To whom it may concern

Concern: BACHI response to the TRIS notification 2022/162 B issues by Belgium

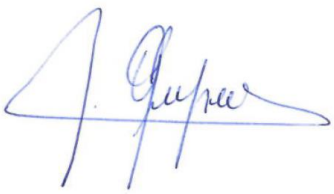
Topic: preliminary draft law setting out various provision on health

Lasne, June 20, 2022

Dear Madam,
Dear Sir,

Please find below the contribution of BACHI, the Belgian Association of the Consumer Healthcare Industry, to the TRIS notification 2022/162 B issued by Belgium.

Kind regards,



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I. CONTEXT

1. Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (hereinafter Directive 2001/83), prescribes that the invented name of the medicinal product may not be confused with the common name (Article 1er, 20° Directive 2001/83).

2. The name is a characteristic of the medicinal product (Article 11, par. 1er, 1 of Directive 2001/83). It is also one of the first items of information that must be communicated with the application for marketing authorisation (Article 8, par. 3, b of Directive 2001/83).

3. The provision on the name of the medicinal product is contained in Article 1er, § 1er, 26 of the Medicines Act of 25 March 1964 (hereinafter the Medicines Act).

4. The legislator intends to add to this requirement, the risk of confusion with medical devices, food supplements or other medicinal products. Article 1 of the Medicines Act is to be supplemented by a §3 which reads as follows:

> "Without prejudice to the law on the protection of industrial and commercial property, an invented name for a medicinal product may not create confusion with other medicinal products, medical devices or food supplements, nor with the quality and/or properties of the medicinal product concerned.
> Paragraph 1er applies to medicinal products for which a marketing authorisation has not yet been granted at the time of the entry into force of Article 2 of the law of XX XX XX on various provisions relating to health, as well as to medicinal products for which a marketing authorisation has been granted for five years or for an unlimited period and for which the holder of the authorisation has submitted an application for a change of name." [1]

5. The scope of application will therefore generally exclude:

> (i) medical devices and food supplements,
> (ii) medicinal products under a Belgian market authorisation issued before the entry into force of the draft law (except in the case of an application for a name change).
> (iii) medicinal products under European market authorisation (centralised Community procedure), and
> (iv) a priori, medicinal products whose market authorisation is obtained according to the decentralised Community procedure or mutual recognition (in particular, when Belgium is not the Member State of reference).

6. The scope of the law would thus be significantly reduced to only some of the medicinal products marketed in Belgium.

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[1] Translation from French : « § 3. Sans préjudice de la loi relative à la protection de la propriété industrielle et commerciale, un nom de fantaisie d'un médicament ne peut créer de confusion avec d'autres médicaments, des dispositifs médicaux ou des compléments alimentaires ni quant à la qualité et/ou aux propriétés du médicament concerné.
L'alinéa 1er s'applique aux médicaments pour lesquels une AMM n'a pas encore été octroyée au moment de l'entrée en vigueur de l'article 2 de la loi du XX XX XX portant des dispositions diverses en matière de santé, ainsi qu'aux médicaments pour lesquels une AMM a été octroyé pour cinq ans ou pour une durée illimitée et pour lesquels le titulaire de l'autorisation a introduit une demande de changement de nom. »

II. ARGUMENT – IN A NUTSHELL

7. The proposed measure will have an impact on the marketability of the medicinal products that it targets, because it would imply -in practice- the change of the name of a medicinal product when a (new) medical device or food supplement is placed on the market under a name similar to that of the medicinal product.

8. In this context, two main objections can be raised.
They are as follows:

(i) Firstly, the measure will not achieve the objective it claims to pursue (preventing the risk of confusion between a medicinal product and a medical device or a food supplement) because it reaches only a part of the products legally placed on the market and therefore leaves the health risk on the market untouched.
The measure would thus be ineffective (the objective will not be achieved) and inconsistent (the legislator leaves the health risk on the market untouched by allowing the marketing of products that carry a risk of confusion).
(ii) Secondly, the measure only takes into consideration the medicinal product and places on it the entire burden of risk (change of name; adaptation of production/distribution lines; loss of reputation; consumer information), whereas it is not necessarily the cause of the confusion and, therefore, of the risk to health.

The measure therefore breaks the principle of equality and is disproportionate.

9. These objections are based on fundamental principles of European law,and domestic law. These fundamental principles prevail over domestic law and can form the basis for a judicial remedy before the Constitutional Court (action in annulment of the law) or before the Council of State (action against a decision that would be taken by the regulatory authority/monitoring body - FAMHP), if necessary, with a preliminary question to the Court of Justice of the European Union.

III. GROUNDS IN SUPPORT OF THE ARGUMENT

A. Framework

i. Restrictive measure

10. The limit of the Member States' autonomy is the respect of the Treaty on the Functioning of the European Union (TFEU), in particular the free movement of goods (guaranteed by Article 28 TFEU and, in particular, Articles 34 and 36 as regards restrictive measures). These provisions read as follows:

> Article 34:
> Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.
> Article 35:
> Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States.
> Article 36:
> The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

11. However, in exercising their discretion relating to the protection of public health, the Member States must comply with the principle of proportionality. The means which they choose must therefore be confined to what is actually necessary to ensure the safeguarding of public health; they must be proportionate to the objective thus pursued, which could not have been attained by measures less restrictive of intra-Community trade (see Sandoz, paragraph 18, and Commission v Denmark, paragraph 45).
Furthermore, since Article 36 TFEU provides for an exception, to be interpreted strictly, to the rule of free movement of goods within the Union, it is for the national authorities which invoke it to show in each case, that their rules are necessary to give effective protection to the interests referred to in that provision and, in particular, that the marketing of the products in question poses a real risk to public health (see CJEU, 5 February 2004, Greenham and Abel C-95/01, J. Greenham et L. Abel, §§ 39 and 40 (ECLI:EU:C:2004:71), and cited case law). These principles are superior to domestic law.

12. We are of the opinion that the draft measure may constitute an obstacle to the free movement of goods, since it may impede or render more difficult the entry into the Belgian market of medicinal products legally produced and/or market in another Member State.

13. The measure will have consequences for the medicinal product (Belgian MA after the entry into force of the law). Indeed, the name of the medicinal product is a characteristic of the medicinal product and is covered by the MA. The marketing of a medical device or food supplement (or other medicinal product) with a similar name has an impact on this characteristic. Indeed, the name of the medicinal product becomes problematic, as it can be confused with the name of the product. It is therefore a change in a characteristic of the medicinal product, taken into account for the MA (no confusion). Therefore, the measure puts the MA to the risk of variation (Article 23 of the Directive 2001/832), suspension or withdrawal (Article 116(2) of the Directive 2001/8), because the characteristics are no longer the ones that were taken into account for the MA.

14. The risk to the MA is serious. It is the change in the name of the drug as a consequence of a modification of its characteristic (its name can enter into a relationship of confusion on another market with a product whose name is close to its own), whereas the cause of the problem may not the medicinal product but this other product. 2 Art. 23(2) of Directives 2001/83 states: “The marketing authorisation holder shall forthwith provide the national competent authority with any new information which might entail the amendment of the particulars or documents referred to in Article 8(3), Articles 10, 10a, 10b and 11, or Article 32(5), or Annex I”. Article 8(3) includes the name of the medicinal product.

15. The infringement of the rights of the producer of the medicinal product is profound, both operationally (packaging, production lines, etc.) and in the market (the new name will have to be campaigned on to inform the medical profession and the public). It is therefore a measure restricting the free movement of goods, insofar as it hinders (makes more difficult or more expensive) the free movement of medicinal products (i.e. their marketing under the name covered by the MA).

16. The measure is considered to have an impact on the internal market if it can a.o. affect medicinal products produced in another Member State and put into circulation in Belgium on the basis of a MA obtained by a decentralised European procedure before the marketing of another product bearing the problem of confusion of names.

ii. Criteria able to justify the measure

17. For what it regulates, Directive 2001/83 recalls these principles in recitals 2 and 3:
(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.
(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.

B. First criticism: Questionable necessity

18. The measure that a Member State intends to adopt with the view to regulate practices on a market, must be necessary to achieve the (public health) objective pursued, since it is this objective that justifies the measure.

19. At first, one must determine whether the existing regulatory framework does not already address the potential risk of confusion between a medicinal product and a medical device or food supplement due to similarity of names.

20. The question must be asked all the more as the term "confusion" is general and vague and therefore implies interpretation (what are the criteria for confusion?), which is likely to evolve over time according to the behaviour of the actors on the market (producers, distributors, consumers) and, in particular, consumer information.

21. The legislator must demonstrate that the risk of confusion between the name of a medicinal product and a medical device or food supplement is a current public health risk of sufficient concern to justify a restrictive measure.

C. Second criticism: Violation of fundamental principles

22. On the other hand, the measure proposed by the legislator will only affect the MA holder, even though the medicinal product may not be the cause of the risk of confusion. The question of the necessity of the measure must then also be asked, taking into account the interests of the companies and their behaviour: In what way is it necessary to require the MA holder to modify the name of the medicinal product in order to protect public health from the risk of confusion with a medical device or a food supplement subsequently placed on the market?

23. This question is closely linked to the principle of equality (the risk concerns, on the one hand, the medicinal product and, on the other, the medical device or food supplement, but the measure does not affect the author of the confusion, i.e. the medical device or food supplement), and the principle of proportionality (the measure places the entire burden of the risk on the person who is not the author of the confusion, the medicinal product). It raises the question of the effectiveness of the restrictive measure (is it likely to achieve the objective pursued?).

24. The validity of a restrictive measure depends on compliance with fundamental principles, in particular the principle of proportionality.
In simplified terms, the measure:
- must reach the cause of the public health concern that the legislator intends to reduce,
- must not infringe the rights of economic operators disproportionately, considering the expected benefits for the public health objective pursued, and
- must be of such a nature as to achieve that objective.

25. We are of the opinion that, in the case at hand, there are sufficient grounds to consider that those conditions re not met.

26**. Firstly, the measure infringes upon the principle of equality by artificially placing the entire burden of risk on the MA** ("the medicinal product cannot create confusion"), whereas from the point of view analysed, it is not necessarily the cause of the confusion (the confusion may be created by the medical device or the food supplement subsequently placed on the market)

27. **Secondly,** in order to assess the measure that the Belgian legislator intends to adopt, a balance must therefore be struck between:

(i) the interests of the producer of the medicinal product (or of the MA) threatened by the risk of the restrictive measure, and
(ii) the general interest (public health) that could be harmed by the possible confusion between the medicinal product and a medical device or a food supplement subsequently placed on the market.

In this balance, the public health risk appears relative. Indeed, this risk depends to a large extent on consumer behaviour (confusion); it is therefore uncertain.
In the balancing of interests, the intensity of the public health risk is probably not high enough to take such a far-reaching measure against the medicinal product as a name change, induced by the draft text. This is especially so if the medicinal product is not the cause of the confusion. The confusion may indeed be caused by the name of a medical device or a food supplement subsequently placed on the market.

28. **Thirdly**, the measure is only aimed to apply to a part of the medicinal product market; it does not affect the medicinal product under a MA obtained at European level through the centralised procedure, nor, a priori, under a MA obtained by the decentralised procedure or mutual recognition, or under a Belgian MA obtained before the entry into force of the law. The legislator will therefore allow a large proportion of the medicinal products to be placed on the market, although it considers them as carrying a public health risk.
However, if one considers that the risk for the consumer is present on the medical device or food supplement, the exclusion of the application of the rule to pre-existing MAs no longer makes sense, since the risk of confusion exists for these consumers. In this respect, the restrictive measure may well be partially ineffective.

29. **Fourthly**, as no total harmonisation of the legal status for active ingredients and dosages exists across Europe the measure creates an additional criterium against the free movement of goods and the use trade names of medicines. Some dosages of vitamins are e.g., regulated as food supplements in the Netherlands and as medicines in Belgium and in this case the measure would not allow a company to use the same trade name in both countries. As such the risk exists that a company is prevented from asserting its rights.

Because of its partial scope, the measure is unsuitable for achieving the public health objective pursued. It is ineffective.

D. Third criticism: Lack of predictability of the law

30. It follows from the fundamental principles in the European legal order and in the national legal order that the law" must be sufficiently clear and precise to enable its addressee to anticipate the risk of his action and to adapt his behaviour.
One of the key requirements in this respect is that the law provides for definitions of the terms that determine its scope.

31. As it is conceived, the draft text conflicts with this primary quality requirement of the norm: the term “confusion" is vague and general. It leaves a lot of room for interpretation by the actor: what is the risk of confusion? The economic operator (the producer of the medicinal product) does not know how to direct his action and the national regulatory/monitoring authority (FAMHP or FASFC) cannot control.

32. To meet this concern, the legislator has to go further and:

(i) either define what is meant by “confusion”, i.e. define the criteria according to which there could be a serious risk of confusion, or,
(ii) if it intends to entrust this task to a national regulatory/control authority (e.g. the FAMHP), set the limits within which this authority can act.