raised in this section: the need to ensure that staff are content to support children in the use of the emergency inhaler, and have appropriate training in administering it.

A number highlighted that if a school was taking appropriate steps to ensure children with asthma could manage their condition, this would be in line with the new statutory duty on schools in the Children and Families Act 2014 and represented a reasonable fulfilment of a school's duty of care. There were frequent comments that having an emergency inhaler would make a school a safer place, and so reduce a school's liability.

No – helping a known asthma sufferer administer life-saving medication would certainly fall into acting in loco parentis. I am sure a reasonable, prudent and careful parent would not hesitate to administer a spare inhaler to their own child.

Surrey County Council

ix) DH estimates the cost of an inhaler to be £10. If the school you are referring to became eligible for access to salbutamol asthma inhalers, would it consider holding a spare inhaler in its premises and completing training to administer it safely?

A number of respondents felt that a cost of £10 was too high, citing the prices in the British National Formulary (e.g. £1.50 for a 200 dose CFC inhaler, although this would not necessarily be the price from a supplier). No respondent felt that the cost would prevent a school from purchasing an inhaler. It was also suggested that the guidance should indicate that schools would have to pay for an inhaler – that they could not be supplied *gratis* by pharmacies.

x) Are you aware of any other costs associated with this proposal?

The chief potential additional cost identified was the training of staff, ideally from a health professional, although as highlighted above, some respondents did not feel that much training would be needed in how to administer an inhaler safely.

If this scheme is to be implemented safely then there will be costs associated with providing “appropriate” training, which we would suggest needs to be from a health professional, and update training. Time involved in ensuring correct cleaning, and checking kit is in correct place hasn’t been tampered with etc., maintenance of records, monitoring notifying parents. Cost of disposal of waste pharmaceuticals
Primary and Community Care Pharmacy Network (PCCPN)

One respondent estimated that implementation of the policy might only cost 10 hours of staff time to implement, with some regular time needed for checking of stocks and maintaining the register.

The costs of the proposals to schools are minimal. As the inhaler would only be for emergency use when a child could not access their own inhaler, it should not need to be used very frequently. Replacement costs would be kept to a minimum since only the spacer device would need to be replaced after each use of the inhaler.

The cost of an admission to hospital for asthma, on the other hand, is between £600 and £2,200, depending on the complexity of the case.

Asthma UK

C. Manufacturers

Manufacturers were asked for their views on likely demand. Orion Pharma UK estimated that with around 25,000 schools in the UK, they would expect to sell in the range of an additional 100,000 salbutamol inhalers, assuming each school required 4 inhalers per year (although recognising that some schools may not choose to exercise their power to hold emergency inhalers, they envisaged this could be reduced by a half to 50,000 additional inhalers sold each year).

3. Response and next steps

The Department of Health and the Medicines and Healthcare Products Regulatory Agency are grateful to everyone who has supported the research into the potential for the use of an emergency salbutamol inhaler which preceded the public consultation, and everyone who responded to the consultation.

The Department wishes to thank in particular Asthma UK, the George Coller Memorial Fund, North Staffordshire Hospital, Dudley Metropolitan Borough Council and Margot James MP for their support.

The responses received were overwhelmingly supportive of changing the law to allow schools to hold emergency salbutamol inhalers. The Government therefore laid before Parliament on 18th July the Human Medicines (Amendment No. 2) Regulations 2014. <http://www.legislation.gov.uk/id/uksi/2014/1878>

These Regulations amend the Human Medicines Regulations 2012, to allow schools to hold stocks of asthma inhalers containing salbutamol for use in an emergency. These regulations come into effect on 1st October 2014.

From this date onwards, schools can buy inhalers and spacers (the plastic holding chambers which make it easier to deliver asthma medicine to the lungs) from a pharmaceutical supplier in small quantities provided it is done on an occasional basis and is not for profit.

A supplier will need a request signed by the principal or head teacher (ideally on appropriately headed paper) stating:

- the name of the school for which the product is required;
- the purpose for which that product is required, and
- the total quantity required.

The Department of Health has also consulted on draft non-statutory guidance to support schools in England in their management of inhalers, and has revised this to take on board comments received from respondents. It is hoped that the guidance (to be published shortly covers) the major implementation issues raised in the consultation. DH will keep the guidance under review in the light of any further comments received – particularly from schools as they implement the new arrangements.

As devolved administrations, Wales, Northern Ireland and Scotland will have respective responsibility for issuing their own guidance to their schools.

Annex A: List of organisational respondents to the consultation

Anaphylaxis Campaign
Association of School and College Leaders
Asthma UK
ATL
Axiom Training Ltd
Boots UK Ltd
British Thoracic Society
Committee for Education, Northern Ireland Assembly
Dispensing Doctors Association
Dudley Metropolitan Borough Council – Office of Public Health and Directorate of Children’s Services.
East Staffordshire Clinical Commissioning Group
Education for Health
Fife Respiratory Managed Clinical Network
George Coller Memorial Fund
Greater Manchester, Lancashire and South Cumbria Strategic Clinical Network
NASUWT
Neonatal and Paediatric Pharmacy Group
NHS Lothian
Orion Pharma UK Ltd
Pharmacy Voice
Primary and Community Care Pharmacy Network
Royal College of General Practitioners
Royal College of Nursing
Royal Pharmaceutical Society
Royal College of Physicians
Royal College of Paediatrics and Child Health
St. John Ambulance
Surrey County Council
UNISON

Annex B: Original consultation response template

To: Judith Thompson
MHRA
5th Floor
151 Buckingham Palace Road
LONDON SW1W 9SZ

From: _____

CONSULTATION LETTER MLX 385 : PROPOSALS FOR AMENDMENTS TO THE HUMAN MEDICINES REGULATIONS 2012 TO ALLOW SUPPLY OF SALBUTAMOL ASTHMA INHALERS TO SCHOOLS FOR EMERGENCY USE

•

A. Your response to the proposals

- * 1. I support the proposals contained in the MLX
- * 2. I have no comment to make on the proposals in the MLX
- * 3. My comments on the proposals in the MLX are below/attached.

Comments:

B. The relevance and impact of the criteria

If you are someone who:

- comes into regular contact with a child/children suffering from asthma
- works in a school/education environment

please indicate in what capacity you have contact with children suffering with asthma and answer questions i-x below:

school education authority parent doctor/health worker other (please specify)

i) Does the school you refer to have a spare salbutamol inhaler for emergency use? If yes, through what mechanism?

ii) Do you think this proposal would allow schools to access/receive salbutamol asthma inhalers? What could be the implementation issues?

iii) If the school you are referring to became eligible for access to salbutamol asthma inhalers, would it consider holding a spare inhaler in its premises and completing training to administer it safely?

iiia) If you answered question iii) with yes, can you please indicate how many salbutamol asthma inhalers and compatible spacers you are expecting to request/buy and use in a twelve month period under this proposal?

iv) Can you identify any practical problems if schools are allowed to supply salbutamol asthma inhalers for emergency use?

v) Are you aware of any risks associated with the use of salbutamol asthma inhalers?

vi) Do you think this could encourage parents to not make sure that their children have asthma inhalers when they go to school?

vii) If you currently work in a school, how often have you seen a child suffering an acute asthma attack, not in possession of their own asthma inhaler, in the past 12 months?

viii) Do you think this proposal increases the liability of schools?

ix) DH estimates the cost of an inhaler to be £10. If the school you are referring to became eligible for access to salbutamol asthma inhalers, would it consider holding a spare inhaler in its premises and completing training to administer it safely?

x) Are you aware of any other costs associated with this proposal?

C. Manufacturers

If you are a manufacturer of salbutamol inhalers or compatible spacers: Considering the likely demand for salbutamol inhalers or compatible spacers among the eligible groups under this proposal, how many additional salbutamol inhalers or compatible spacers might you expect to sell per year?

D. How we treat your response

- * My reply may be made freely available.
- * My reply is confidential.
- * My reply is partially confidential (indicate clearly in the text any confidential elements)

Signed: _____

* Delete as appropriate