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PROPOSAL FOR EARLY ACCESS

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Farmaindustria believes that a revision of the processes for improving time-to-access indicators is essential, thus also achieving compliance with Council Directive 89/105/CE, of 21 December 1988 (Article 6.1), and Article 3.4 of Royal Decree 271/1990 of 23 February, on the reorganisation of the price intervention process of medicines for human use, both of which establish a period of 180 calendar day

Moreover, there are medicines whose inclusion for reimbursement is more urgent as they provide a significant benefit to patients. Many are medicines that have a conventional and complete authorisation through a centralised procedure, with others being authorised by the EMA using special programs such as the Priority Medicines (PRIME) scheme, which entails an accelerated process for authorisation (150 days instead of 210). Medicines following the PRIME scheme target unmet medical needs, those for which no treatment option exists, or which can provide a significant therapeutic advantage with respect to existing treatments. There are also special conditional authorisations for medicines aimed at treating severely debilitating or potentially fatal illnesses and which show a favourable benefit-to-risk ratio and for which the benefit of immediate availability outweighs the risks related to required additional data. There is also the example of extraordinary authorisations, indicated for diseases with a very low prevalence, for which applicants cannot be expected to be able to provide exhaustive evidence and complete data on efficacy and security of the medicine in normal conditions of use is unavailable.

Access to medicines prior to the reimbursement decision is regulated by Royal Decree 1015/2009, of 19 June, which regulates the availability of medicines in special situations, and is limited to exceptional situations where patients suffer a chronic, seriously debilitating, or life-threatening disease which cannot be satisfactorily treated with an authorised medicine. This Royal Decree includes an individualized access process as well as a process for access to medicines not authorised in Spain through a usage protocol (developed by the Spanish Medicines Agency, or AEMPS). All of these are medicines that have not been authorised in Spain or that have been authorized but whose decision for inclusion in the reimbursement list is still pending. That is to say, they are medicines that have not previously been included for reimbursement by the NHS. The price of a medicine in this phase is not intervened, but is rather established by the pharmaceutical company. Delays in the pricing & reimbursement process also create uncertainty among regional

health-services managers and even among prescribers. Given that the same medicines are reimbursed in neighbouring countries, doctors, hospitals and patients themselves are looking to identify individual solutions to mitigate access deficiencies, which creates inequity and inefficient management. Proof of this troubling situation is that, at this moment in time, in some Spanish Autonomous Regions but not in others - or even in some hospitals and not in others within the same Autonomous Region - patients are able to receive treatment with new medicines where a decision for inclusion for reimbursement is still pending.

Farmaindustria's proposal does not call for any legislative revision as it is complementary to that provided for in Royal Decree 1015/2009, of 19 June, which regulates the availability of medicines in special situations, and is in compliance with Title VIII of Royal Decree 1/2015, of 24 July, approving the consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices. This proposal suggests equitable conditions throughout the entire NHS and provides a solution of an immediate nature.

The early-access process has two different phases. The first takes place from the moment a medicine becomes eligible for the AEMPS' special procedure up until a positive decision is made on reimbursement, and the second takes place from the moment when DG Pharmacy (DGCCyF) agrees to begin the process up until a decision for reimbursement has been made for the medicine in question.

GIVEN THAT THE SAME MEDICINES ARE REIMBURSED IN NEIGHBOURING COUNTRIES, DOCTORS, HOSPITALS AND PATIENTS THEMSELVES ARE LOOKING TO IDENTIFY INDIVIDUAL SOLUTIONS TO MITIGATE ACCESS DEFICIENCIES, WHICH CREATES INEQUITY AND INEFFICIENT MANAGEMENT.

A. SELECTION OF MEDICINES

The criteria for selecting medicines that may be eligible for this early-access process must be published and be applied at national level across the entire NHS. The medicine can have a complete and conventional authorisation through the centralised procedure, but also an authorisation which prioritises the medicine as necessary for the benefit of the patient or which has been made available through the Prime scheme. The following criteria for selection could be considered:

- The treatment is meant for a rare, serious or debilitating disease.
- No available authorised treatment exists.
- In the event the medicine shows significant improvement in health outcomes (efficacy or safety) over existing authorised treatments.

B. FIRST PHASE: ACCESS PRIOR TO REIMBURSEMENT DECISION

This phase begins with a medicine becoming eligible for the early-access process. The Spanish Medicines Agency is responsible for selection, with a prior positive report by the DGCCyF following positive opinions in the monthly meetings of the CHMP.

After becoming eligible, companies will express their interest in marketing their medicine in Spain and both the Administration (AEMPS & DGCCyC) and the pharmaceutical company will accordingly agree on access to the medicine under this procedure.

Companies with medicines eligible under this scheme will submit an application for a national code within a maximum of 15 days following the authorisation by the European Commission.

Keeping in mind the wide range of medicines and possibilities of marketing authorisation holders, the price at this phase will be determined by the company and notified to the DGCCyF.

With the aim of reaching an agreement for reimbursement as soon as possible, from the moment a positive opinion is issued by the CHMP and the medicine is eligible for early-access, setting up a suite of meetings would be necessary to facilitate early dialogue between the company and the DGCCyF.

C. SECOND PHASE: ACCELERATED REIMBURSEMENT

Public reimbursement of medicines is regulated by Title VIII of Royal Decree 1/2015, of 24 July, approving the consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices. Spanish regulatory framework requires a positive decision from the responsible body of the Ministry of Health in order for a medicine to be included in the NHS' pharmaceutical provision. The reimbursement process must comply with the provisions of Law 39/2015, of 1 October, on the Common Administrative Procedure of the Public Administration.

The Ministry of Health begins the procedure once the pharmaceutical company obtains a national code. At this point, Farmaindustria's proposal is to guide the procedure towards speedier reimbursement than is convential, and it is therefore referred to as "accelerated".

The accelerated process would have a maximum duration of 90 days from the moment the process is agreed to until a final decision on reimbursement is issued.

The result of the reimbursement process will be a decision that includes reimbursement conditions and a price set by the Inter-Ministerial Medicines Pricing Committee (CIPM) and inclusion on the reimbursement list of the NHS' pharmaceutical provision.

Depending on the fixed price, the corresponding regularisations will be made to the price difference concerning the price established by the pharmaceutical company during the first stage.

In cases of a negative decision following the accelerated process, the pharmaceutical company and the Ministry of Health must, where necessary, agree on the continuity of treatment for patients included in the first stage, distinguishing the temporary nature of these patients being treated (and whose treatment would become the responsibility of the pharmaceutical company) for those patients needing long-term treatment by the medicine in question.

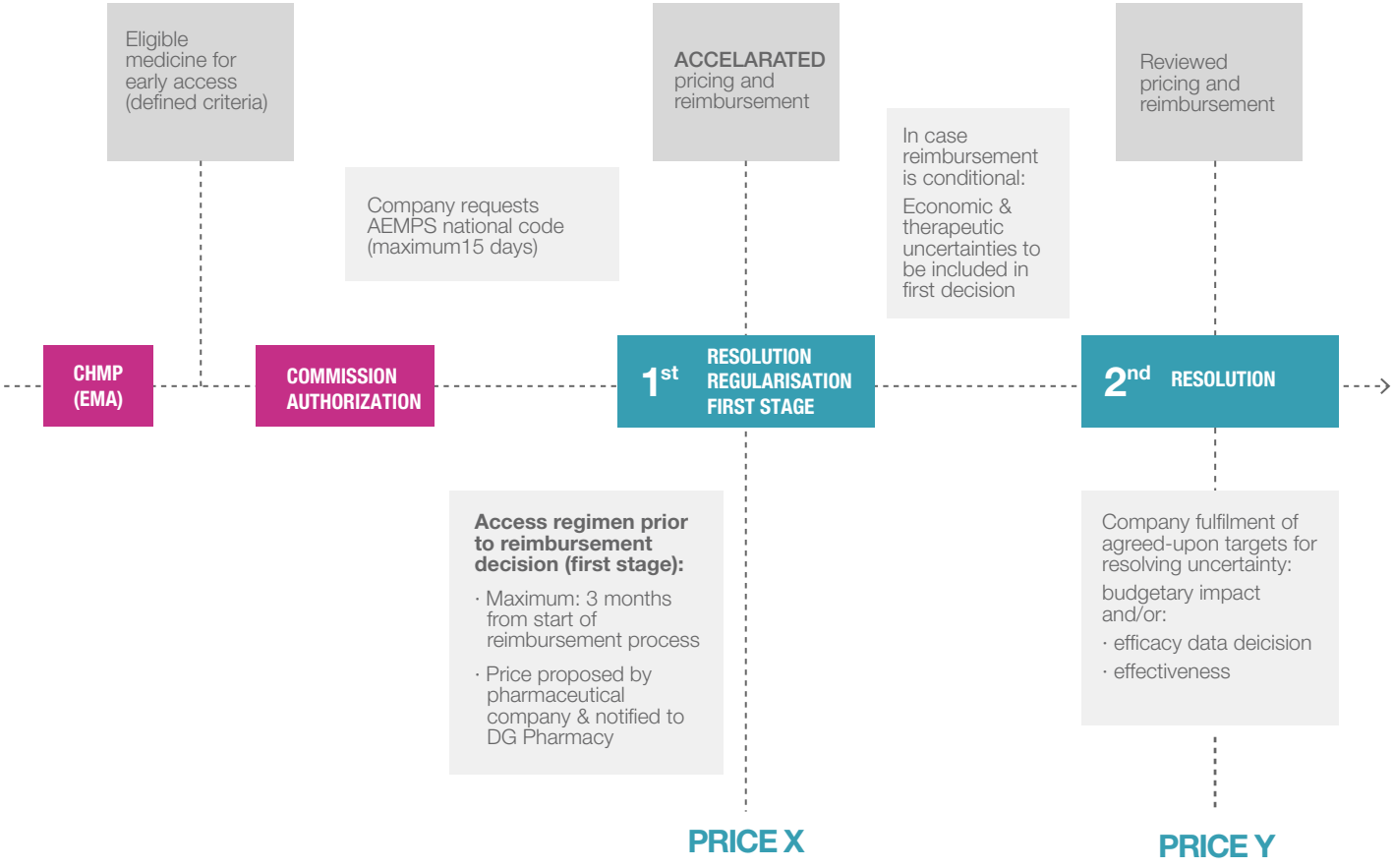
For cases of therapeutic and/or economic uncertainty, a decision on conditional and reviewable reimbursement could be made. To this end, it would be necessary to transparently and

predictably establish the criteria which define uncertainty, justifying a medicine's inclusion for reimbursement through an agreement which in addition to the price, allows for uncertainty to first be managed and subsequently resolved.

When a decision on reimbursement is conditional the first decision would, besides price, have additional agreements determined by the CIPM as well as the requirements to be met by the company to be able to have a second revised reimbursement decision. The second decision on reimbursement could establish additional conditions different to those of the first decision, including the price.

D. PROCEDURE SUMMARY

The following chart summarises the process of the stages described above.



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