



Solving the challenge of combination treatments: discussion points from key stakeholder groups on implementing Takeda's proposed solution

Introduction

In 2021 Takeda UK Ltd held four roundtables, each focusing on a different stakeholder group involved in the landscape of combination treatments: the patient, clinical, health economic and competition law communities. These roundtables were organised to debate and critique Takeda's proposed solution to the combination treatments issue, as detailed in two [Whitepapers](#) published in 2021, and to discuss the potential role of each stakeholder in supporting and advocating for a solution to be found and implemented.

Following each roundtable, a report summarised the discussion and areas for further exploration. These individual reports are on the [Takeda UK website](#).

This document summarises the key discussion points from the four roundtables that Takeda will consider when taking the proposed solution forward.

Overview of key discussion points

Addressing uncertainties with imperfect information within the Attribution of Value Methodology

- Explore potential evolution of the Attribution of Value Methodology to reflect a more accurate value attribution to an add-on treatment that has been trialled only as part of a combination (and consequently does not have any data on its value as a monotherapy)
- Consider if there is a role for NICE during negotiations to provide indicative base-case QALY and ICER ranges

Ensuring an acceptable level of burden when using the Voluntary Arbitration Framework

- Undertake individual assessments on the competition law risks at the outset of each negotiation to determine if there are elements of the Framework that can be omitted or modified (e.g., negotiations taking place without the Arbitrator present or using internal clean teams) where the risk of an anti-competitive outcome is minimal

Determining entry criteria for the Voluntary Arbitration Framework

- Produce clear entry criteria for the Voluntary Arbitration Framework that are applied to applicants
- Define which stakeholders could be permitted to signal candidates for consideration through the Framework and who will be responsible for granting entry

Involvement of different stakeholders throughout the proposed solution

- Develop guidance (in collaboration with stakeholders) on how and when health technology assessment (HTA) agencies, payers, patient organisations, clinicians, and clinical groups, and other third parties can input into the process
- Determine which information is made publicly available throughout negotiations to ensure transparency of process and decision-making

Accountability for the operation of the Voluntary Arbitration Framework

- Formalise the exact roles and responsibilities of NICE and NHS England (NHSE) within the Framework, if required
- Develop a draft 'terms of engagement' agreement to outline the conditions that manufacturers must agree to before they can take part in the Framework

The role of the Arbitrator within the Voluntary Arbitration Framework

- Determine who should fulfil the role of the Arbitrator, whether an existing or new entity, and what expertise they require to conduct their functions effectively
- Reflect on whether the outcome of the arbitration process should remain voluntary
- Consider whether a maximum timeframe for company negotiations is adopted and the role of the Arbitrator in setting and managing those timeframes
- Clarify whether there would be any role for the Arbitrator in NICE/NHSE commercial negotiation processes
- Consider the level of involvement the Arbitrator should have during negotiations and whether the 'terms of engagement' could sufficiently govern the behaviour of clean teams, with a mechanism for escalation to an Arbitrator included if required

The constituents of a clean team within the Voluntary Arbitration Framework

- Develop guidance and/or a job specification on the appropriate requirements of a clean team for external validation – including the qualifications/expertise required and whether teams can be wholly internal, or a mix of internal and external, participants

Implementation of non-uniform pricing within the Attribution of Value Methodology

- Secure consensus with NHSE on the consideration of non-uniform pricing within the Commercial Framework in the case of combination treatments

Encouragement of manufacturers to participate in a final solution

- Ensure that a final solution to this issue is included in the next Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) agreement between industry and government to require participation
- Continue to consider additional mechanisms to incentivise and encourage meaningful participation in the process (that reflects the existence of power dynamics between manufacturers)

Next steps

Takeda is continuing its engagement with all interested stakeholders to discuss further the proposals contained within its solution. Takeda continues to welcome comments on its proposed solution from all interested parties, and you can contact the team via: combinationmedicinesUK@takeda.com.