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Study on the Availability of Medicinal Products for Human Use

Feedback on the report by Matrix Insight, as applicable to Malta, based on the experience of the last ten years

This report by Matrix Insight specifies that 'the availability of medicinal products is understood to mean the availability to patients of medicinal products in a pharmacy setting'. This definition has a number of limitations from a public health point of view, because it is not an indicator of actual availability and affordability of medicines for a patient. Although medicines may be available in a pharmacy, if the medicine is not reimbursed then the patient may not afford the product and the patient remains without the product. Moreover if the market forces do not work and if there is lack of competition on the supply side, the prices of medicines remain very high. Moreover the fact that a medicine is theoretically available on the market does not mean that it is in stock in pharmacies, and in small states medicinal products are frequently out of stock. Thus from the public health perspective of a small market, the measures taken should address beyond the possible theoretical availability of one active substance on the market. Regulation should in no way place unnecessary hurdles on public health aspects.

EU pharmaceutical legislation does not result in a true single market for medicinal products. The main shortcoming in the legislation is that MAHs are not obliged to register their products in all MSs. Moreover, although the legislation places a public service obligation on MAHs and wholesale dealers to place authorised products on the market, the authorities in small MSs which need to get most of the products from abroad are helpless to address situations where products which are authorised are not placed on the market. The only measures that such NCAs may be able to take are to issue fines on MAHs or to take action on licenses, in line with article 81 of Directive 2001/83/EC. However any such measures may be counterproductive and may make MAHs less motivated to register products on the local market of a small MS. The legislation permits that MAHs register their products only in MSs where it is feasible for them to register. Small markets are less attractive for MAHs. Unfortunately this issue is also manifested in MRP and DCP procedures, even in cases where adding in a small MS as a CMS will not cause the MAH any additional burden, as is the case of Malta where fees are very low and there are no additional national requirements.

National legislation allows for parallel trade. If products are not registered, then there cannot be parallel importation of these products. If a product is authorised but not placed on the market, the availability of a marketing authorisation gives the possibility of parallel importation, and thus parallel importation can also help address the problem of availability to patients. The benefit in lowering of prices of medicines which is expected through parallel trade is limited in Malta.

Malta has used article 126a as its main tool to address the lack of authorised products on its market following accession. Article 126a was considered a better alternative to article 5(1) Directive 2001/83/EC as amended by Directive 2004/27/EC for the registration of products in cases where there are more than a few patients (which is the situation for most medicinal products). The use of Article 126a allowed the address of gaps in products arising out of the transition from the situation prior to Malta's accession into the EU to after accession. Article 126a should not be used by MAHs as an alternative route to for the registration of medicinal products. In Malta Article 126a is being implemented in such a way as to discourage abuse of the pharmaceutical legislative framework, whereby MAHs fail to include Malta as a CMS in MRP/DCP and then they try to register these

products by 126a in Malta. However Article 126a has allowed the gap in availability of products due to lack of authorisations to be filled. In such situations where MAHs do not register the product in Malta (and thus there cannot even be parallel importation) Article 126a gives the opportunity for these products to be on the market. The Commission suggests that MS set up their own framework for the operation of article 126a and states that the framework for article 126a is the same as for parallel imports. The Commission clarifies that the MAH is responsible to take up any issues with pharmacovigilance which arise through products authorised through article 126a. Malta has already adopted a framework on these lines.

The report notes that some MS did not adopt article 126a because they consider that there is lack of definition of responsibility and they claim the possibility of problems with safety. The report suggests that the legislation should be altered to address the concern of these MSs. The MS which are not using article 126a may have other fundamental concerns, including a concern that the NCA in the MS will lose its 'sovereignty' in terms of power as a national regulator by accepting products authorised in other MSs.

The report 'questions' the interpretation 'public health need' as adopted by Malta in its implementation of Article 126a. The report is of the opinion that if there is a product authorised for a particular active ingredient, there is no public health need to authorise products with the same active ingredient through article 126a. Malta does not agree with the restrictive interpretation adopted by the report. Just as there are no restrictions for the number of parallel import licences for a product, the same applies for article 126a. In Malta there can be more than one authorisation by article 126a for the same product in Malta. This supports the achievement of the 'public health need'. The more different products available on the market for the same active ingredient (whatever the method of authorisation), the more chance of improved affordability for the patients. One must not underestimate the criticality of affordability of medicines, particularly where patients are buying their medicines. Moreover, if one product is out of stock (which is something of a common occurrence on a small market which depends on products which are not manufactured locally) there is more chance that another product with the same active ingredient is actually available on the market.

If the legislation forces the NCA to enforce the public service obligation of Article 81, there is negative impact on the availability of medicinal products in small MSs. Article 81 is counterproductive for small member states. MAHs are not local and application of any sanctions to oblige foreign MAHs to supply the product on a national market may lead to a reaction by the MAH. The MAH may even decide to withdraw the marketing authorisation. The legislation should leave it at the discretion of the MS on how to apply the public service obligation so that it achieves positive public health impact in the MS.

The use of the Sunset provision is counterproductive in the case of small markets. Of course, ideally for products where there is a marketing authorisation the product is actually physically placed on the market. However if the MAH does not place the product on the market, there is little that the NCA can really do to force/motivate the MAH. if the authorisation is withdrawn, all hope of having the product placed on the market is lost and also the possibility of parallel importation is removed. If there is a valid marketing authorisation if the MAH does not market the product, at least there is the possibility for parallel importation.

Just as the Baltic States adopt a strategy for the common pack, Malta has a less formal strategy whereby MAHs are encouraged to place on the market a 'joint pack' for Malta and the UK and/or Ireland. This arrangement works out very well, particularly as Malta has both Maltese and English as its official languages and accepts products which are only in English, which is in line with the amended EU legislation. Clinical practice in Malta is very similar to that in the UK and Ireland and Malta does not impose additional requirements during marketing authorisation process, thus facilitating the joint pack.

There is an agreed procedure between the NCAs of Malta, the UK and Ireland, whereby the UK and Ireland invite MAHs who go to them to act as RMS to include Malta as CMS in MRP/DCP.

The zero day procedure is quite novel and has been used by Malta for a few procedures. It is recommendable and should be encouraged by the NCAs who have difficulties with getting products on their market. More MS acting as Reference Member State should be willing to use it to help the smaller Member States. There should be a possibility of reduced fees in the RMS for applicants considering that the CMS will accept the assessment report of the RMS without any updates and any further comments. This would greatly reduce the use of article 126a for authorisation of products already in other MS markets and would increase the use of European procedures. Malta is encouraging MAHs to include Malta in the zero day or 30 day procedure, particularly if this is applied for other Member States (MAHs can use the same cycle for different MSs).

Most new products are centrally authorised and this removes the hurdle of authorisation in selected MSs. While centrally authorised products are authorised in all MSs, MAHs may not market the products in some MSs, particularly if the volume is low or if this in any way affects the prices and marketing of their products in other MSs. NCAs in small MSs end up begging and making arrangements for certain centrally authorised products to be supplied on their markets. The fees for parallel importation of centrally authorised products to EMA are prohibitive and these life saving medicinal products are not available for vulnerable patients unless procured through the MAH who in many instances would not be willing to get the product to Malta because of the small quantities. Sometime the patients are ready to purchase them themselves if the products are not on the national formulary but the MAH is not willing to provide. Having more reasonable fees for parallel import of centrally authorised products would encourage other wholesale dealers (and if need by the government) to procure these medicinal products. This should be considered by the European Commission and EMA, in particular for small markets.

Recommendations for revision to the current EU pharmaceutical legislative framework

1. This report chooses not to clearly set the recommendation for the EU legislation to address the lack of a true single market because MAHs are not obliged to register their products in all MSs. It is understandable that this ideal situation has a lot of implications for the operation of the pharmaceutical market in the EU. In view of this, most probably the current 'compromise' is the best balance that can be achieved.

2. The current measures used by MSs help them to address their internal issues with availability and at the same time have minimal impact on the balance of the EU framework. MSs should be allowed to adopt their own policies/legislation, as long as these are within the framework set by the EU legislation. Certain provisions which are counterproductive for small MSS should allow national discretion. For example: Malta should be allowed to interpret its criteria for public health need and the sunset provision and the public service obligation should be interpreted nationally.

3. A clarification of the responsibilities of the players for implementation of Article 126a is deemed beneficial. This may also help applicants choose other methods for registering products e.g. MRP.

4. The Sunset provision (article 24 (4), (5), (6) should be optional for the MS to apply it if they want. Some MSs may choose to apply the Sunset provision to clear up idle authorisations. On the other hand some small MSs may prefer not to remove idle authorisations because these give a basis for parallel importation of the products concerned.

5. While article 81 (the public service obligation) may be of benefit to some MS, it is unenforceable and counterproductive in other countries (especially small MSs where there is little local manufacturing). The level of implementation and enforcement of article 81 as imposed by the legislation should be left up to the discretion of the MS.

6. The system of parallel importation of centrally authorised products currently imposes high expenses for small operators in small markets. The restrictions for parallel importation of centrally authorised products and the fees involved should be revised.