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THE ITALIAN MEDICINES AGENCY AIFA OPENS A PUBLIC CONSULTATION ON THE DRAFT GUIDELINES FOR THE PREPARATION OF THE DOSSIER SUPPORTING A PRICE AND REIMBURSEMENT APPLICATION

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Legal Briefings

This is the last step before the implementation of the new procedure for the price and reimbursement negotiation set out in the Decree on price and reimbursement negotiation of 2 August 2019.

The Italian Medicines Agency (AIFA) has launched a **one week public consultation, closing 30 September 2020,** on the draft "**Guidelines for the preparation of the Dossier supporting the price and reimbursement application**" (the Guidelines), i.e. draft guidelines that set out, in practice, the information and documentation that pharmaceutical companies will now be required to submit before AIFA to support their price and reimbursement applications.

THE GUIDELINES UNDER CONSULTATION

The Guidelines under the consultation implement the long-awaited Decree of 2 August 2019 issued by the Ministry of Health and the Ministry of Economy and Finance (Decree on price and reimbursement negotiation) that updates the previous system introduced almost 20 years ago by Decree no. 3/2001 of the Inter-ministerial Committee for Economic Planning (CIPE) and set out new rules and procedures for to be followed by the MA holder before AIFA to receive a reimbursement status for their product and to negotiate the price as reimbursed by the National Healthcare System (NHS).

This public consultation is the final step before the implementation of the new legal framework. The Decree on price and reimbursement negotiation will come into force at the end of the public consultation and at the end October 2020, AIFA will release the final version of the Guidelines.

THE NEW PROCEDURE FOR THE NEGOTIATION WITH AIFA ON PRICE AND REIMBURSEMENT

To summarise, under the new procedure set out by the Decree on price and reimbursement negotiation, there will be a unique 180-day procedure for the negotiation of the price/reimbursement which applies to all medicinal products for which an MA has been granted, either through a national, decentralised, centralised or mutual-recognition procedure. The price negotiated with AIFA will generally remain in effect for 24 months and will be subject to renewal for a further 24 months, unless the MA holder or AIFA propose amendments to the terms of the agreement prior to the revised term of 60 days before its expiry. Otherwise the price agreed will remain valid for a further 24 months.

AIFA will be entitled to start the procedure, without any input from the MA holder, if:

(i) the price of the product has never been negotiated with AIFA;

(ii) if the previous negotiation failed hence the product has been put among the not-reimbursed medicinal product (i.e. in Class C); and

(iii) most importantly, if the reimbursement of the product has a significant impact on the NHS expenditure or the lack of reimbursement has an adverse impact on the possibility to prescribe the medicinal product at issue.

Pursuant to the Decree on price and reimbursement negotiation, AIFA can also trigger a price revision where there is a medium-term change in the market that could lead to an excessive increase in the level of use of the drug or could make the cost of the drug excessive compared to existing alternative medicines. AIFA can commence the pricing review procedure also in the event there is new evidence on the efficacy and safety of the drug showing a substantial reduction in the clinical benefits estimated at the time of negotiation, as well as in the event of a clear shortage of the drug on the Italian market.

In all other cases, the price and reimbursement negotiation will be left to the initiative of the MA holder who is required to submit a Dossier with documents and information which are specified by the Guidelines under consultation. The final decision of AIFA will ultimately depend on the information and documentation which the applicant MA holder will be able to submit.

For example, the revised procedure entails a preliminary phase before the Technical and Scientific Committee (CTS) that must give an opinion on the "added clinical value" of the product with respect to the available treatment or the therapeutic alternatives that are taken as a benchmark - the so called "comparator medicinal products".

This CTS assessment is crucial. Indeed, if the CTS is not satisfied, it may introduce limitations regarding reimbursement and/or give a negative opinion. In this case, the product will automatically be put in the "class C" category for non-reimbursed products unless the MA holder sets the same price or lower level than that of the cheapest comparator medicinal product, or it is able to demonstrate a specific advantage for the NHS.

The assessment is carried out on the basis of any previous evaluations made at EU level, following a meeting with the MA holder (named "scoping meeting") if needed, but ultimately and mainly on the basis of the information disclosed in the Dossier.

The draft Guidelines under consultation detail the documents to be included in the Dossier, the MA holder must disclose specific information, some of which may be extremely confidential. For example, the MA holder must disclose the price or discount obtained in another Member State. Such information may be disclosed only if it is covered by a NdA agreement. The identity of the counterparty and the expiry date of the agreement must nevertheless be disclosed.

The MA holder does not have the option to refuse disclosure of the requested information, even if commercially relevant or confidential.

Moreover, according to the negotiation procedure, when the CTS assessment is positive, the negotiation progresses before the Price and Reimbursement Committee (CPR) for final agreement on price and reimbursement which takes into account some fixed criteria, including the sales volumes, any public R&D subsidy received and/or ad hoc discount granted to the NHS. The outcome of this phase also largely depends on the information disclosed by the company.

Pursuant to the draft Guidelines under consultation, in order to support its price and reimbursement application during this phase, the MA holder must disclose some highly confidential information: for example, specific annual reports regarding sales data, revenues and marketing expenses. Moreover, with respect to public R&D subsidy, the MA holder must specify the total amount received, if there are any IP rights arising from said R&D activity (even if not related to the product at issue) and if so, the patent details such as the number patent and the identity of the patent owner. Moreover, the MA holder must provide information on any pending patent rights protecting the product. In this case, the information to be disclosed under the consultation draft of the Guidelines is of an even more sensitive nature: for each "patent right that is relevant for the market exclusivity of the medicinal product at issue", the MA holder must disclose, in addition to general information such as expiry date, also information potentially confidential, such as any patent licence or any action pending or settled regarding this right.

LAST CALL FOR COMPANIES AND STAKEHOLDERS TO COMMENT

If these draft Guidelines are implemented, in conducting its assessment and ultimately in setting the price and reimbursement , AIFA will rely heavily on the extensive and often confidential or commercially sensitive information that will need to be submitted by the MA holder in the dossier. The importance of the current public consultation opened up by AIFA is therefore clear. This is the last occasion for companies and stakeholders to negotiate the documents and information that AIFA would be entitled to request and, ultimately, to safeguard the companies' confidential and commercially sensitive information.

For more information on AIFA's public consultation or on the price and reimbursement procedure set out by Decree of 2 August 2019, do not hesitate to contact the below key contacts.

KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.

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