**Annex D MLX 388: PROPOSALS FOR AMENDMENTS TO HUMAN MEDICINES REGULATIONS 2012**

To: Paul Jenkins

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Policy and Strategy Unit

Department of Health

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LONDON

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From: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**CONSULTATION LETTER MLX 388: PROPOSALS FOR AMENDMENTS TO HUMAN MEDICINES REGULATIONS 2012 TO ENABLE PUBLIC HEALTH ENGLAND TO DEVELOP AND AUTHORISE PATIENT GROUP DIRECTIONS**

**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.

**B. The relevance and impact of the criteria**

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| --- |
| Q1: Do you agree with the proposal to include PHE and PHA in the list of authorising bodies under the provisions in medicines legislation to develop, authorise and administer Patient Group Directions? If not, why not? |
| A: |
| Q2: We would welcome information on any instances where you believe that there will - or could be - any adverse effect on equality issues under any of the following:  • competition assessment;  • small firms impact test;  • legal aid;  • sustainable development;  • carbon assessment;  • other environment;  • health impact assessment;  • race equality;  • disability equality;  • gender equality;  • human rights;  • rural proofing. |
| A: |
| Q3: You are invited to comment on the proposed changes to medicines regulations governing the use of PGDs. |
| A: |
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**C. 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