



Department
of Health

Proposed amendments to the Human Medicines Regulations 2012:

to allow schools to hold spare adrenaline auto-injectors (AAIs) without a named individual prescription, for use as emergency back-up to treat anaphylaxis in children registered by the school as being in receipt of a medical prescription for an AAI.

Response to the consultation

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Response to the consultation

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Proposed amendments to the Human Medicines Regulations 2012:

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Response to the consultation

Prepared by the Dementia and Disabilities Unit, 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) which ran from 10 March 2017 to 5 May 2017 on proposed changes to the Human Medicines Regulations 2012, to allow schools to hold spare adrenaline auto-injectors (AAI), without a named individual prescription, for use in emergencies. Over 500 people completed an online form hosted on <https://consultations.dh.gov.uk/hmr/adrenaline-auto-injectors/>

Respondents included parents, schools, education authorities, school nurses, consultant paediatric immunologists and allergy specialists, general practitioners, pharmacists and key organisations (which are listed in Annex B).

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

Anaphylaxis is a severe, potentially life-threatening, allergic reaction for which the recommended treatment is an injection of adrenaline.

AAI are potentially life-saving products prescribed to people at risk of anaphylaxis which enable the administration of adrenaline by non-healthcare professionals.

Children and young people at risk of anaphylaxis are prescribed AAI and should have two available to them at all times but evidence suggests that children may not bring their prescribed AAI to school or that the AAI may be out of date or may misfire.

The response template used for this consultation, which includes specific questions for respondents, is included at Annex A.

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 following the order of the topics as set out in the consultation response template (Annex A).

A. Support for the proposals

There was overwhelming support for the proposals. 533 respondents supported the proposals to allow schools to hold spare AAIs, without a prescription, for use in emergencies and 33 respondents said they had no comments to make on the proposals. However, three respondents highlighted that there was not an option to disagree with the proposals and would have welcomed the opportunity to respond with, "I do not support the proposal."

Many respondents made important points in relation to safe practice by schools in their management and storage of AAIs, staff training and ensuring that a valid consent from parents/guardians has been given to schools in case there is a situation where they need to administer the spare AAI. A number of parents of children with allergies who responded to the consultation said they would be reassured knowing that the school held a spare AAI in case their child had an allergic reaction while at school.

A small number of respondents questioned whether it should be mandatory for schools to hold a spare AAI. Another respondent stated that before amending the legislation it would be helpful to understand if schools would actually buy a spare AAI to keep at school. A small number of respondents stated that a school that chose to purchase a spare AAI should not have to pay for the AAI out of the school's budget.

A respondent who did not support the proposals to allow schools to hold spare AAIs, without a prescription, for use in emergencies said they felt the proposals placed an unnecessary extra burden on schools.

In relation to the guidance on AAIs, several respondents said that advice should be included on the supply, storage, care and disposal of AAIs and training of staff. A number of respondents said the guidance should make clear that any spare AAI held by a school should not be seen as a replacement for a pupils' own device. A number of respondents said that advice on whether there is any difference between the different brands of AAI should be included and several respondents requested that the guidance included a section on what a school should do if they have a child who has an anaphylactic reaction, but hasn't been prescribed an AAI. These issues will all be covered in the Department of Health's guidance for schools which will be issued before the regulatory change comes into effect on 1st October.

B. The relevance and impact of the criteria

This section of the consultation 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. Direct quotations are italicised.

If you come into regular contact with a child/children at risk of anaphylaxis or work in a school or education environment please indicate in what capacity you have contact with children at risk of anaphylaxis.

This was a multiple choice question. Respondents answered as follows:

School	179
Education Authority	18
Parent	211
Doctor of Health Worker	109
Other	62

Do you think this proposal would allow schools to access/receive AAls? What could be the implementation issues?

365 respondents answered this question. The consensus was that the proposals were suitable for allowing schools to hold spare AAls, without a prescription, for use in emergencies, provided schools had a reasonable AAI policy, in line with guidance, and school staff were properly trained and supported. Implementation issues raised by respondents were around the cost of the spare AAI and who would be expected to pay for the device.

“No issues that I can for see as long as staff are trained to fully recognise signs and parents are informed of the school policy.”

Individual

“Cost would no doubt be a factor if schools are having to purchase their own on already tight budgets.”

Individual

“There could be funding issues, although I think most PTAs would be open to fundraising specifically for this purpose once the legislation is approved.”

Individual

If you are aware of a school that has pupils at risk of anaphylaxis can you confirm whether the school has existing protocols in place for the use of AAls? Are staff trained in the administration of AAls?

364 respondents answered this question. The majority of respondents were aware of a school that has pupils at risk of anaphylaxis having existing protocols in place for use of

AAls and trained staff to administer the AAls. However, a small number of respondents said they were aware of a school that has pupils at risk of anaphylaxis but were either unsure whether the school had existing protocols in place for use of AAls or said the school did not have existing protocols in place. Regarding staff training the majority of respondents said they were aware that school staff were trained in the administration of AAls. However, this ranged from all staff been trained to a small number of staff been trained in the administration of AAls.

“We have pupils with severe nut allergies and we have protocols in place to deal with anaphylaxis. We have whole staff training once a year from our school nurse. The local authority has an indemnity policy that covers staff who administer AAI's. Fortunately we have never once had to use an AAI.”

Afon Taf High School

“No they do not. The school only have care plans for those children with epipens or risk of anaphylaxis.”

Individual

“Yes - the school has protocols in place and all staff are trained in the administration of AAls.”

St. Anthony's School

“The situation in schools is improving following the amendments to the Children and Families Bill in 2014 which places a duty of care on schools and many schools now have a plan in place for their students with health conditions. Additionally, most schools will have at least one member of staff trained in the use of emergency adrenaline. There are of course schools who have not adhered to the changes and indeed these changes only affected schools in England, so a robust set of guidelines and some basic training are essential as part of these changes.”

The Anaphylaxis Campaign

If the school you are referring to became eligible for access to AAls, would it consider holding a spare device in its premises?

This was a multiple choice question. Respondents answered as follows:

Yes	260
No	19
Not Answered	274

If you answered the above question with yes, can you please indicate how many AAls you are expecting to request/buy and use in a twelve month period under this proposal?

251 respondents answered this question. A range of responses were received to this question. The most common response was that people expected to request/buy 1 to 3 devices in a twelve month period under this proposal. Other responses ranged from 4 to 6

and from 8 to 12 devices. A small number of respondents said they were unable to answer this question and other respondents said this would be dependent on the cost of the devices and the decision of the school.

"I would suggest 2 pens kept by the school at any one time. Replaced if used or expired."
Individual

"Depends on cost incurred."
Individual

"12 AAls (2 for each classroom)."
Individual

If the school you are referring to held a spare AAI would additional training in its administration be necessary?

This was a multiple choice question. Respondents answered as follows:

Yes	155
No	164
Not Answered	232

Can you identify any practical problems if schools are allowed to supply AAls for emergency use?

324 respondents answered this question. Several respondents said they could not identify any practical problems if schools are allowed to supply AAls for emergency use. A large number of respondents identified a range of practical issues that would need to be addressed including:

- ensuring that a valid consent from parents/guardians has been obtained in case the spare AAI needs to be administered by the school;
- the dosage which would need to be administered if a child went into anaphylactic shock;
- instructions on how to administer the AAI and advice on what to do if the AAI misfires;
- what to do if staff misdiagnose a child as having an anaphylactic shock and administer the AAI;
- the storage of AAls;
- monitoring of AAI expiry dates,;
- how to dispose of out of date AAls,
- staff training;
- the costs involved with purchasing a spare AAI,
- protocols for when children with allergies go on school trips or when children with allergies are off site;

- guidance for staff on how to manage an allergic reaction in a child who has not been prescribed an AAI or in a child who is experiencing their first allergic reaction.

“In secondary schools where the pupils can be off site, such as at sports fields, or on a large campus like setting the location of the AAI maybe a significant distance from the pupil. A high school pupil at risk of anaphylaxis should carry their own AAI, but if they forget, they would need to access the generic AAI if needed. School policy should cover offsite locations etc and take into consideration how it deals with these types of scenarios, to safeguard 'at risk' pupils.”

Allergy UK

“The AAI must be in a known and accessible place but safe from unauthorised access.”

Individual

“The only problem I see is that all parents would have to give consent for use on their children and this information would require updating regularly? Also the cost involved?”

Individual

“Dose and product selection.

By the time the auto injector is obtained, pupil may not be able to self-inject.

Cost

Mis "diagnosis" of anaphylaxis”

Primary and Community Care Pharmacy Network

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

This was a multiple choice question. Respondents answered as follows:

Yes	131
No	360
No Answered	59

Are you aware of any incidences of anaphylactic reaction where the pupil could not use their own AAIs, in the past 12 months?

This was a multiple choice question. Respondents answered as follows:

Yes	69
No	371
Not Answered	11

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

Manufacturers were asked for their views on likely demand. Only one manufacturer replied to this question and a small number of individuals gave estimates.

3. Our response and next steps

The Department of Health and the Medicines and Healthcare Products Regulatory Agency are grateful to everyone who has taken the time to respond to this consultation.

The responses received were overwhelmingly supportive of changing the law to allow schools to hold spare AAls, without a prescription, for use in emergencies. The Government therefore laid before Parliament on 5 July 2017 the Human Medicines (Amendment) Regulations 2017. <http://www.legislation.gov.uk/id/uksi/2017/715>.

These Regulations amend the Human Medicines Regulations 2012, to allow schools to hold spare AAls, without a prescription, for use in emergencies. These regulations come into effect on 1 October 2017.

From this date onwards, schools can buy AAls, without a prescription, for use in emergencies 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 is also producing non-statutory guidance to support schools in England in their management of AAls.

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

Annex A: Original consultation response template

Overview

This consultation seeks views on whether legislation should be changed to allow schools to choose to hold spare adrenaline auto-injectors (AAIs) for use in emergencies.

Currently, AAIs are prescription only medicines, which means that schools cannot keep spares for use in emergencies. Following the recommendation of the Commission on Human Medicines, the government is proposing to change the Human Medicines Regulations 2012 to enable schools to purchase and hold spare AAIs for use in emergencies.

This would enable schools in England, Scotland, Wales and Northern Ireland that choose to do so to hold spare AAI for use in emergencies. No school would be required to hold spare AAIs as a result of the change.

Introduction

Anaphylaxis is a severe, potentially life-threatening, allergic reaction for which the recommended treatment is an injection of adrenaline.

Auto-Injectors (AAIs) are potentially life-saving products prescribed to people at risk of anaphylaxis which enable the administration of adrenaline by non-professionals.

Children and young people at risk of anaphylaxis are prescribed AAIs and should have two available to them at all times but evidence suggests that children may not bring their prescribed AAIs to school or that the AAIs may be out of date or may misfire.

Currently AAIs are prescription only medicines which means that schools cannot keep spares for use in emergencies. Following the recommendation of the Commission on Human Medicines the Government is proposing to change the Human Medicines Regulations 2012 to enable schools to purchase and hold spare AAIs for use in emergencies. This would enable schools in England, Scotland, Wales and Northern Ireland which chose to do so to hold spare AAI for use in emergencies. No school would be required to hold spare AAIs as a result of the change.

As well as changing the law, we will produce guidance for schools. This will provide advice on a range of issues in particular the symptoms of anaphylaxis, administration of AAIs, record-keeping and storage.

In particular the guidance will be clear that:

1. The school's spare AAIs are **not** a replacement for pupils' own devices. Pupils should continue to bring their own AAIs to schools.

2. Use of the spare AAI should be restricted to pupils prescribed an AAI whose parents have given consent for its use.
3. Schools should hold a list of all pupils who can access the spare AAI.
4. Where pupils are prescribed more than one brand of AAI, schools are free to decide whether to purchase one brand of AAI or each brand used by pupils.
5. Schools should keep a record of the spare AAIs held and their expiry date and ensure they are replaced appropriately.

We are asking for your comments on both the proposed changes to legislation and the proposed principles of the accompanying guidance.

Tell us about yourself

Question 1. What is your name?

Title (Mr, Mrs, Ms, Dr, Professor)

First name

Surname

Question 2. What is your email address?

If you enter your email address then you will automatically receive an acknowledgement email when you submit your response.

Email

Question 3. Are you responding as an individual or as part of an organisation?

Please select only one item

- Individual
- Organisation

If you selected organisation, what is the name of your organisation?

What is the role of your organisation?

Where are you/your organisation based?

Please select only one item

- England
- Wales
- Scotland
- Northern Ireland
- Other

If other, please tell us where you or your organisation are based.

Question 4. If you are responding as an individual, please tell us your ethnic origin:

White

Please select only one item

- English / Welsh / Scottish / Northern Irish / British
- Irish
- Gypsy or Irish traveller
- Any other white background, please describe:

If other, please describe your ethnic origin

Mixed/multiple ethnic groups

Please select only one item

- White and Black Caribbean
- White and Black African
- White and Asian
- Any other mixed/multiple ethnic background, please describe:

If other, please give details of your ethnic background.

Asian/Asian British

Please select only one item

- Indian
- Pakistani
- Bangladeshi
- Chinese
- Any other Asian background – please describe:

If other, please enter details of your ethnic background

Black / African / Caribbean / Black British

Please select only one item

- African
- Caribbean
- Any other Black/African/Caribbean background, please describe:

If other, please give details of your ethnic origin.

Other ethnic group

Please select only one item

- Arab
- Any other ethnic group, please describe:

If other, please provide details of your ethnic background

Prefer not to say

Please select only one item

- Prefer not to say

Consultation Questions

If you are a manufacturer of AAls please answer question 5 and then go to question 15 (you do not need to answer questions 6 to 14).

Question 5. Your response to the proposals

This question requires a response - Please select one of the following:-

- I support the proposals.
- I have no comments to make on the proposals.

Please let us know if you have any comments on the proposals

Please let us know if you have any comments on the issues intended to be addressed in the draft guidance

Question 6. If you come into regular contact with a child/children at risk of anaphylaxis or work in a school or education environment please indicate in what capacity you have contact with children at risk of anaphylaxis.

Multiple choice checkboxes

Please select all that apply

- School
- Education authority
- Parent
- Doctor or health worker
- Other

If you ticked other please specify below

Question 7. Do you think this proposal would allow schools to access/receive AAls? What could be the implementation issues?

Comments

Question 8. If you are aware of a school that has pupils at risk of anaphylaxis can you confirm whether the school has existing protocols in place for the use of AAls? Are staff trained in the administration of AAls?

Comments

Question 9. If the school you are referring to became eligible for access to AAls, would it consider holding a spare device in its premises?

Multiple choice checkboxes

Please select all that apply

- Yes

- No

Question 10. If you answered the above question with yes, can you please indicate how many AAls you are expecting to request/buy and use in a twelve month period under this proposal?

Comments

Question 11. If the school you are referring to held a spare AAl would additional training in its administration be necessary?

Please select all that apply

- Yes
- No

Question 12. Can you identify any practical problems if schools are allowed to supply AAls for emergency use?

Comments

Question 13. Do you think this could encourage parents to not make sure that their children have AAls when they go to school?

Multiple choice checkboxes

Please select all that apply

- Yes
- No

Question 14. Are you aware of any incidences of anaphylactic reaction where the pupil could not use their own AAls, in the past 12 months?

Multiple choice checkboxes

Please select all that apply

- Yes
- No

Question 15. If you are a manufacturer of AAls: Considering the likely demand for AAls among the eligible groups under this proposal, how many additional AAls might you expect to sell per year?

Comments

Question 16. Are you happy for the Department of Health to use your email address to contact you to clarify points in your response if necessary?

Single choice radio buttons

Please select only one item

- Yes
- No

Question 17. How we will use your response

We might share your response with other government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future. We need your permission to do this. Are you content for a government policy official to use your email address to contact you in relation to this consultation response?

Please select only one item

- Yes
- No

Are you content for the policy team to use your response and/or name in the final published report?

Please select only one item

- Yes
- No

If yes, please tick if we can use the following information about:

Please select all that apply

- Your response
- Your name (individual name)
- Your organisation's name

Question 18. Would you like to receive information about other DH consultations?

Please select only one item

- Yes
- No

Question 19. Help us improve how the department runs consultations by answering the following questions:

How satisfied are you with the consultation process?

Please select only one item

- Very satisfied
- Satisfied
- Somewhat satisfied

- Disappointed

Further comments:

How satisfied are you with the digital consultation experience?

Please select only one item

- Very satisfied
- Satisfied
- Somewhat satisfied
- Disappointed

Further comments:

Annex B: List of organisational respondents to the consultation

The below list of organisations agreed to the Department of Health publishing their names in the response to the consultation:

Aberdeenshire Council
Afon Taf High School
Allergy Action
Allergy UK
Ambulance Pharmacists Network
Antrim Grammar School
Ashtons Hospital Pharmacy Services Ltd
Association of School and College Leaders (ASCL)
Bedford Modern School
Blue Door Nursery
Central North West London NHS Foundation Trust
Community Pharmacy Wales
County Durham and Darlington NHS Trust
Down High School
Executive Training Ltd
Fane Street Primary School
Guild of Healthcare Pharmacists
International School of Aberdeen
Law Society of Northern Ireland
Leeds Children's Hospital
Market Bosworth School
Moulsford Boys' Prep School
National Pharmacy Association
NHS Lothian
North West Paediatric Allergy Network
Paediatric Committee of British Society for Allergy & Clinical Immunology
Powys County Council
Primary and Community Care Pharmacy Network (PCCPN)
Renfrewshire Council
Rescue Emergency Care
Royal Belfast Academical Institution
Royal Manchester Children's Hospital
Royal Pharmaceutical Society
Scarborough College
Scottish Outdoor Education Centres
Seaview P.S
Severe Allergy Group - West Yorkshire
SNAP Cymru
Southern Health and Social Care Trust
Southern Trust Children and Young People
ST4 Training
St. Anthony's School

St. Francis' Primary School, Lurgan, NI
St. George's University Hospitals NHS Foundation Trust
St. Johns School
St. Joseph's High School, Crossmaglen
St. Mark's High School, Warrenpoint
St. Mary's P.S.
St. Peter's School
The Anaphylaxis Campaign
The London Football Academy
The Royal College of Paediatrics and Child Health
Tor Bank Special School
Western Sussex Hospitals Trust
West Essex Children Services
Wilmslow High School