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| *[Letter to be given to the GP. This provides the GP with some background on the request for a test]* | **MHRA**  151 Buckingham Palace Road  London  SW1W 9SZ  United Kingdom  www.gov.uk/mhra |

Dear Colleague

**Referral for genetic testing**

We are writing to support this patient’s request for a referral to their local Genetics Service for further diagnostic investigations.

For many years, the longstanding suspicion that Hormone Pregnancy Tests could have led to adverse birth outcomes meant that many children with congenital anomalies may not have been investigated, as might have been expected.

In 2015 a Scientific Expert Working Group of the Commission on Human Medicines (CHM) was convened at the request of George Freeman, the then Minister for Life Sciences, into whether taking Primodos or other hormone pregnancy tests in the 1960s-70s to confirm a pregnancy, could have led to birth defects. The report on the Expert Group findings is available on the CHM website[[1]](#footnote-1) and recommends that a full up-to-date genetic clinical evaluation, in line with current best practice, should be offered to families of the Association for Children Damaged by HPTs, whose lives have been impacted by adverse pregnancy outcomes and who were given HPTs to diagnose pregnancy.

To facilitate this, we attach a template for the referral letter that you may like to use. You can find your nearest genetics centre at the following website: <http://www.bsgm.org.uk/information-education/genetics-centres/>.

With many thanks for your help.

**Medicines and Healthcare products Regulatory Agency**

**MHRA**

**Referral letter from GP to Genetic Service**

*[To be completed by the GP on the surgery’s headed notepaper and sent to the test centre. A Word version of this letter may be accessed at:* <https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-hormone-pregnancy-tests>*or alternatively by Googling CHM HPT and selecting the second tab on the front page: “Referral letter for genetic testing”]*

Dear Colleague

**Re: *[Patient’s details]***

I would be most grateful if you could offer ***[patient’s name****]* an appointment to investigate the possibility of an underlying genetic cause of his/her *[****patient’s condition****]*.

This referral follows the publication of the report from the Scientific Expert Working Group on Hormonal Pregnancy Tests which recommended that a full up-to-date genetic clinical evaluation, in line with current best practice, should be offered to families of the Association for Children Damaged by HPTs, whose lives have been impacted by adverse pregnancy outcomes and who were given HPTs to diagnose pregnancy.

For many years, the question of whether Hormone Pregnancy Tests could have led to adverse birth outcomes meant that many children with congenital anomalies, and other disorders, may not have been investigated as thoroughly as is now possible, for a genetic cause of their features. ***[Patient’s name****]* would now welcome detailed investigations as to the cause of **his / her** problems, as appropriate.

With many thanks for your help and understanding.

***[GP contact details]***

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| To: Genetic Services  *[**To accompany the letter from the GP to the test centre and provide background information to support the request for a test]* | **MHRA**  151 Buckingham Palace Road  London  SW1W 9SZ  United Kingdom  Website: [www.gov.uk/mhra](http://www.gov.uk/mhra)  e-mail: pharmacovigilanceservice@mhra.gov.uk |

Dear Colleagues

**Re: Expert Working Group on Hormonal Pregnancy Tests**

**Undertaken for the Commission on Human Medicines, Medicines and Healthcare products Regulatory Agency, UK**

Following many years of uncertainty as to whether taking Primodos, or other oral hormone pregnancy tests in the 1960s-70s, could have led to birth defects, a Scientific Expert Working Group of the Commission on Human Medicines (CHM) was convened at the request of George Freeman, the then Minister for Life Sciences, to review the available evidence. The report on their findings is now available on the CHM website1. The Group concluded that the available scientific evidence, taking all aspects into consideration, does not support a causal association between the use of HPTs, such as Primodos, during early pregnancy and adverse outcomes, either with regard to miscarriage, stillbirth or congenital anomalies.  
  
One of the recommendations of the Group was that the families and members of the ‘Association for Children Damaged by Hormone Pregnancy Tests’ group, who had requested the enquiry, consider seeking a referral to Clinical Genetics for a full diagnostic assessment. The individuals who were exposed to Primodos or HPTs *in utero* will now be in their 40's and 50's but may never have been assessed by a Clinical Geneticist, whether due to the uncertainties related to Primodos or due to lack of availability of wider genetic testing at the time of their birth. We thought it would be useful for you to know about the report from the Expert Working Group, and their recommendations, should you receive such a referral. A full work up including referral to the 100,000 genome project, if other testing does not provide an aetiology, is likely to be welcomed to help provide them with much needed answers.

With many thanks for your help and understanding,

**Medicines and Healthcare products Regulatory Agency**

**MHRA**

<https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-hormone-pregnancy-tests>

1. <https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-hormone-pregnancy-tests> [↑](#footnote-ref-1)