HEALTHCARE PROFESSIONAL EDUCATION/DISCUSSION GUIDE

The prescriber/HCP should discuss the information below pertaining to the following risks with the patient at first prescription, and give the patient the Patient Card.
Please see the SPC for full prescribing information.

Patient's first name:	Patient's age:
First visit date:	Patient's gender: Male □ Female □
First prescription date:	Today's date:

HEPATIC EFFECTS

□ Discuss the risk of liver effects, and the need to check liver function tests before treatment and periodically during treatment as per label. Educate the patient about signs and symptoms of liver disease, and about the need to contact their doctor if these develop.

PREGNANCY & LACTATION

In women of childbearing potential, exclude pregnancy and emphasise the need for effective contraception before starting, and during treatment with Aubagio®.

□ Advise the patient that she should contact the doctor/HCP immediately if she stops contraception or prior to changing contraceptive measures.

□ If a female patient becomes pregnant despite using contraceptive measures, she should stop using Aubagio® and contact her doctor immediately who should:
- consider and discuss with the patient the accelerated elimination procedure
- encourage the patient to enroll in a pregnancy registry.

□ Discuss the availability of optional reminder services for effective contraception.

HEMATOLOGICAL EFFECTS

□ Discuss the risk of decreased blood cell counts (affecting mainly white blood cells). Discuss the need for complete blood cell counts before treatment, and when sign and symptoms show during treatment.

HYPERTENSION

□ Discuss the risk of blood pressure increase. Educate the patient to tell their doctor if they have hypertension, and discuss the need for blood pressure checks before and periodically during treatment.

INFECTIONS

□ Discuss the risk of infections/serious opportunistic infections, including the need to contact their doctor in case of signs or symptoms of infection, or if the patient takes other medicines that affect the immune system. If serious infection occurs, an accelerated elimination procedure may be considered.

PATIENT CARD

□ **Please provide the patient with the Patient Card, to be used as a tool to remind the patient and to relay information to other doctors/HCPs involved with their incidental medical care (especially in case of medical emergencies and/or if new doctors/HCPs are involved). Please remind the patient to contact their doctor/HCP in case of signs or symptoms discussed in the Patient Card.**

The patient has been informed about and understands the benefits of and risks associated with this treatment. Female patients have been checked for pregnancy, advised of the need for reliable contraception, informed about the option of the Aubagio® accelerated elimination procedure and the existence of a pregnancy registry.

At prescription renewal, adverse events are checked, ongoing risks and their prevention are discussed, and checks are made to ensure adequate monitoring is taking place.

Prescriber's name:	Prescriber's signature:

Call for reporting:
Healthcare professionals should report any adverse events suspected to be associated with the use of Aubagio to Sanofi Malta Ltd., 3rd Floor, Avantech Building, St. Julian's Road, San Gwann SGN 2805. Tel: 21493022, fax 21493024

Alternatively any suspected ADRs and medication errors can be reported to the Medicines Authority. Report forms can be downloaded from HYPERLINK "http://www.medicinesauthority.gov.mt/adrportal" www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to HYPERLINK "mailto:postlicensing.medicinesauthority@gov.mt" postlicensing.medicinesauthority@gov.mt