NJOY Innovations Ltd has submitted an application in December 2017 to MHRA for marketing authorization of a medicinal e-cigarette product.

- The application is currently under review by the MHRA and we expect to hear from them soon on their questions resulting from their review. We believe there is significant interest and unmet need for such a product.
- It is our intent for the marketed product to be manufactured in the United Kingdom. To that end, NJOY has already invested in the development of initial manufacturing capacity and infrastructure and are pursuing further capacity also within the United Kingdom.
- We are earnestly working through the regulatory process with a view to bringing the product to market. We believe this is viable as long as MHRA exercises its authority in the full context of a policy framework that considers the significant potential benefits of such a product and its relatively small risks for its users compared to continued smoking.

The following additional information may be helpful

1. NJOY Innovations Limited is a UK-chartered company formed in 2013. NJOY Innovations is a wholly-owned subsidiary of NJOY LLC, a U.S.-based ENDS company. NJOY was one of the pioneers of the U.S. ENDS industry and is, and has been since its inception, independent from the tobacco industry.

2. Since its formation, NJOY Innovations has closely followed the development of UK ENDS regulations – recognizing the UK’s leadership position on the subject of pragmatic and proportionate regulation of ENDS products. NJOY Innovations has conducted several formal scientific advice meetings with MHRA in anticipation of a possible medicinal filing, and appreciates the efforts of the Health Ministry and MHRA in creating and evolving a medicinal pathway for ENDS products that may be viable for independent companies like NJOY Innovations that lack the resources of the major tobacco companies, while still adequately assuring safety and efficacy. NJOY Innovations encourages the continued refining of the medicinal pathway to ensure that it strikes the right balance between protecting the public, while incentivizing the development and approval of potentially life-saving ENDS products.

3. NJOY Innovations believes that there remains an important role within the UK for a medicinally approved ENDS product, which by virtue of its approval will be able to provide smokers and health care practitioners with sufficient assurance of the approved product’s safety and efficacy for the intended purpose. As well, for many smokers, the availability of NHS reimbursement for a medicinally-approved ENDS may be the single factor that precipitates quitting. Continuing uncertainty and confusion regarding the relative safety of ENDS products has, in the view of NJOY Innovations, unnecessarily slowed the displacement of combustion products by ENDS. NJOY Innovations therefore believes that there could be significant public health impact to the achievement of medicinal approval for ENDS within a UK context.

4. Medicinal approval will only have true public health significance if it is followed by commercial distribution of the approved product within the UK, and NJOY Innovations is committed to securing the national distribution of an approved product within the UK as rapidly as possible following approval.

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