

PREParing the next step

BAT has taken an important first step towards less hazardous cigarettes with the launch of a clinical study of prototype cigarettes designed to produce less toxicants in smoke.

The vast majority of tobacco users are smokers. Providing them with less harmful, consumer-acceptable combustible alternatives to their conventional cigarette, amidst a growing jungle of anti-tobacco legislation and so far mostly unclear regulations, is a long-term task for the leading cigarette manufacturers. Concrete results in the form of marketable products are approximately ten to fifteen years away. This May, British American Tobacco (BAT), the world's second-largest cigarette manufacturer, shed some light on the progress of its development of potentially reduced exposure products (PREPs) when it announced that it had initiated a clinical study on experimental prototype cigarettes designed to produce less toxic smoke than conventional products.

While the study is not the first clinical study BAT has done, it is the first time they have tested the three new technologies in a clinical setting. These technologies – tobacco treatments, blend additives and novel filters – are used in various combinations to produce three prototype combustible products.

The clinical study, a single-blinded, controlled study, began in March in Hamburg, Germany. It involved 300 volunteers, 250 healthy habitual smokers and 50 healthy non-smokers and was designed to evaluate the effects of novel cigarette designs on biomarkers of exposure, filter analysis and sensory tests.

Over a six-week period, study participants were confined within the clinic on three occasions where they were asked about their medical and smoking histories and completed a questionnaire on quality of life. Physiological measurements such as blood pressure and lung

function were taken, as well as samples of urine and saliva. The 250 smokers were divided into five groups of 50, two of which habitually smoke 6 mg ISO tar cigarettes, and the remaining three smoke 1 mg ISO tar cigarettes. During the study all groups smoked a conventional cigarette at their normal ISO tar yield for two weeks. After this time, one group at each ISO tar yield continued to smoke the conventional cigarette while the remaining groups of the smokers were asked to switch to one of the three prototype products. The aim is to determine whether the smokers who switch to a prototype product have fewer markers of toxicants, i.e. biomarkers of exposure, in their biological fluids than those who continue to smoke their regular cigarettes. The non-smokers act as a control.

The prototypes used in the study are referred to as “reduced toxicant products” (RTPs). BAT defines RTPs as products that produce lower amounts of specific smoke toxicants per unit of tar compared to a reference or benchmark product, as measured under “intense” machine conditions. The study targets well-recognised toxicants that are implicated in smoking-related diseases. An

example of the toxicants the prototypes seek to reduce is the volatile compound acrolein, which is an irritant and may be associated with both COPD [chronic obstructive pulmonary disease] and heart disease. Nevertheless, the company admits that at this stage it does not know if it has targeted all the relevant toxicants or if it has reduced them sufficiently to make a difference on the potential health effects. It is only at this stage that an RTP can be accepted as a PREP. It is also not possible to say as yet whether reducing toxicant levels in smoke will reduce toxicant exposure in the smoker although the results of the clinical trial will clarify this.

The three prototypes all use various combinations of novel technologies, of which only one component, an ion exchange resin used as an additive in the filter, is not compliant with TVO. TVO is the German tobacco ingredients regulation setting out permitted ingredients. BAT has been granted a temporary exemption for the ion-exchange resin for testing in the clinical study.

One prototype uses a two-part filter with activated carbon dispersed in cellulose acetate in the section nearest to the tobacco rod. The remaining prototypes were designed with additives dispersed in the two sections away from the mouth end. The resin used in this filter is a commercially produced material similar to that used in water purification facilities.

The modified tobacco blend is a selection of specially selected tobaccos, tobacco that is processed to generate fewer toxicants as it burns and a blend additive that releases a non-toxic substance to dilute the cigarette smoke. One such treatment used enzymes similar to those in biological washing powders to break down proteins in the tobacco.

The trial costs BAT about GBP 5 to 6 million (EUR 5.87 to 7.06 million) and is part of a research and development programme that costs about GBP 105 million annually, a substantial portion of which is invested in research related to potential reduced risk tobacco products. BAT hopes to publish the results of the clinical trial in a scientific journal.

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In essence

- ▶ BAT's clinical study tests three new prototype combustible products
- ▶ Prototypes combine novel filter technologies, new blends
- ▶ Aim is to prove reduction of certain toxicants