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

From:
Adfam
25 Corsham Street
London
N1 6DR
020 7553 7640
www.adfam.org.uk
policy@adfam.org.uk

CONSULTATION LETTER MLX : Amendments to the Human Medicines Regulations 2012 to widen access to naloxone for use in an emergency

A. Your response to the proposals

* 1. I support the proposals contained in the MLX

* 3. My comments on the proposals in the MLX are below.

Comments:

Adfam supports the proposals contained in the MLX.

Parents and other family members/friends and cohabitees of people with drug problems should be able to receive direct supplies of naloxone, following training, to keep at home for emergency purposes.

There is a positive precedent for supplying families and carers with naloxone. In 2009-2010 the NTA ran a pilot project across 16 sites, training 495 carers. The evaluation report stated that there were then 18 cases where carers used the naloxone, and all of the drug users survived; there may have been more cases since. Families said the programme increased their knowledge of overdose, their feelings of empowerment and their confidence. They also valued the measure of control that the ability to intervene in an overdose gave them, compared to previous feelings of powerlessness. The evaluation of the pilot scheme contains a number of points relevant to the design of a new programme, and we encourage the MHRA to review *The NTA Overdose and Naloxone Training Programme for Families and Carers* (NTA, 2011).

If the amendment to the regulations is to have its intended impact of reducing the number of overdose deaths, families' and carers' access to naloxone should not be determined by their family members' treatment status. Families should have access to naloxone even if their family member is not in treatment, and treatment services should make it available to the families of non-clients. Drug users who are not in treatment are arguably more at risk of overdose than those who are, and families may feel the need for the 'safety net' provided by naloxone more keenly if their relative is not seeking support for their addiction from a treatment service.

It is Adfam's view that services supporting families affected by substance use should be able to dispense naloxone, subject to the relevant approval processes undergone by the other services named in the consultation document (treatment agencies and hostels) and any others identified as partners in the programme. These services would also be well placed to support the rollout of training on the administration of naloxone, providing it in a safe and comfortable environment for family members. Many family support services are commissioned by their local authority and work closely with local commissioners, so this process can run effectively alongside other planned activities involving locally commissioned services.

Adfam cannot see any negative consequences of widening access to naloxone in this way. The risks of diversion of naloxone into the illicit market is minimised already because it cannot be misused, and the fact that training is necessary to have access to it means that only families with a genuine concern in avoiding overdose deaths would become involved in the process of widened access.

B. The relevance and impact of the criteria

If you are someone who:

- does not yet have access to naloxone
- interacts with opiate users on a regular basis
- can reasonably be expected to be present when a user experiences an overdose

please indicate in what capacity you have contact with users and answer questions i-vii below:

□housemate of user □parent of user □outreach worker □hostel staff/operator □friend of user □other (please specify)

i) Do you currently have access to naloxone? If yes, through what mechanism?

ii) If you did not have access to naloxone before, would this proposal allow you to access/ receive it?

iii) If you are eligible to access naloxone under the proposal, would you or your organisation consider stocking naloxone and completing (mandatory) training in administering it?

iiia) If you answered question iii) with yes, can you please indicate how many units you are expecting to request/buy and use in a twelve month period under this proposal (assuming that one unit of naloxone would treat one overdose)?

iv) Are you aware of any risks associated with the use of naloxone? Do you think there is potential for abuse in allowing wider access to naloxone?

v) Do you have regular contact with individuals who inject opiates such as heroin? How often do you see them?

vi) How many overdoses have you observed in the past 12 months?

vii) Where/in what setting have these overdoses occurred (e.g. hostel/private home of drug user etc.)?

C. Naloxone manufacturers

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

D. How we treat your response

* My reply may be made freely available.

Signed: 

Joss Gaynor
Director of Policy and Regional Development

* Delete as appropriate