Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Bimzelx 160 mg solution for injection in pre-filled syringe
Bimzelx 160 mg solution for injection in pre-filled pen

PLGB 00039/0802 & 0803

bimekizumab

UCB Pharma Ltd

LAY SUMMARY

Bimzelx 160 mg solution for injection in pre-filled syringe
Bimzelx 160 mg solution for injection in pre-filled pen
bimekizumab

This is a summary of the Public Assessment Report (PAR) for Bimzelx 160 mg solution for injection in pre-filled syringe and Bimzelx 160 mg solution for injection in pre-filled pen. It explains how these products were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

These products will be referred to as Bimzelx in this lay summary for ease of reading.

For practical information about using Bimzelx, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Bimzelx and what is it used for?
These products have been authorised by MHRA for Great Britain (consisting of England, Scotland and Wales). This procedure relies on a European Commission (EC) decision on 20th August 2021 (EMEA/H/C/005316/0000), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP). This is known as the EC Decision Reliance Procedure.

Bimzelx is used in the treatment of a skin condition called plaque psoriasis in adults.

How does Bimzelx work?
Bimzelx contains the active substance bimekizumab and is used in adults to treat a skin condition called plaque psoriasis. Bimzelx reduces the symptoms, including pain, itching, and scaling of the skin.

Bimekizumab belongs to a group of medicines called interleukin (IL) inhibitors. Bimekizumab works by reducing the activity of two proteins called IL-17A and IL-17F, which are involved in causing inflammation. There are higher levels of these proteins in inflammatory diseases such as psoriasis.

How is Bimzelx used?
The pharmaceutical form of these medicines is pre-filled syringe and pre-filled pen and the route of administration is subcutaneous injection.

The recommended dose for adult patients with plaque psoriasis is 320 mg (given as 2 subcutaneous injections of 160 mg each) at week 0, 4, 8, 12, 16 and every 8 weeks thereafter. Consideration should be given to discontinuing treatment in patients who have shown no improvement by 16 weeks of treatment.

For further information on how Bimzelx is used, refer to the PIL and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

These medicines can only be obtained with a prescription.

The patient should ask the administering healthcare practitioner if they have any questions concerning the medicine.

What are the possible side effects of Bimzelx?
For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPCs available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on behalf of someone else they care for, directly via the Yellow Card scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

The most common side effects with Bimzelx (which may affect more than 1 in 10 people) are upper respiratory infections with symptoms such as sore throat and stuffy nose.

Why was Bimzelx approved?
MHRA decided that the benefits are greater than the risks and recommended that these medicines can be approved for use.

What measures are being taken to ensure the safe and effective use of Bimzelx?
A Risk Management Plan (RMP) has been developed to ensure that Bimzelx is used as safely as possible. Based on this plan, safety information has been included in the SmPC and the PIL, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored and reviewed continuously.

Other information about Bimzelx
Marketing authorisations were granted in Great Britain (consisting of England, Scotland and Wales) on 25 August 2021.

The full PAR for Bimzelx follows this summary.

This summary was last updated in October 2021.

TABLE OF CONTENTS

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the applications for Bimzelx 160 mg solution for injection in pre-filled syringe & Bimzelx 160 mg solution for injection in pre-filled pen (PLGB 00039/0802-3) could be approved.

The products are approved for the following indication:
Bimzelx is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

The name of the active substance is bimekizumab.

Bimekizumab is a humanised IgG1/κ monoclonal antibody that selectively binds with high affinity to IL-17A, IL-17F and IL-17AF cytokines, blocking their interaction with the IL-17RA/IL-17RC receptor complex. Elevated concentrations of IL-17A and IL-17F have been implicated in the pathogenesis of several immune-mediated inflammatory diseases including plaque psoriasis. Bimekizumab inhibits these proinflammatory cytokines, resulting in the normalization of skin inflammation and as a consequence improvement in clinical symptoms associated with psoriasis. From in vitro models, bimekizumab was shown to inhibit psoriasis-related gene expression and cytokine production to a greater extent than inhibition of IL-17A alone.

These products have been authorised by MHRA for Great Britain (consisting of England, Scotland and Wales). This procedure relies on a European Commission (EC) decision on 20th August 2021 (EMEA/H/C/005316/0000), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP). For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the European Medicines Agency (EMA), please refer to the European Public Assessment Report, available on the EMA website.

These applications were submitted under Regulation 50 of the Human Medicines Regulation 2012, as amended (previously Article 8.3 of Directive 2001/83/EC, as amended).

In line with the legal requirements for children's medicines, the application included a licensing authority decision on the agreement of a paediatric investigation plan (PIP) {P/0375/2019}

At the time of the submission of the application the PIP was not yet completed as some measures were deferred.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these products at all sites responsible for the manufacture, assembly and batch release of these products.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Marketing Authorisations were granted on 25th August 2021.

II. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION SUMMARY OF PRODUCT CHARACTERITICS (SmPC)

The SmPCs are in line with current guidelines and are satisfactory.

PATIENT INFORMATION LEAFLET

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

MHRA considered that the quality data submitted for these applications is satisfactory.

The grant of marketing authorisations is recommended.

IV. NON-CLINICAL ASPECTS

MHRA considered that the non-clinical data submitted for these applications is satisfactory.

The grant of marketing authorisations is recommended.

V. CLINICAL ASPECTS

MHRA considered that the non-clinical data submitted for these applications is satisfactory.

The grant of marketing authorisations is recommended.

VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) has been provided with the application, in accordance with legal requirements.

The PIL has been evaluated via a user consultation study in accordance with legal requirements. The results show that the PIL meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

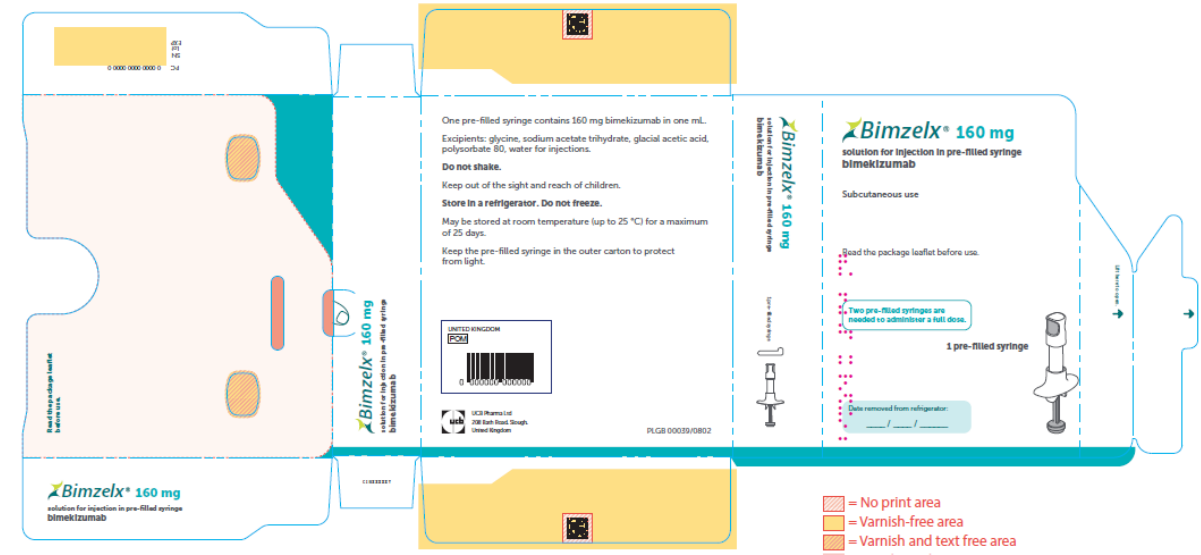
VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

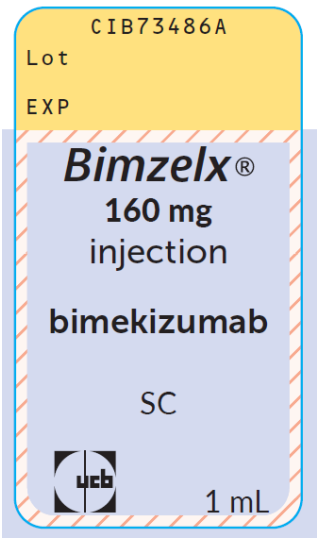
The quality of the products are acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

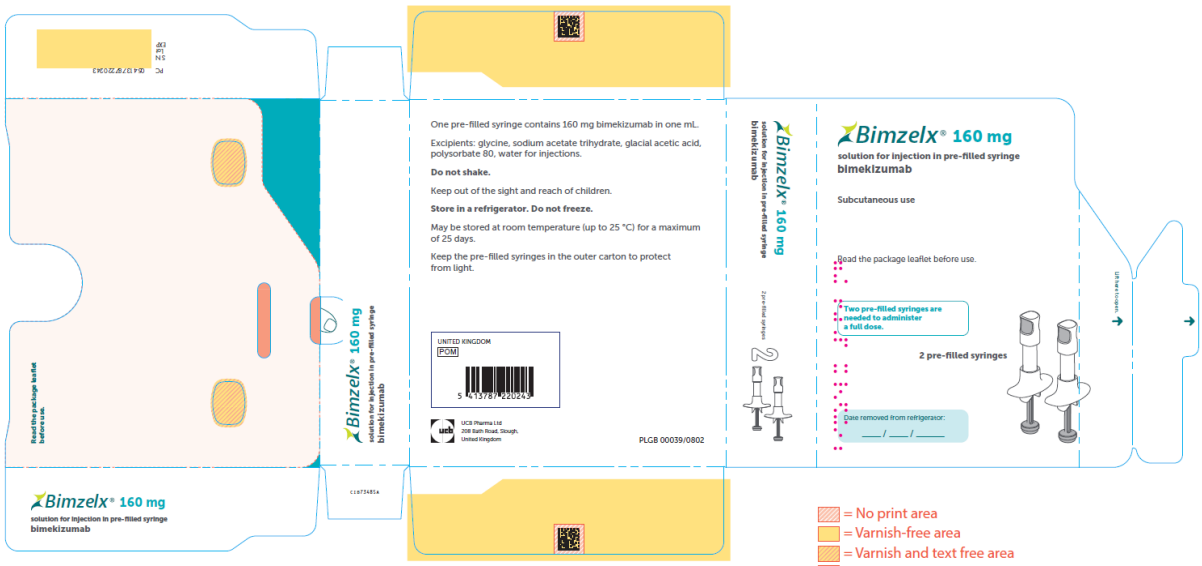
The Summaries of Product Characteristics (SmPCs), Patient Information Leaflet (PIL) and labelling are satisfactory.

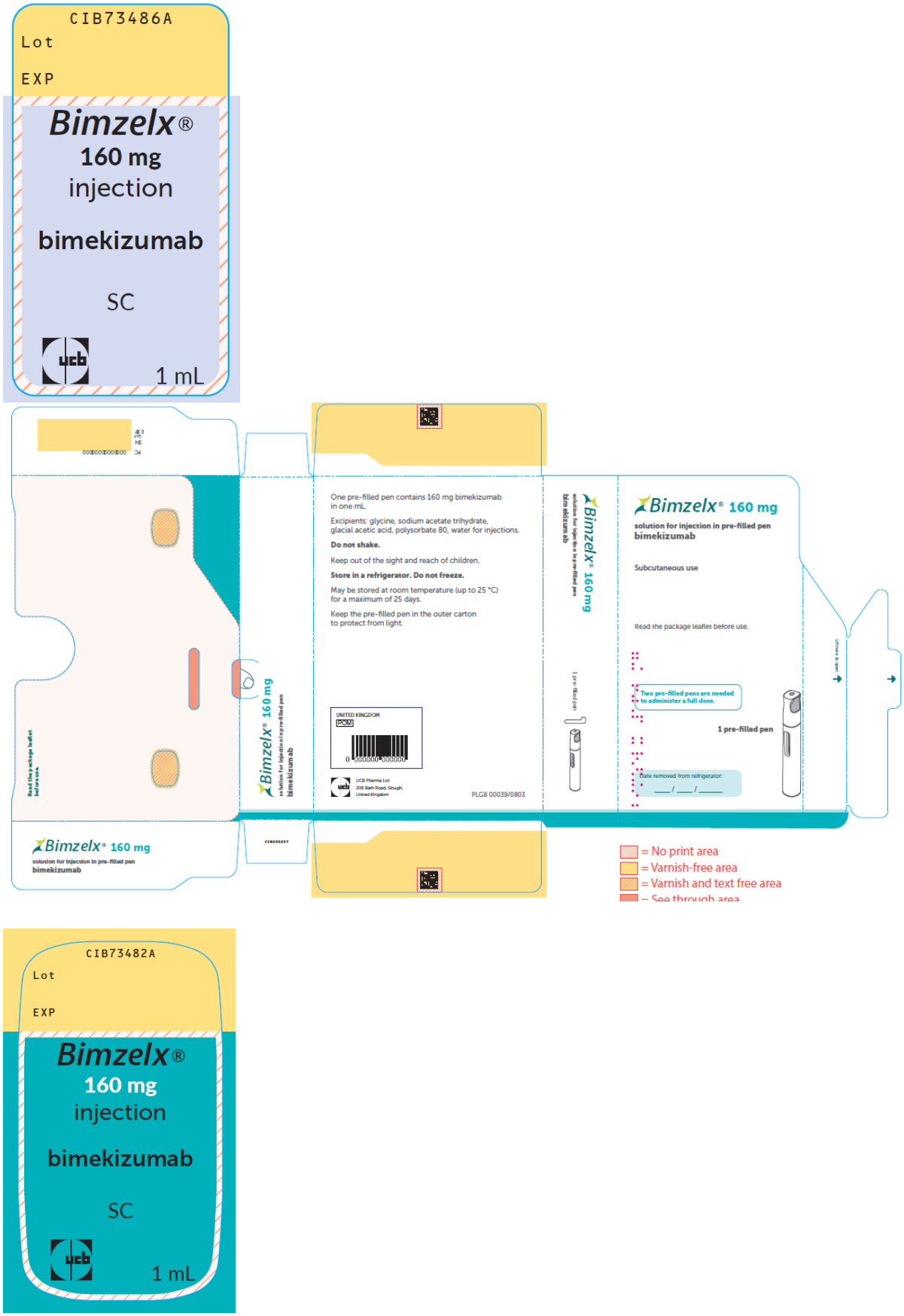
In accordance with legal requirements, the current approved UK versions of the SmPCs and PIL for these products are available on the MHRA website.

Representative copies of the labels at the time of UK licensing are provided below.








CIB73486A
Lot
EXP
Bimzelx®
160 mg
injection
bimekizumab
SC
1 mL
One pre-filled pen contains 160 mg bimekizumab in one mL.
Excipients: glycine, sodium acetate trihydrate, glacial acetic acid, polysorbate 80, water for injections.
Do not shake.
Keep out of the sight and reach of children.
Store in a refrigerator. Do not freeze.
May be stored at room temperature (up to 25 °C) for a maximum of 25 days.
Keep the pre-filled pen in the outer carton to protect from light.
UNITED KINGDOM
POM
PLGB 00039/0803
Bimzelx® 160 mg
solution for injection in pre-filled pen
bimekizumab
Subcutaneous use
Read the package leaflet before use.
Two pre-filled pens are needed to administer a full dose.
1 pre-filled pen
Date removed from refrigerator:
___/___/____
= No print area
= Varnish-free area
= Varnish and text free area
= See through area
CIB73482A
Lot
EXP
Bimzelx®
160 mg
injection
bimekizumab
SC
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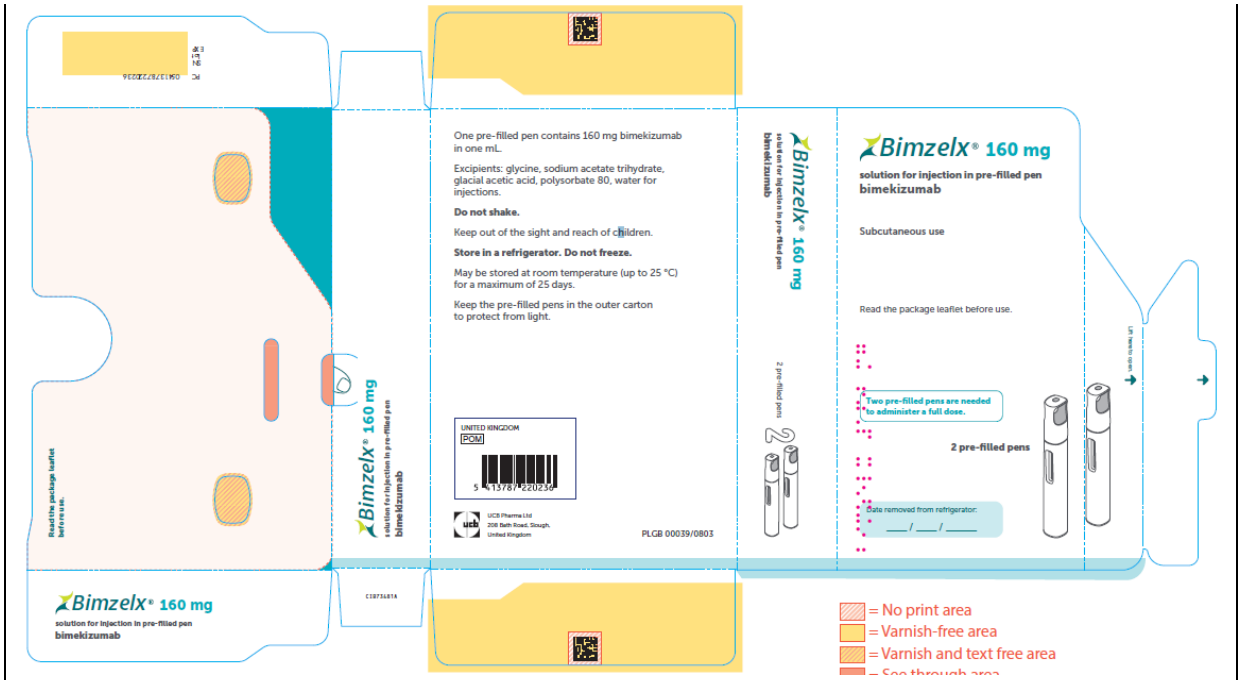
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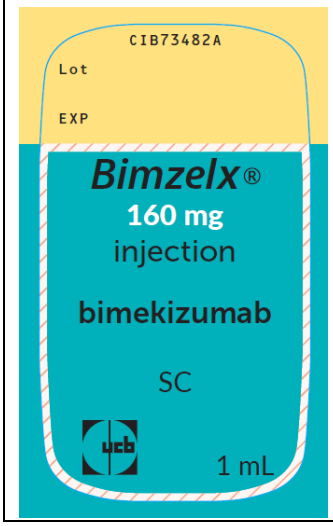
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TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**