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RESOLUTION OF STANDING COMMITTEE 12
(**Hygiene and Health**)

(*Rapporteurs:* BOSONE and SACCOMANNO)

adopted at the sitting of 28 March 2012

CONCERNING THE

PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND THE COUNCIL RELATING TO THE TRANSPARENCY OF MEASURES REGULATING THE PRICES OF MEDICINAL PRODUCTS FOR HUMAN USE AND THEIR INCLUSION IN THE SCOPE OF PUBLIC HEALTH INSURANCE SYSTEMS (COM(2012)84 FINAL)

pursuant to Article 144(1) and (6) of the Rules of Procedure

Communicated to the Office of the Prime Minister on 13 April 2012

TYPOGRAPHICAL SERVICE OF THE SENATE (200)

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The Committee,

having examined Community document COM(2012)84 final, setting out a "Proposal for a directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems",

whereas:

a) the provision contained in the final sentence of Article 3(3) states that Member States must ensure that a decision on the price that may be charged for the medicinal product concerned is adopted and communicated to the applicant within 15 days in the case of generic medicines, provided that the competent authorities have approved the price of the reference medicinal product;

b) again in relation to generic medicines, the last sentence of Article 7(4) states that Member States must ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system is adopted and communicated to the applicant within 15 days, provided that the reference medicinal product has already been included in the public health insurance system;

whereas, based on information that also emerged during the informal hearings organised by the Committee on this proposal, this acceleration of the proceedings to regulate the prices of generic medicines and include them in the public health insurance system risks jeopardising the evidence gathering of the relevant national authority, the Italian Medicines Agency (AIFA). This makes it necessary to find a temporary solution that provides a sustainable way of meeting the new administrative processing time limits introduced by this proposal;

whereas a problem has emerged, again during the informal hearings organised by the Committee on this proposal, regarding the correct interpretation of the provisions in Chapter III on the coverage of medicinal products by public health insurance systems, which could create the impression, when read in conjunction with the provisions in Chapter II on the pricing of medicinal products, that the automatic mechanisms described in Chapter II – which in Articles 3(6) and 4(5) provide for a form of tacit consent regarding the decisions to be taken on regulating the prices of medicinal products and decisions on requests to increase the prices of medicinal products – also apply to the decisions dealt with in Chapter III;

whereas, however, these interpretations do not seem to be consistent with the wording of the proposal in question, which instead indicates that the tacit-consent mechanism will only be applied to the decisions specified in Article 3(3) and (5) on regulating the prices of medicinal products, while no automatic procedure is contained in Chapter III on the coverage of medicinal products by the public health insurance system;

whereas an automatic mechanism of this kind would be unacceptable in terms of controlling the pharmaceutical spending of our national health service, which is based on a tried-and-tested process for evaluating the real value of pharmaceuticals eligible for reimbursement, including in relation to other treatments already in use, in order to avoid any inappropriate measures that could jeopardise efforts to meet cost-containment targets;

whereas, in relation to Protocol 2 to the Lisbon Treaty on the Application of the Principles of Subsidiarity and Proportionality, the Committee believes that the proposal complies with the principle of subsidiarity as regards both the need for the institutions of the European Union to act and the added value for the European Union, and that, as far as proportionality is concerned, the proposal is proportionate to the objectives it is intended to achieve;

issues a favourable opinion on the proposal for a Directive, with the following comments:

1) in relation to generic medicines, the time limits pursuant to Article 3(4), final sentence, and Article 7(3), final sentence, should be increased from 15 to 45 days, in order to reconcile sector operators' interest in earlier completion of the above-mentioned administrative procedures with the evidence-gathering requirements of the competent national body, for which more time is needed than is provided for in the proposal for a Directive;

2) at the time of the transposition and implementation of the provisions of Chapter III, it should be definitively clarified that the automatic procedures in form of the tacit-consent mechanism governed by Chapter II (on decision relating to the pricing of medicinal products and requests to increase those prices) do not apply to the decisions on the coverage of medicinal products by public health insurance systems.

OPINION AND PROPOSALS OF STANDING COMMITTEE 14

(EUROPEAN UNION POLICIES)

(Rapporteur: Mauro Maria MARINO)

4 April 2012

The Commission, having examined document COM(2012)84 final,

whereas it agrees with the necessity of adapting the provisions of Council Directive 89/105/EEC of 21 December 1988 (relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems) to changes in the conditions in the pharmaceuticals market and the re-emergence of cost-containment measures introduced by Member States;

whereas it appreciates that the proposal for a Directive is informed by the principle of minimal interference in the organisation of domestic social security policies, in line with Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), under which Member States retain responsibility for the definition of health policy and the organisation and delivery of health services and medical care;

noting the public consultation carried out by the European Commission prior to the presentation of this document;

issues a favourable opinion, within its remit, with the following comments:

the legal basis chosen is rightly identified as Article 114 TFEU, according to which "The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market";

the proposal appears to comply with the principle of subsidiarity:

1) as regards the need for the European Union to act, in order to overcome disparities between national procedures, which can hinder or distort the trade in medicinal products within the European Union and distort competition;

2) as regards the added value for the European Union, since national measures on regulating prices and reimbursement have a cross-border impact. In light of this, the smooth functioning of the internal market requires Member States to take transparent and prompt decisions. However, since interpretations of the concept of transparency differ within the European Union, individual

countries acting alone would be unable to guarantee sufficient transparency for economic operators;

as far as the principle of proportionality is concerned, the proposal appears to be appropriate to the objectives it is intended to achieve;

as regards substance, the Committee wholeheartedly supports – with a view to ensuring legal certainty, the smooth functioning of the market and the protection of human health – setting fixed, objective, verifiable and short time limits for the adoption of final decisions on regulating prices and on the coverage offered by public health insurance systems. It would also seem appropriate to set different time limits for generic products where the price of the reference medicinal product has already been approved (Article 7(6)). In this regard in particular, it is to be hoped that every effort is made to ensure that these time limits can be met in Italy as well;

it is also hoped that Article 8 of the proposal will be carefully evaluated, in light of the fact that:

1) ascribing the provisions of this article to the proposed legal basis would appear problematic. The definition of legal proceedings (those set out in Article 8 are not generic, but instead describe in detail the powers to be conferred upon the national body charged with evaluating any appeals) would appear to fall under the legislative autonomy of the Member States;

2) establishing compensation arrangements for a mere failure to comply with the specified time limits would introduce a new element into the Italian legal system, which should be subject to close and careful scrutiny, including the potential impact on public finances. In its contribution to the public consultation carried out by the European Commission, the Italian Medicines Agency (AIFA) reported longer average response times for the 2009-2011 period than those proposed in this document. It is therefore important that due consideration is given to the potentially significant financial liabilities that Italy could incur if it is possible to "award damages to the applicant in case of non-compliance with time limits set in Article 7 where damages are claimed" (Article 8(2b)) or "impose a penalty payment, calculated by day of delay" (Article 8(2c)). In reference to the latter option, we would highlight that AIFA itself reported that response times have reached peaks of 352 days for proprietary products and 165 days for generic products;

3) it is important to clarify whether the definitive time limits set are understood as the total time for the patient to obtain access to the medicines, regardless of the authority involved. This is relevant given that authorisation times for innovative medicines remain above the European average and, most importantly, differ at regional level, despite the recent measures adopted by the Ministry of Health. This anomaly is due to the current structure of our national health system and the resulting proliferation at local level of regional and provincial supervisory bodies, which has caused the distortions mentioned above. This should be understood in a context where innovative medicines, once they have been authorised by the European Medicines Agency (EMA), are quickly made available to patients in other European countries, whereas Italian

patients have to wait a year on average. At the same time, it is necessary to identify, in the context of the Directive, a shared and accepted definition of health technology assessment (HTA) procedures. As regards the exclusion of the re-assessment of the safety and efficacy of generic medicines, we believe this exclusion should be reconsidered. In our view, at least a specific assessment of the safety and efficacy of generic medicines should not be excluded from the process of determining pricing and the reference framework. It remains to be clarified whether the reimbursement mechanism is one of the measures to be regulated and what the impact will be, in financial terms and as regards access, of the decision to exclude procedures regulated by voluntary contractual agreements, known as "conditional reimbursement", from the scope of the Directive;

4) the creation of an ad hoc body to perform the functions described in Article 8(2) would be extremely expensive. It is therefore recommended that these functions are assigned to one of the organisations already present in the Italian public sector;

in order to allow a suitable timeframe for adapting Italian law to the stricter time limits contained in the Directive, the deadline for the transposition of the Directive should be extended by a further six months compared to the deadline indicated in Article 18;

on a strictly linguistic point, it should be noted that the term "progetto di misura" [*English term: draft measure*] used in Articles 15 and 16 does not appear to be correct in Italian: we suggest replacing it with "progetto di provvedimento".