Läkemedelshandlarna

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Yttrande över EU-läkemedelslagstiftning: Kommissionens förslag på förordning och direktiv om humanläkemedel

Läkemedelshandlarna (LH) tackar för möjligheten att svara på rubricerad remiss och välkomnar kommissionens förslag om en revidering av EU:s allmänna lagstiftning på läkemedelsområdet. De övergripande målen är att stärka tillgången till läkemedel i EU, öka försörjningstryggheten samt förebygga och avhjälpa brister, stärka konkurrensen och minska administrationen.

LH företräder de läkemedelsföretag som parallellimporterar läkemedel till Sverige, och vi står för ca 10% av omsättningen av läkemedel som säljs på svenska apotek. På den europeiska läkemedelsmarknaden leder parallellimport/distribution till besparingar i hälso- och sjukvårdssystemen på 5–7 miljarder euro varje år.

Parallellhandeln leder till stora besparingar och en ökad tillgång till läkemedel och därmed större motståndskraft inför bristsituationer.

En väl fungerande inre marknad är en förutsättning för att fullt ut kunna dra nytta av de fördelar parallellimporten bidrar med. Idag föreligger ogrundade nationella handelsrestriktioner, konkurrensbegränsande beteenden från originalföretagen och administrativa hinder, som vi nu hoppas att den svenska regeringen agerar för att komma till rätta med.

Läkemedelshandlarnas synpunkter på förslagen:
Detaljerade förslag till ändringar och tillägg framgår av bilaga 1: Affordable Medicines Europe, Position Paper.

PSO
Den svenska modellen med enkanalsdistribution innebär att Sverige saknar fullsortimentsgrossister i traditionell mening. Den så kallade "Public Service Obligation" (PSO) påverkar dock den svenska tillgången på läkemedel. PSO är ett avgörande inslag i lagstiftningen för att uppnå en läkemedelsförsörjningskedja som skapar trygghet för patienter i hela EU. LH stöder därför förslaget till direktiv i kapitel 5, om skyldigheter och ansvar för innehavaren av godkännandet för försäljning, artikel 56, st. 3. Den innefattar en skyldighet för innehavare av försäljningstillstånd att säkerställa adekvat och fortlöpande läkemedelsförsörjning till grossister, apotek eller personer som är auktoriserade att expediera läkemedel, så att behoven hos patienterna i den aktuella medlemsstaten tillgodoses.

Då parallellimporterade läkemedel inte tillverkas av parallellimporterande bolag är det problematiskt att de svenska försäljningstillstånden för en produkt har samma benämning som det tillverkande bolaget—Försäljningstillstånd (marketing authorisation holder).
Det skapar otydlighet om vilket ansvar som kan avkrävas en parallellimportör som aldrig kan styra tillgång i exportland. Med fördel bör tillstånden särskiljas på samma sätt som europeiskt godkända läkemedel dvs. tillståndshavare (MAH) är tillverkaren/direktimportören och en distributionslicens/eller notifiering för de bolag som distribuerar samma produkt parallellt till den svenska marknaden.

LH föreslår samtidigt att det i bestämmelsen införs en hänvisning till artiklarna 166 och 167. De reglerar skyldigheterna för innehavare av partihandelstillstånd att tillhandahålla läkemedel till apotek m.m. och betonar sammanhållningen i försörjningskedjan.

LH noterar att den föreslagna lydelsen av artikel 166, mom. 1, punkt l, innebär att medlemsstaterna måste se till att alla innehavare av grossisttillstånd måste uppfylla leveransplikten när det gäller ett lämpligt urval av läkemedel i ett visst geografiskt område. LH föreslår att formuleringen ändras så att det framgår att medlemsstaterna ska utse en eller flera innehavare av partihandelstillstånd som ska uppfylla nämnda skyldigheter.

LH föreslår också att lydelsen i artikel 166 mom 1, punkt m, som handlar om grossisternas skyldighet att samarbeta med innehavare av försäljningstillstånd och myndigheterna om försörjningstrygghet, utvidgas så att samarbete sker med största möjliga hänsyn till skyddet av kommersiellt känslig information.

Elektroniska bipacksedlar
LH anser att den svenska regeringen med mycket hög prioritet bör verka för en bindande, harmoniserad och snabb övergång till elektroniska bipacksedlar i hela EU. Elektroniska bipacksedlar kommer få flera positiva effekter, i synnerhet minskad klimat- och miljöpåverkan, en effektivare inre marknad och snabbare/enklare marknadstillträde i de enskilda medlemsländerna och därmed ökad tillgänglighet. Dessutom kommer elektroniska broschyrer att möjliggöra ökad läsbarhet för personer med nedsatt syn än vad de nuvarande broschyrerna erbjuder eftersom de kan visas i större teckenstorlek eller läsas upp av en robot när de är elektroniska.

LH noterar att förslaget till direktiv föreskriver att medlemsstaterna kan besluta att bipacksedeln ska vara tillgänglig elektroniskt, i pappersformat eller i båda formaten. Kommissionen är bemyndigad att fatta beslut om övergång till elektronisk bipacksedel fem år efter direktivets ikraftträdande. LH anser att denna tidsram, som i praktiken snabbt kan närma sig tio år, är alldeles för lång och föreslår att den uppsatta tidsfristen för befogenhet att fatta beslut om att göra den elektroniska bipacksedeln obligatorisk, jfr kapitel 6, artikel 63, st. 5, reduceras till 2 år.

LH uppmanar regeringen att ta vara på möjligheten att så snart som möjligt fatta beslut om övergången till en elektronisk broschyr för den svenska marknaden. Det gäller inte minst sjukhusläkemedel, där pappersinlagan i de enskilda läkemedelsförpackningarna är överflödig och bidrar till onödig pappers- och förpackningskonsumtion. Det är avgörande att Sveriges och andra medlemsländers beslut om att införa en elektronisk bipacksedel fattas i enlighet med en helt harmoniserad standard, som föreskrivs i artikel 63.1 i förslaget i kapitel 6.
Vidare är det helt avgörande att hänsyn till skyddet av patienternas känsliga personuppgifter säkerställs i samband med patienters åtkomst/uppslag i elektroniska broschyrer. LH föreslår mot denna bakgrund att elektroniska broschyrer görs tillgängliga för patienter och vårdpersonal via de

nationella myndigheternas/EMA:s läkemedelsdatabaser i samband med de registrerade marknadsföringstillstånden.

MRV miljöriskbedömning
Det föreskrivs i direktivförslaget att ansökningar om försäljningstillstånd ska åtföljas av en miljöriskbedömning (MRV), eftersom närmare villkor och innehåll för detta föreslås i artiklarna 22-24 i direktivförslaget.
LH stödjer att ansökningar om försäljningstillstånd för läkemedel ska innehålla ett starkt och bindande MRV, som ska göras allmänt tillgängligt och från vilket myndigheter och offentliga upphandlare av läkemedel m.m. kan extrahera nödvändig information. Detta bidrar till att öka konkurrensen, den fria rörligheten för varor och marknadstillträde för bland annat parallellimporterade läkemedel, till exempel i samband med deltagande i offentliga upphandlingar av läkemedel. Idag är avsaknaden på tillgång till miljöinformation ett onödigt hinder för parallellimportörerna att delta i anbud, vilket orsakar svag konkurrens och förlorade besparingar för samhället.
LH föreslår att sådan information inkluderas som en del av kraven för MRV som anges i bilaga II, avsnitt 1.6, 4:e meningen, enligt följande:

Informationen ska bestå av:
- en introduktion som minst innehåller:
o juridiska namn och fysiska adresser för slutliga tillverkningsanläggningar för produkten/produkterna/sortimentet
o lagliga namn och fysiska adresser till tillverkningsanläggningar ett (1) steg bortom, slutlig tillverkning av produkten/produkterna/sortimentet.
o lagliga namn och fysiska adresser till tillverkningsanläggningar för komponent(er) i produkten/sortimentet/sortimentet
o indikationer på smältverk/raffinörer för tenn, volfram, tantal och guld (3TG), kobolt och glimmer i produkten/produkterna/sortimentet
o juridiska namn och fysiska adresser till utvinningsanläggningar för råvaran för produkten/produkterna/sortimentet

EMVS
När det gäller det etablerade systemet för förebyggande av förfalskade läkemedel i läkemedelsförsörjningen (EMVS-systemet), artikel 67, mom. 6. kan medlemsstaterna använda den registrerade informationen för andra ändamål, inklusive ersättning, säkerhetsövervakning, farmakoepidemiologi eller utvidgning av dataskyddet. LH hävdar bestämt att informationen vid alla tillfällen endast är tillgänglig för myndigheterna så att de ska kunna använda dem vid berättigade överväganden. Samtidigt måste kommersiellt känsliga uppgifter skyddas så att de inte blir tillgängliga för konkurrerande företag.

När det gäller att förhindra att förfalskade läkemedel kommer in i försörjningskedjan har det varit de svenska myndigheternas ståndpunkt att parallellimporterade läkemedel, måste packas om i nya förpackningar med en ny obruten försegling och den unika 2D streckkoden tryckt direkt på förpackningen, snarare än att förpackningarna öppnas, förses med svensk bipacksedel och etiketter/klistermärken samt täckning av brutna förseglingar (ommärkning). Detta eftersom den senare metoden, enligt de svenska myndigheternas uppfattning, antas öka risken för att förfalskade läkemedel kan föras ut på marknaden och ut till patienter, vilket kan få konsekvenser för folkhälsan och patientsäkerheten. Regeringen har därför påpekat för EU-domstolen att ommärkning inte utgör ett tillräckligt skydd mot förfalskning av läkemedel. EU-domstolen har nyligen slagit fast att

medlemsstaterna inte kan ha som huvudregel att parallellimporterade läkemedel ska packas om i nya förpackningar, trots att en majoritet av medlemsstaterna har en önskan om detta.
Mot denna bakgrund vill LH starkt uppmuntra den svenska regeringen att verka för ett tillägg till direktivets artikel 67, av vilken det ska framgå att medlemsländerna av patientsäkerhetsskäl kan besluta att läkemedel som importeras eller distribueras parallellt ska packas om i en ny ytterförpackning. Det minskar osäkerheten kring läkemedlet hos partihandlare, apotek och andra.

Administration
På flera områden innehåller förslaget till direktiv administrativa lättnader, vilket LH stöder till fullo. Det gäller möjligheten för medlemsstaterna att, när det är motiverat av folkhälsoskäl, att ansöka om försäljningstillstånd enligt det decentraliserade förfarandet eller förfarandet för ömsesidigt erkännande, jfr artikel 34 mom. i förslaget till direktiv. 3, och artikel 36, mom 4. Enligt LH:s bedömning kommer det att bidra till att öka tillgängligheten till läkemedel, särskilt till nya läkemedel, för patienter i fler medlemsländer, bland annat genom ökade möjligheter till parallell distribution.

LH stöder också att artikel 30, i det föreslagna direktivet, där den maximala handläggningstiden för ansökningar om försäljningstillstånd kortas från 210 dagar till 180 dagar. LH ställer sig också helt bakom skrivningarna om att försäljningstillstånd i princip kommer att utfärdas utan tidsbegränsning, jfr skäl 79, och artikel 46, mom. 1., eftersom LH utgår från att tillstånd till parallellimport på motsvarande sätt kommer att gälla utan tidsbegränsning.

EMA
Förslag till förordning om fastställande av EU:s förfaranden för godkännande och övervakning av humanläkemedel och om regler för Europeiska läkemedelsmyndigheten.

Läkemedelsförsörjningen är ett växande problem i hela EU. LH haruppfattningen att den föreslagna förordningen syftar till att förebygga och råda bot på läkemedelsbrist på ett strukturerat och samordnat sätt på EU-nivå, till skillnad mot nationella protektionistiska åtgärder som skadar den fria rörligheten och i slutändan riskerar läkemedelsförsörjningen. LH ser tillägget i kapitlet om tillgång och leveranssäkerhet av läkemedel i förordningen, jfr kapitel X, som ett positivt och viktigt steg för att införa de verktyg och incitament som inte bara bidrar till att råda bot på bristsituationer, utan också förebygger dem.

Det är helt avgörande att förordningen också strävar efter att säkerställa ett korrekt informationsflöde och samordning av de åtgärder som vidtas på nationell nivå när en bristsituation uppstår. Erfarenheterna från covid-19-pandemin, och i viss mån antibiotikakriserna hösten/vintern 2022, visar mycket tydligt att åtgärder som vidtas av enskilda medlemsstater kan påverka den inre marknaden, varurörelsen och tillgängligheten till patienternas nackdel. De nödvändiga förfarandena bör därför fastställas för att säkerställa att EMA får information med en mycket kort tidsfrist och effektivt kan övervaka och agera på sådana åtgärder utan dröjsmål för att undvika negativa konsekvenser för patienter i hela samhället.

Läkemedelsbrister
Det är avgörande för en effektiv alleuropeisk hantering av läkemedelsbrister att insatsen bygger på en tydlig och entydig gemensam förståelse av begreppet ”läkemedelsbrist”. LH stöder helt de föreslagna definitionerna av "brist" och "kritisk brist" i den föreslagna förordningens artikel 2, punkt 2. 14-16. Det betonas här att en brist är en situation där leveranserna av ett läkemedel som godkänts och saluförs i en medlemsstat inte är tillräckliga för att möta efterfrågan på detta

läkemedel i den medlemsstaten. Det är därför inte fråga om brist om ett läkemedel är på restorder hos vissa grossister eller apotek, men finns hos andra apotek eller grossister inom samma medlemsland. Vidare är det inte fråga om en kritisk brist om det finns ett lämpligt alternativt läkemedel på marknaden i den aktuella medlemsstaten.

Kritiska bristsituationer definieras som bristsituationer där en samordnad EU-insats är nödvändig i enlighet med den föreslagna förordningen.

De tydliga gränserna för vad som är (kritiska) bristsituationer är enligt LH väsentliga för en effektiv och målinriktad hantering av sådana situationer. Det innebär att medlemsländernas åtgärder, inklusive till exempel införande av exportrestriktioner på läkemedel som inte har brist enligt definitionen blir obefogade.

Remissen är framtagen av Fredrik Skepp och Andreas Rosenlund på Läkemedelshandlarna.

Dag som ovan

Andreas Rosenlund, VD
Läkemedelshandlarna

Bilaga 1

AFFORDABLE MEDICINES EUROPE

WORKING IN PARALLEL FOR A BETTER DEAL

GENERAL PHARMA LEGISLATION

POSITION PAPER

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INTRODUCTION

Affordable Medicines Europe welcomes the European Commission proposals for revision of the general pharmaceutical legislation, and its primary objectives of availability and affordability of medicines. Especially, we positively welcome the proposed Directive and Regulation in relation to the measures aimed at improving the security of supply and alleviation of shortages in Europe.

Affordable Medicines Europe calls on legislators to strengthen the functioning of the Internal Market for medicinal products, and especially to improve the situation that distributors face with regards to insufficient volumes of medicines placed on the market by Marketing Authorisation Holders (MAHs), leading to increased numbers of shortages in individual Member States and increasingly across Europe.

As a reminder, members of Affordable Medicines Europe, who are parallel distributors recognised by national and EU law:

- bring European healthcare systems savings of EUR 5-7 billion every year;
- that these savings could be significantly higher if:
    - anti-competitive behaviour from multinational pharmaceutical companies were more effectively addressed, and;
    - Member States would ensure better frameworks nationally for parallel imports and exports;
- via their extensive network across all Member States, on a daily basis help pharmacists and patients fill the gap when shortages occur;
- contribute to the general agility of the European medicines supply chain – including re-boxing medicines for manufacturers if they need to re-distribute stocks as part of shortages mitigation efforts.

Members of Affordable Medicines Europe have committed to ensure that our sector helps alleviate shortages and never exacerbate or create shortages as a consequence of their activities. We ask policymakers to remember, that while parallel distribution have declined as a share of the total pharmaceutical market over the past decade, and while export bans have been erected in most Member States, shortages have continued to increase and negatively impact patients across Europe. We believe these facts speak their clear language: limiting the activities of our sector has in no way contributed to reduced shortages – on the contrary.

In relation to tackling the increase in shortages Europe have witnessed in recent years, we consider that the proposal for a new Directive can deliver a Public Service Obligation (PSO) which better outlines the responsibilities of the different supply chain stakeholders. The importance of a well-balanced and appropriate PSO should not be underestimated. We also consider the addition of the Chapter on *Availability and Security of Supply of Medicinal Products* in the Regulation (cf. Chapter X) as a positive and important step to put in place the tools and incentives that will help not only to alleviate shortages, but also more importantly prevent them from occurring in the first place.

In this position paper, we will outline points where we believe the texts of the Directive and Regulation should be still further improved in the form of proposals for amendments. We will also highlight a number of proposed provisions which we strongly encourage the legislators to maintain as they are.

REVISED DIRECTIVE

Affordable Medicines Europe draws attention to the following points in the proposed Directive.

The Public Service Obligation

Affordable Medicines Europe consider the PSO one of the key elements to secure a European medicines supply chain that can deliver security of supply to patients across the Union. The proposed Directive takes significant step towards clarifying and improving the already existing PSO.[1]

One key aspect is the inclusion of the PSO directly in Chapter V outlining *Obligations and Liability of the MAH*, Article 56(3). In the current Directive, the PSO mentions MAHs, but is mentioned only in the wholesale chapter. This has led to legal discussions on the extent to which MAH had obligations and liability. With the introduction of an explicit PSO for MAHs in the proposed text, any such discussion becomes obsolete. MAHs must be responsible for their actions, and we therefore fully support this change.

We do, however, note, that a clear reference to the wholesalers' PSO is missing. Any supply chain must be seen in context of the individual links of that chain. Manufacturers deliver to wholesalers, who in turn deliver to hospitals and pharmacies. References to Articles 166 and 167, regulating the obligations of wholesale distribution holders, are therefore proposed.

There has been an increase in the share of products which are sold directly from manufacturers to pharmacies (DTP) over the past decade. This is not only damaging to the environmental sustainability of the supply of medicines (increasing the total number of transports to pharmacies), but also has led to an increase of shortages, according to pharmacists[2]. In some cases, pharmacies wish to be directly supplied (primarily when generic manufacturers offer additional discounts). In these cases, MAHs are free to do so; an obligation to deliver to wholesalers, who in turn must deliver to pharmacies vis-à-vis Articles 166 and 167 does not hinder the MAH to also supply directly to pharmacies and/or persons authorised to supply medicinal products. However, it is important that there is a minimum requirement which allows the supply chain stakeholders to choose to go via their usual channels – wholesalers. Therefore, we propose that the PSO on MAH is seen in context of the PSO on wholesalers with a responsibility to supply pharmacies and persons authorised to supply medicinal products; that is, to ensure primarily the reference to wholesalers, who in turn are responsible to supply pharmacies etc.

Article 56 - paragraph 3	
Text proposed by the Commission	*Amendment*
3. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies *or* persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered. **The arrangements for implementing the first subparagraph should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of**	3. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors ***in accordance with Article 166(2) new and Article 167(2)***, pharmacies ***and*** persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered. The arrangements for implementing the first subparagraph should, moreover, be justified on grounds of public health protection and be

[1] Article 81 Directive 2001/83.
[2] The reference here is to the European Community Pharmacists (PGEU), Position Paper on Medicine Shortages, 2019: https://www.pgeu.eu/publications/position-paper-on-medicine-shortages/

such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.	proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.

As for the PSO proposed in Chapter XXI on *Wholesale Distribution and Sale at a Distance* we note that it is inserted in two different manners in two consecutive Articles, namely Articles 166(1), point (l) and Article 167(2).

We strongly recommend that the PSO on wholesalers is therefore clarified in its scope and relation to Article 56(3). As Article 166 is worded in the proposal, all wholesalers in Europe must have defined ranges of products and geographical coverage by the respective Member States. This not at all aligned to practice nor implementable. In example, all parallel importers must hold a wholesaling authorisation to do business, however, they do not function as traditional wholesalers in relation to supply to pharmacies. Rather in many instances they supply their products to the market via national wholesalers just as MAHs do. Hence, having to define all entities authorised to do wholesale with a range and geographical scope is not practical nor what we believe was the intention. Instead, we propose to clarify that those wholesalers who supply typically the full range of medicines to pharmacies, and hence act as a one-stop-shop for the daily orders of pharmacies, shall be designated to meet these obligations by Member States. In turn, they have a legitimate expectation of being supplied by MAHs vis-à-vis Article 56(3).

We note that in the MAH PSO above, the word "ensure" is used. We consider the same word should be used for wholesalers. Wholesalers cannot "guarantee" anything if e.g., MAHs have supply breakdowns.

Article 166 – paragraph 1, subparagraph (l) MOVED to Article 166 – paragraph 2 (new)	
Text proposed by the Commission	*Amendment*
1. **Member States shall *ensure that* wholesale distribution authorisation holders shall:** **[…]** **(l) continuously *guarantee* the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe, which shall be defined in the national legislation;**	**2.** Member States shall ***designate one or more*** wholesale distribution authorisation holders ***who*** shall***, on the basis of Article 56(3),*** continuously ***ensure*** appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe which shall be defined in the national legislation.

Article 167 - paragraph 2	
Text proposed by the Commission	*Amendment*
2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ***considering article 56(3),*** ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

On this basis we also propose to adjust the definition laid out in Article 4(1), point (70).

Article 4 – paragraph 1, subparagraph (70)	
Text proposed by the Commission	*Amendment*
(70) 'public service obligation' means to *guarantee* permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a *very short* time over the whole of the area in question.	(70) 'public service obligation' means to ***ensure*** permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a ***reasonable*** time over the whole of the area in question.

(Other) Wholesale Obligations

The proposed Article 163(1) reflects the existing Article 77(1) of the current Directive 2001/83/EC. However, the Commission has added that the wholesale distribution authorisation (WDA) shall indicate not only the premises for which it is active, but also "the medicinal products and the wholesale distribution operations". We strongly encourage a precision in relation to this addition by the Commission: notably that the WDA doesn't need to specify each individual medicinal product for which it is valid but rather the categories of medicinal products for which it applies (e.g., narcotics, blood products, cold chain products etc.). If not, this would be an absurd burden as many wholesalers hold thousands of products in their portfolio and changes in the range happen almost daily. We therefore propose the following amendment:

Article 163 – paragraph 1	
Text proposed by the Commission	*Amendment*
1. The competent authority of the Member State concerned shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to an authorisation to engage in activity as a wholesaler in medicinal products ("wholesale distribution authorisation"). The wholesale distribution authorisation shall indicate the premises, the medicinal products and the wholesale distribution operations for which it is valid.	1. The competent authority of the Member State concerned shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to an authorisation to engage in activity as a wholesaler in medicinal products ("wholesale distribution authorisation"). The wholesale distribution authorisation shall indicate the premises, the ***categories of*** medicinal products and the wholesale distribution operations for which it is valid.

In relation to the obligations on wholesalers we would finally suggest a small change to Article 166(1), point (m). We welcome the obligation to cooperate placed on wholesalers. In daily practice, this already happens – especially with national competent authorities (NCAs). However, we ask that the obligation is not limited in terms of non-state actors to MAHs. We consider cooperation with all stakeholders as key. Furthermore, we suggest, to make a reference to the respect for the nature of commercially sensitive information, so as to ensure that competition in the market is not unintentionally affected.

Article 166 – paragraph 1, subparagraph (m)	
Text proposed by the Commission	*Amendment*
1. Member States shall ensure that wholesale distribution authorisation holders shall: **[…]**	1. Member States shall ensure that wholesale distribution authorisation holders shall: […]

(m) cooperate with *marketing authorisation holders* and competent authorities of the Member States on the security of supply.	(m) cooperate with ***all relevant stakeholders, respecting the nature of commercially sensitive information,*** and competent authorities of the Member States on the security of supply.

E-leaflet

Affordable Medicines Europe support the effort to move towards electronic patient leaflets in Europe. We believe all patient groups will be empowered by the possibilities offered by electronic leaflets, such as in example machine reading the leaflets for elderly people who cannot read the small font size used. While we would have liked to see an immediate transition in Europe to e-leaflets, we welcome the phased approach proposed by the Commission. However, we regret that the timeframe set out very quickly may approach 10 years in total. Hence, we propose to reduce the delegation powers of the Commission from 5 to 2 years (+18 months and the time for negotiating the adopting the file between co-legislators).

Article 63 – paragraph 5	
Text proposed by the Commission	*Amendment*
5. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version of the package leaflet. That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request. The delegation of powers shall apply as of [OP please insert the date = *five* years following 18 months after the date of entering into force of this Directive]	5. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version of the package leaflet. That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request. The delegation of powers shall apply as of [OP please insert the date = ***two*** years following 18 months after the date of entering into force of this Directive]

In context of the e-leaflet we would like to expressly state our strong support for the necessity to ensure that any introduction of e-leaflets in individual Member States follow a fully harmonised procedure as laid out in Article 63(6) and that patients cannot be tracked in any way as laid out in Article 63(7). We consider the right to privacy absolutely essential and **we propose that e-leaflets are stored in and routed to the NCA/EMA databases containing the marketing authorisation dossiers.**

Article 63 – paragraph 7	
Text proposed by the Commission	*Amendment*
7. Where the package leaflet is made available electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes.	7. Where the package leaflet is made available electronically, the individual right to privacy shall be ensured, ***and must happen via the national or EMA marketing authorisation databases***. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes.

Re-boxing of medicines

A parallel distributor/importer must carry out a re-packaging of each product imported into a Member State. Such re-packaging can either be in the form of re-boxing the medicines into a new outer packaging, or in the form of re-labelling the original outer packaging with stickers.

Following the adoption and implementation of the Falsified Medicines Directive (implemented into Directive 2001/83), our sector has continuously pointed out that re-boxing rather than re-labelling of medicines was the predominant preference for patients and pharmacists in most Member States. However, the European Court of Justice have recently ruled, that the current Directive does not allow Member States to demand re-boxing vs. re-labelling at large, despite the wish from a majority of Member States to do so. In the interest of patient safety in the Member States affected we propose the following amendment:

Article 67 – paragraph 8 (new)	
Text proposed by the Commission	*Amendment*
	8. Member States may, for the purposes of patient safety, require that medicinal products imported or distributed in parallel must be re-packaged in new outer packaging in order to remove any potential doubt on the part of wholesalers, persons authorised or entitled to supply medicinal products to the public and consumers about the integrity of the re-packaging product.

Environmental Risk Assessment

Affordable Medicines Europe fully supports the inclusion of a strong and obligatory Environmental Risk Assessment (ERA). This means maintaining Articles 6(2), 22, 23 and 24. However, we would like to see some further basic information be included. This is information only manufacturers normally have (non-commercially sensitive), but which other stakeholders are sometimes asked to provide by e.g., public tenders/procurement. To this end, we propose that such information is included as part of the requirements for ERA listed in Annex II, Section 1.6, 4th Sentence, as follows:

Annex II – Section 1.6 – 4th sentence	
Text proposed by the Commission	*Amendment*

The information shall consist of:
 	
- **an introduction**
 	
- **a copy of […]**
	The information shall consist of:
	
	- an introduction***, which as a minimum includes:***
	  ○ ***the legal names and physical addresses of final manufacturing facilities for the product(s)/range***
	  ○ ***the legal names and physical addresses of manufacturing facilities one (1) step beyond, final manufacturing of the product/products/range.***
	  ○ ***the legal names and physical addresses of manufacturing facilities for the component(s) of the product(s)/range***

	○ ***indications of smelters/refiners for tin, tungsten, tantalum, and gold (3TG), cobalt and mica in the product(s)/range*** ○ ***the legal names and physical addresses of extraction facilities for the raw material for the product(s)/range*** - a copy of….

Penalties

Affordable Medicines Europe considers that penalties should be foreseen more generally for MAH's when they fail to meet their obligations as set out in Chapter V.

Article 206 – paragraph 2	
Text proposed by the Commission	*Amendment*
2. The rules referred to in paragraph 1, first subparagraph, shall address, inter alia, the following:	2. The rules referred to in paragraph 1, first subparagraph, shall address, inter alia, the following:
(b) the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well as sale at distance of falsified medicinal products to the public;	(f) the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well as sale at distance of falsified medicinal products to the public;
(c) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, import and export of active substances;	(g) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, import and export of active substances;
(d) non-compliance with the provisions laid down in this Directive on the use of excipients;	(h) non-compliance with the provisions laid down in this Directive on the use of excipients;
(e) non-compliance with the provisions laid down in this Directive on pharmacovigilance;	(i) non-compliance with the provisions laid down in this Directive on pharmacovigilance;
(e) non-compliance with the provisions laid down in this Directive on advertising.	(e) non-compliance with the provisions laid down in this Directive on advertising. ***(f) non-compliance with the obligations laid down in this Directive in Chapter V***

General Support

Affordable Medicines Europe would like to highlight a number of provisions we fully support in the proposed Directive, why we hope these will be maintained by the co-legislators.

In Chapter II, we fully support the changes proposed to the decentralised and mutual recognition procedures I relation to the possibility for Member States to opt-into these procedures. **Hence, we fully support recitals 39 and 40 as well as Article 34(3), and Article 36(4)**. We believe this can help increase availability and access to new medicines for more patients.

In Chapter III, **we fully support the changes proposed to the reduction in examination period from 210 to 180 days in Article 30. We also specifically support the change towards making marketing authorisations unlimited in time referring to recital 79 and Article 46(1).**

In Chapter V **we support the earlier notification of withdrawal paediatrics from 6 to 12 months.**

REVISED REGULATION

Affordable Medicines Europe draws attention to the following points in the proposed Regulation.

Scope of the Regulation

Affordable Medicines Europe strongly supports the inclusion of Chapter X on *Availability and Security of Supply of Medicinal Products* in the Regulation. Hence, we believe it is very important that the scope mentions both parts of Chapter X, Section 1, *Monitoring and Management of Shortages and Critical Shortages* and Section 2, *Security of Supply*. Hence, we call for the insertion of the headline of Chapter X, Section 1 in Article 1 to reflect this important objective of the Regulation in the scope.

Article 1	
Text proposed by the Commission	*Amendment*
This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.	This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the ***monitoring and management of shortages and critical shortages and*** security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.

Alleviating Shortages and Security of Supply

First and foremost, Affordable Medicines Europe keenly welcome the Commission's proposal in relation to the handling of shortages and security of supply. Hence, generally, we fully support the proposals put forward by the Commission in Chapter X.

We would, however, **consider it crucial, that the Regulation also seeks to ensure a proper information flow and coordination of the actions taken at national level when shortages occur.** We have seen very clearly during COVID – and to some extent during the anti-biotics crises in the fall/winter of 2022 – that some measures taken by Member States may perversely affect the Internal Market and patients across the Union. While Member States will always attempt to act in the best interest of their citizens, we propose that in doing so, a mechanism is established whereby the Commission and EMA obtain information and may provide oversight on such actions, should they have unintended problematic consequences for the EU as a whole. If this would be the case, immediate dialogue and alternative solutions should be found in cooperation between Member States, the Commission, EMA, and stakeholders.

To this effect we propose the following number of amendments, outlining six steps, that must be seen in combination as establishing such a mechanism in an efficient and practical manner.

First, we propose that there is need for the reporting of national measures taken by the NCA to EMA.

Article 121 – paragraph 1 – subparagraph b	
Text proposed by the Commission	*Amendment*

(b) publish information on actual shortages of medicinal products, in cases in which that competent authority has assessed the shortage, on a publicly available website.	(b) publish information on actual shortages of medicinal products, in cases in which that competent authority has assessed the shortage, on a publicly available website. ***The Member State shall, within one week, inform the Agency of any measure foreseen or taken at national level to mitigate the shortage.***

Second, we consider it essential, that some deadlines are put in place, as the cross-border effects may need immediate remedy by NCA's in other Member States, or a fast resolution towards other possible measures instead of the initially proposed.

Article 121 – paragraph 2 – subparagraph f	
Text proposed by the Commission	*Amendment*
(f) inform the Agency of any actions foreseen or taken by that Member State to mitigate the shortage at national level	(f) inform the Agency of any actions foreseen or taken by that Member State to mitigate the shortage at national level ***without undue delay***.

Article 121 – paragraph 5 – subparagraph d	
Text proposed by the Commission	*Amendment*
(d) inform the Agency of any actions foreseen or taken by that Member State in accordance with points (b) and (c) and report on any other actions taken to mitigate or resolve the critical shortage in the Member State, as well as the results of these actions.	(d) ***within one week,*** inform the Agency of any actions foreseen or taken by that Member State in accordance with points (b) and (c) and report on any other actions taken to mitigate or resolve the critical shortage in the Member State, as well as the results of these actions***, within one month***.

Third, we consider it essential, that the Agency assesses the measures foreseen or taken at national level by Member States to mitigate the shortage when these can have an impact the availability of medicines in other Member States. In cases where there could be an effect of national measures on the availability in other Member States, the Agency should report this to the Commission, who will then have to act in relation to safeguarding the integrity of supply in all Member States and the functioning of the Internal Market.

This is necessary in cases where the MSSG does not consider the shortage in question to be a 'critical shortage' across the Union, and therefore does not include it in the list of critical shortages, and thereby provide recommendation on how to handle it. However, measures taken nationally to tackle 'critical shortages in the Member State' or 'shortages' may still have adverse effect on other Member States. Hence, a mechanism needs to be in place to assess this, and subsequently take the appropriate action.

Article 122 – paragraph 6 (new)	
Text proposed by the Commission	*Amendment*
	6. The Agency shall assess the measures notified by Member States under Article 121(1), point (b); 121(2), point (f); and 121(5), point (d) in relation to the effects they may have on the availability of medicines in other Member States, and report on this to the Commission.

Fourth, we consider it important, that MSSG provides its recommendations without any undue delay in context of alternative measures that could be taken by Member States.

Article 123 – paragraph 4	
Text proposed by the Commission	*Amendment*
4. The MSSG may provide recommendations on measures to resolve or to mitigate the critical shortage, in accordance with the methods referred to in Article 122(4), point (d), to relevant marketing authorisation holders, the Member States, the Commission, the representatives of healthcare professionals or other entities.	4. The MSSG may provide ***without any undue delay*** recommendations on measures to resolve or to mitigate the critical shortage, in accordance with the methods referred to in Article 122(4), point (d), to relevant marketing authorisation holders, the Member States, the Commission, the representatives of healthcare professionals or other entities.

Fifth, we consider it essential, that in the context of management of shortages, access to documents is granted to marketing authorisation holders and other relevant actors without prejudice to commercially confidential information that shall therefore not be disclosed. This is important for the collaboration in the supply chain, as well as for being able to assess the nature and validity of the data provided by MAH's and other stakeholders.

Article 124 – paragraph 4 (new)	
Text proposed by the Commission	*Amendment*
	4. Marketing authorisation holders as defined in Article 116(1) and other actors listed in Article 120(2) that are directly affected by the measures notified under Article 121(1), point (b); 121(2), point (f); and 121(5), point (d) shall be granted access to the documents, while protecting commercially confidential information. The Agency may set a deadline within which marketing authorisation holders and other actors may submit their comments.

Sixth, and as the next step following the reporting from EMA and the MSSG, the Commission will need to consider and take appropriate action as also outlined by the proposal.

In situations where Member States initiate national measures, which should be notified vis-à-vis the above provisions and amendment to Article 121, for shortages that are not deemed critical across the Union, cf. the definition of a 'critical shortage', by the MSSG, action is still needed in order to ensure that the national measure proposed/enacted does not worsen the situation on availability unnecessarily in other Member States. To this effect, we have proposed Article 122(6) (new). In these situations, it is still, if not even more important, for the Commission to take appropriate action based on the assessment from EMA. Hence, we propose to include a new paragraph 3 to Article 126.

Article 126 – paragraph 1	
Text proposed by the Commission	*Amendment*
1. The Commission shall, where it considers it appropriate and necessary:	1. The Commission shall, where it considers it appropriate and necessary ***to manage shortages and critical shortages***:

(a) take into account the MSSG recommendations and implement relevant measures; **(b) inform the MSSG of those measures taken by the Commission.**	(a) take into account the MSSG recommendations and implement relevant measures; (b) inform the MSSG of those measures taken by the Commission.

Article 126 – paragraph 3 (new)	
Text proposed by the Commission	*Amendment*
	(3) The Commission shall take the appropriate steps to address any concerns raised by the report of the Agency in Article 122(6) (new).

Definitions

Affordable Medicines Europe would like to **express a very strong support to the definitions on shortages proposed in Article 2, points 14-16**. The debate on how to define shortages have raged for many years now, and it is pivotal if we are to have an effective pan-European approach to tackling shortages, **that we have a coherent set of definitions to work from. The importance of this cannot be understated.**

The proposed definitions are fully aligned with the definition already established by EMA/HMA (Heads of National Medicines Agencies). Only one minor difference to the usual terminology occurs as the Commission has proposed 'appropriate alternative' whereas usually we always speak of 'therapeutical alternatives'. It is a small point, but the healthcare professionals we have spoken to strongly prefer to use the usual terminology of 'therapeutical alternative', rather than appropriate. 'Therapeutic', according to them, is a fixed terminology leaving no room for individual assessments. I.e., disagreements between doctors, pharmacists and the NCA could arise with the more ambiguous 'appropriate'.

Article 2 – point 15	
Text proposed by the Commission	*Amendment*
(15) 'critical shortage in the Member State' means a shortage of a medicinal product, for which there is no *appropriate* alternative medicinal product available on the market in that Member State, and that shortage cannot be resolved.	(15) 'critical shortage in the Member State' means a shortage of a medicinal product, for which there is no ***therapeutical*** alternative medicinal product available on the market in that Member State, and that shortage cannot be resolved.

Some Member States and patient organisations tend to put withdrawals and unavailability as well in the category of "shortages". While we understand fully that for a patient it doesn't matter why the medicine is not there – for the work done in this Regulation, it matters that e.g., a product that has never been launched in a country, is not put into a "shortage" category. Usually, EMA and most NCA's agree that products not launched at all in a given market is labelled/defined as an "unavailability". Once products are withdrawn permanently (either for quality or commercial reasons (so Art. 116(1), point (a) and (b)) it would also be considered "unavailable". Most would also consider temporary marketing suspension as "unavailability" (Article 116(1), point (c)) since there is no knowledge on the end date (cf. Annex IV, Part I). We therefore propose it may be valuable to include a definition of unavailability as well.

Article 2 – point 17 (new)	
Text proposed by the Commission	*Amendment*
	(17) 'unavailability' means a situation a product has not been launched, has been permanently withdrawn or marketing has been ceased or suspended.

MAH notifications

Affordable Medicines Europe **strongly supports the efforts done in the Regulation to ensure proper reporting of shortage by MAHs**. This includes strong support for the requirements to notify under Article 16(4), Article 24, as well as under Article 116(1). **We consider the timelines for notifications proposed by the Commission are appropriate and should not be changed**.

In relation to Article 116(2), on the information MAHs must provide in relation to shortages, we consider it very important, that Annex IV, Part III, point 2 (e) is elaborated, so that the indication of the reasons for a shortage are somewhat harmonised. This allows for better more uniform data gathering and information sharing on the causes of shortages, which again could help make better decisions in the future in relation to shortages management.

Annex IV - Part III - point 2 – subpoint e	
Text proposed by the Commission	*Amendment*
(e) Reason for shortage;	(e) Reason for shortage; • ***Raw material disruption, due to…*** • ***API disruption, due to…*** • ***Excipient disruption, due to…*** • ***Production problem, due to..*** • ***Quality problem, due to…*** • ***Production capacity, due to…*** • ***Logistics problem, due to…*** • ***Distribution problem, due to…*** • ***Inventory and storage practices*** • ***Increase in demand*** • ***Commercial reasons***

Shortage Prevention Plans

Affordable Medicines Europe **strongly supports the inclusion of MAH prevention plans in the proposed Regulation**. We consider they are appropriate measure to ensure MAHs reflect and consider on a *preventive* basis their business processes and product management. Hence, it is clear to us, that such prevention plans must be put in place by MAH's on a permanent basis – and not only when shortages occur or are at risk of occurring. In many instances prevention will be too late at that stage, and rather mitigation plans are necessary.

In addition, we strongly believe that it is important to have in the prevention plans a good overview of the actual quantities delivered to the market over a reasonable timeframe, so as to be able to quickly assess whether the MAH is providing a stable flow of products in general. This is also requested in the shortage mitigation plan (albeit at monthly basis, since this is regarding established or expected shortages (see for this Annex IV, Part IV (1), point (c). Hence, we propose to include yearly quantities to the prevention plan information set out in Annex IV, Part V.

Annex IV - Part V – point 1, subpoint l (new)

Text proposed by the Commission	*Amendment*
	(l) Quantities delivered each year per Member State in previous 5 years

Obligations on other stakeholders

We consider that the requirements on the provision of data by other stakeholders than the MAH's goes much further than what the Regulation establishes for MAH's themselves - where information required is clearly set out. Hence, we do support of course giving information, but would like to see at least a reference to "relevant" and to ensure that only NCA's have access to commercially sensitive information.

Article 120

Text proposed by the Commission	*Amendment*
2. **For the purposes of Article 118(1), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any information requested in a timely manner.**	2. For the purposes of Article 118(1), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any ***relevant*** information requested in a timely manner. ***Commercially sensitive information shall only be available to the relevant authorities.***

Article 129

Text proposed by the Commission	*Amendment*
For the purposes of Article 127(4) and Article 130(2), point (c), and Article 130(4), point (c), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any information requested in a timely manner.	For the purposes of Article 127(4) and Article 130(2), point (c), and Article 130(4), point (c), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any ***relevant*** information requested in a timely manner. ***Commercially sensitive information shall only be available to the relevant authorities.***

We also consider it essential, that in context of fighting shortage in a collaboration between authorities and stakeholders, there is still a strong focus on protecting commercially sensitive information between the stakeholders. Hence, we propose that such information may be made available to the authorities, but should not be made available to the other stakeholders.

Article 127	
Text proposed by the Commission	*Amendment*
4. For the purposes of the identification of critical medicinal products referred to in paragraph 1, the competent authority of the Member State may request relevant information from other entities including other marketing authorisation holders, importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public.	4. For the purposes of the identification of critical medicinal products referred to in paragraph 1, the competent authority of the Member State may request relevant information from other entities including other marketing authorisation holders, importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public. ***Commercially sensitive information shall only be made available to the relevant authorities.***

Environmental Risk Assessment

Affordable Medicines Europe fully supports the establishment of a register of environmental risk assessment studies, and the publication of the information included in such register. This means maintaining Article 104(3). However, we would like to make sure that some further basic information, that we propose (see above) to have included as part of the requirements for ERA listed in Annex II, Section 1.6 of [revised Directive 2001/83/EC], is also made public. This is information only manufacturers normally have (non-commercially sensitive), but which other stakeholders are sometimes asked to provide by e.g., public tenders/procurement. The publication of such information would therefore allow more stakeholders to participate in procurement procedures and enter the market. To this end, we propose to include in Article 104(3) a reference to the proposed requirements listed in Annex II, Section 1.6, as follows:

Article 104	
Text proposed by the Commission	*Amendment*
4. The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a register of environmental risk assessment studies conducted for the purpose of supporting an environmental risk assessment for medicinal products authorised in the Union, unless such information is made public in the Union by different means. **Information in such register shall be publicly available, unless restrictions are necessary to protect commercially confidential information. For the purpose of setting up such register, the**	4. The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a register of environmental risk assessment studies conducted for the purpose of supporting an environmental risk assessment for medicinal products authorised in the Union, unless such information is made public in the Union by different means. Information in such register shall be publicly available and ***includes as a minimum the information reported in Annex II – Section 1.6 of [revised Directive 2001/83/EC]***, unless

Agency may request marketing authorisation holders and competent authorities to submit results of any such study already completed for products authorised in the Union within [OP please add the date = 24 months after the date of application of this Regulation].	restrictions are necessary to protect commercially confidential information. For the purpose of setting up such register, the Agency may request marketing authorisation holders and competent authorities to submit results of any such study already completed for products authorised in the Union within [OP please add the date = 24 months after the date of application of this Regulation].

General Support

Affordable Medicines Europe would like to highlight that we fully support the provision according to which a marketing authorisation for a medicinal product shall be valid for an unlimited period, as stated in Chapter II of the revised Regulation. **Hence, we fully support Article 17(1).**

Affordable Medicines Europe represents Europe's licensed parallel distribution industry, an integral part of the European pharmaceutical market that adds value to society by introducing price competition for pa-tented medicines and a supplementary layer of product safety. We represent 125 companies in 23 EU/EEA Member States. These members account for approximately 85% of the total parallel import market volume in the EU/EEA. Membership in Affordable Medicines Europe is

exclusive to companies holding a wholesale (GDP) license (export and import). All importing members furthermore are GMP licensed.