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Patient access to combination therapies

What is a combination therapy?

- A combination therapy combines two or more individual medicines (components) into a single treatment regimen. The challenges and solutions needed that are described in this paper relate to combination therapies that comprise two or more branded (on patent) medicines that are not packaged together (this is the norm for not t x Comos[illegible]PLB@[illegible]diseases, including COVID-19, rheumatoid arthritis and non-alcoholic steatohepatitis (N the most severe form of non-alcoholic fatty liver disease.
    - Combination therapies can improve patient outcomes by targeting different disease pa in a synergistic way. They can also reduce disease resistance to the beneficial effects medicines. In cancers, this can reduce tumour growth and prevent the spread of cance other areas of the body.

What are the challenges in enabling patient access to combination therapies?

- Challenges around patient access to combination therapies have been a growing focus internationally for several years. In the UK, these issues were identified as having an impact on patients when it started becoming apparent that several combination therapies could not be recommended for use on the NHS by the National Institute for Health and Care Excellence (NICE) – the Government's arms-length body which determines whether new healthcare technologies are value for money (clinically and cost effective). The number of

working paper[3], and NHS England in its Commercial Framework for New Medicines[4]. The ABPI considers the key challenges, and solutions required to overcome them, fall within five 'buckets':

1. Cross company dialogue

When components of a combination therapy belong to different companies, dialogue between the companies may be needed to determine a combined price that can be considered cost effective by NICE. Companies consider there is a high level of risk engaging with each other due to concerns about infringing competition law and the penalties associated with this.

2. HTA decision making framework

In England[5], NICE determines whether a combination therapy is cost effective using the same framework as it does for individual medicines. The company who manufacturers the new component is responsible for submitting an evidence package to NICE for the combination therapy and pricing their component accordingly. The existing component(s) will already have a price agreed with the NHS that is not reconsidered d/n <</M(C)2.6 (E)Þ/w 6.96 0 0 6.96 109.8 282005 Tc(w-6)-6.6 (

5. Value attribution

Ideally, the components of a combination therapy would be priced relative to the benefit they offer when they are used in combination. Attributing this value to each component is however not straight forwardhen