Framework for price agreements

Applicable from the 23rd of June 2020

I. Agreements entered into by the Regional Health Authorities (hereafter referred to as RHAs) are a part of decisions made by the Decision Forum of the National System for Managed Introduction of New Health Technologies within the Specialist Health Services (referred to in Norwegian as Beslutningsforum for Nye Metoder), and must, in general, be based upon a simple discount of list price of a pharmaceutical.

II. The RHAs may, when the market and competition situation require so, enter into alternative price agreements. An assessment is made on a case-by-case-basis. No previous agreement is an indicator of future agreements.

III. The RHAs, represented by The Norwegian Hospital Procurement (hereafter referred to as Sykehusinnkjøp HF), assess whether there should be and alternative price agreement and the contents of it. Sykehusinnkjøp HF may, after pre-approval from the medical directors in the RHAs, initiate drafting of simple agreements, such as agreements with volume discounts. Agreements which are more complex, i.e. including registration of treatment outcome or establishment of start- and stop criteria for treatment, require a pre-approval by the Decision Forum before Sykehusinnkjøp HF can initiate negotiations.

IV. Agreements are subjected to the following pre-defined criteria:
    a. The type of agreement and structure should be simple and not cause notable administrative work for the health services. It is required that the agreements can be managed within existing systems in the Norwegian specialised health care, i.e. considering distribution of price files to the wholesaler and pharmacies, accounting systems, etc.
    b. The type of agreement and structure will be described in the decision on nyemetoder.no and will be transparent and publicly available. Access to an agreement is regulated by the Act relating to the right of access to documents held by public authorities and public undertakings [Freedom of Information Act] and the Act relating to procedure in cases concerning the public administration [Public Administration Act]. Commercially sensitive information is subjected to a statutory obligation of confidentiality/ and exempted from the right to access to information. The RHAs consider whether information should be regarded as commercially sensitive information and therefore subjected to the statutory obligation of confidentiality. It is required that all groups of employees with a professional need for information have access to adequate and necessary information regarding the agreement.
    c. The type of agreement and structure should not cause uncertainty with regards to the pharmaceutical's actual price and/or budget impact. The pharmaceutical companies must document and explain the potential risk associated with the agreement. The variables should be objective and be based upon adequate documentation.
    d. Information regarding practical workflow, the need for data sources and administration of the agreement, along with adequate information to healthcare personnel shall be highlighted before an alternative agreement is decided.

e. The agreement shall be evaluated. Before a decision is made, it must be agreed upon how the agreement is to be followed up, including potential re-evaluation of the decision if updated/new information becomes available. The relation to other pharmaceuticals comprised by other agreements (i.e. public procurements) must be described. Also, situations where competing pharmaceuticals is undergoing a health technology assessment involving a pharmaceutical subjected to an alternative agreement as a comparator must be described.
f. The terms of the agreement must be in accordance with the principles for priority setting in health care, White paper No. 34 to the Storting (2015-2016) – Values in the patient's health care, applicable regulations and comply with Sykehusinnkjøp's guidelines for negotiations.

V. The terms of the agreement are in Norwegian.