**New Medicine Service Pilot Patient Information**

**1 Title of Project** New Medicine Service Pilot

**2 Invitation**

You are invited to take part in a research study. Before you decide, it is important that you understand why the research is being done and what it will involve. This *Information Sheet* tells you about the purpose, risks and benefits of this research study. If you agree to take part, we will ask you to sign a *Consent Form*. If there is anything that you are not clear about, we will be happy to explain it to you. Please take as much time as you need to read this information. You should only consent to participate in this research study when you feel you understand what is being asked of you, and you have had enough time to think about your decision. Thank you for reading this.

**3 Purpose of the Study**

This study is concerned with helping patients to understand their condition and get the most out of their new medicine. Your part in the study will last for one month. Between 30% and 50% of prescribed medicines are not taken as recommended. This means that a lot of medicines are wasted or are not as effective as they could be. The study is designed to understand what methods work best in helping patients get the most from their new medicine.

A New Medicine Service is for people who have received their first prescription for a medicine to treat any of the following conditions:

* Asthma
* Lung conditions such as chronic bronchitis and emphysema
* Type 2 diabetes
* High blood pressure
* Conditions where you take a medicine to control the way your blood clots
* High cholesterol
* Chronic pain

You have been asked to participate in the study because you have been prescribed a medicine for the first time for one of these conditions. The study will follow 500 patients from 50 pharmacies around the country for three months.

**4 Taking Part – What it Involves**

This section states what taking part in the study will involve for you. The questions and answers shown below should help you better understand the study.

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this *Information Sheet* to keep and be asked to sign a *Consent Form* and given a copy to keep. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your rights in any way.

**What will happen to me if I take part?**

If you agree to take part, you will randomly be put into one of two groups.

1. The first group will receive a telephone call from the pharmacist after 7-14 days or be asked to come back to the pharmacy and the pharmacist will ask some questions about how you are getting on with your new medicine, find out if you are having problems and give you any information and support you need. After one month, the pharmacist will again make contact, either over the phone or when you come in to collect your next prescription, and ask some further questions about your medicine. At either time, if you have any concerns or questions about your new medicine, you can ask the pharmacist.
2. The second group will only receive contact from the pharmacist after one month, either over the phone or when you come in to collect your next prescription, when they will ask some questions about your medicine. At this time, if you have any concerns or questions about your new medicine, you can ask the pharmacist.

**How long will my part in the study last?**

Your part in the study will last for one month and the pharmacist will collect more data over the next two months but will not need to contact you.

**What are the possible benefits in taking part?**

A New Medicine Service will help provide better value for you and/or the Health Service Executive (HSE) by making sure that your medicine is right for you. The service will:

* help you to find out more about the new medicine you are taking
* help to sort out any problems you are having with your new medicine
* give you a chance to ask questions about your medicine and discuss any concerns
* help to improve the effectiveness of your new medicine, for example, there may be an easier or better way to take it
* help you to make decisions about managing your condition
* help you to improve your health, which could lead to fewer GP and hospital visits.

**What are the possible disadvantages and risks of taking part?**

There are no foreseeable risks attached to taking part in this study. If you find that you are having a lot of problems with your new medicine, the pharmacist will recommend that you go back to see your GP.

**What happens at the end of the study?**

When all of the data has been collected, only general findings will be reported, without reference to any identifiable patients.

**What happens if I change my mind during the study?**

You are entitled to change your mind about participating in this study at any time without disadvantage or penalty.

**Who do I contact for more information or if I have further concerns?**

You can contact your local pharmacist. If you have any concerns about this study and wish to contact someone independent and in confidence, you may contact: Chairperson of the NUI Galway Research Ethics Committee, c/o Office of the Vice President for Research, NUI Galway, ethics@nuigalway.ie.

**5 Confidentiality**

All information that is collected about you during the course of this research will be kept strictly confidential and will not be shared with anyone else. The information collected in this research study will be stored in a way that protects your identity. Results from the study will be reported as group data and will not identify you in any way.

**6 Summary**

If you are unclear about any part of this study or have any questions, you should contact your local pharmacist in the first instance. Alternatively, you can contact the study’s Principal Researcher: Pamela Logan, Director of Pharmacy Services, Irish Pharmacy Union, Butterfield House, Butterfield Avenue, Dublin 14, Tel: 01 493 6401, email: pamela.logan@ipu.ie.

You are free to refuse to take part in the study without any disadvantage. If you do agree to take part in the study, you can change your mind at any point during the study and decide not to continue in the study without any disadvantage.