GIRP'S SUBMISSION OF COMMENTS ON THE CONSULATION DRAFT EU Medicines Agencies Network Strategy to 2020

(EMA/MB/151414/2015)

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GIRP (the European Association of Pharmaceutical Full-line Wholesalers) is the umbrella organisation of pharmaceutical full-line wholesalers in Europe, representing the national associations of over 750 pharmaceutical full-line wholesalers serving 33 European countries, including major pan-European pharmaceutical full-line wholesaling companies.

They are the central element in the healthcare supply chain, around which the legally required guaranteed availability of medicines via pharmacies to the general public revolves. GIRP and its members play a vital and value-adding role in the healthcare supply chain, by supplying about 170,000 retail pharmacies as well as other healthcare professionals (self-dispensing doctors, druggists, hospitals and veterinarians) with more than 100,000 products in a cost efficient and service intensive manner.

The activity of pharmaceutical full-line wholesaling, as part of the legitimate supply chain, consists of the purchase, warehousing, storage, order preparation and delivery of medicines. Pharmaceutical full-line wholesalers carry and distribute the complete assortment of products in range and depth within the framework set by the authorities which may include public service obligation and the market to meet the needs of those with whom they have normal business relations.

In addition to delivering all medicines in their geographical area of activity on the same day/within less than 24 hours, pharmaceutical full-line wholesalers provide working capital and extended financing services, funding of stock and receivables of pharmacies and health care professionals.
Pharmaceutical full-line wholesalers buy medicines required by their customers from the pharmaceutical industry, store them, and deliver them to pharmacies, hospitals and other health care professionals just in time, thereby ensuring through their buffer stock holding function the permanent access to medicines by patients and the pre-financing of the health care system.

GIRP, the European Association of Pharmaceutical Full-line Wholesalers, welcomes the opportunity to provide a contribution to the Consultation Draft on EU Medicines Agencies Network Strategy to 2020 (EMA/MB/151414/2015).

GIRP is very much supportive of the excellent work of the EMA and is committed to working with the Agency where needed and demanded within the scope of responsibilities of pharmaceutical full-line wholesalers on improving the legislative and regulatory environment for the safe, efficient and effective distribution of medicines for European patients.

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Reference to the text	Comments
Chapter 1: Introduction to the European medicines agencies regulatory network 92 In the EU, medicines are governed by a large body of EU legislation, which aims to guarantee high 93 standards of quality, safety and efficacy of medicinal products, as well as appropriate information, and 94 to promote the functioning of the internal market. The EU legislation today covers the whole life-cycle 95 of a medicinal product from the research phase (clinical trials), the approval stage, manufacturing, 96 distribution to post-marketing obligations, including sectorial legislation on orphan and paediatric 97 medicines, advanced therapy medicinal products, as well as maximum residue limits for food safety. 98 There are some exemptions, notably pricing and reimbursement for human medicines, which remain a 99 national competence. The European legislation governing medicines has been strengthened 100 significantly in recent years in the areas of pharmacovigilance, falsified medicines and clinical trials. 101 Drafting of new legislation on veterinary medicines is ongoing. Full and harmonised implementation of 102 recent legislation will be a priority for the network in the coming years.	GIRP is supportive of all new and ongoing revisions of European legislation mentioned in this consultation document. New and improved legislation and regulation can enhance the environment in which wholesale distributors operate in order for them to provide timely, safe and continuous supply of medicines to pharmacies, hospital and other healthcare professional for patients. However, it is important that legislation and regulation takes proportionate account of the individual activities and levels of responsibility of the different operators in the pharmaceutical supply chain. For instance, when obligations are being placed on wholesale distributors, it is important that facilitating obligations are placed on upstream and downstream operators, to ensure that wholesale distributors are effectively able to comply with their obligations. Post marketing surveillance is of utmost importance for national competent authorities when it comes to the oversight of the pharmaceutical supply chain. It is often the case that post marketing surveillance systems involve the requirement for operators in the pharmaceutical supply chain to record certain information about the products. Often we see the requirement for wholesale distributors to record the batch number and expiry date of the different types of products (medicinal products, veterinarian medicinal products, medical devices). It is essential that any requirement to record such information at the level of the wholesale distributor is based on the availability of information in a suitable machine readable format for wholesale distributors and for their data capture and storage. Not requiring the manufacturer or importer to ensure that such information be available in machine readable format, results in wholesale distributors being faced with an insurmountable challenge of having to record such information manually. The manual recording of such information results in a high

	number of errors. Manual recording also substantially slows down the speed of product commissioning and delivery. Finally it is important to mention that new requirements such as the one just mentioned are introduced in a proportionate and pragmatic way to the extent that they do not hinder the continuous supply of products to European patients. In summary, new legislation should not shift post marketing surveillance responsibilities and duties onto the shoulders of wholesale distributors. Legislation and regulation needs to take proper account of the actual activities and responsibilities of wholesale distributors in the supply chain. Wholesale distributors should not be burdened with post marketing surveillance activities which typically lie in the hands of national competent authorities or which are part of the marketing/manufacturing authorization holder or importer obligations. Wholesale distributors are authorised, in accordance with the principles and guidelines of Good Distribution Practices, to carry out wholesale distribution activities. Any legislative or regulatory obligation which would lead wholesale distributors to interfere with the packaging or the product itself would require additional licensing such as Manufacturing authorisations. Therefore, new legislative or regulatory obligations need to reflect the nature of activities and responsibilities of the wholesale distributors.

Chapter 3: Strategy for the network ***Theme 1: Contributing to human health*** 178 At the same time, we must ensure that patients in the network continue to have access to existing 179 medicines by taking action when supply issues arise, by supporting the development of generics and 180 biosimilars and by facilitating access to medicines through appropriate classification Picture: ensure timely access to new beneficial and safe medicines for patients	It is important to mention that access to medicines is not only about authorising the placing of new products on the market. Pharmaceutical full-line wholesalers provide a framework for the safe, effective and efficient distribution of all medicines authorized to be marketed in the various national markets. Pharmaceutical full-line wholesalers provide the full range of medicines, in range and depth, to pharmacies, hospitals and other healthcare providers, within a very short timeframe. The timely access to safe medicines for European patients can only be fully guaranteed by ensuring that a sustainable framework is in place for the actual distribution of medicines by operators such as pharmaceutical full-line wholesalers. Therefore, as part of the strategy for the network, due account of the actual activities and responsibilities of pharmaceutical full-line wholesalers in the overall health care system should be taken into account. When speaking about ensuring "timely access to new beneficial and safe medicines for patients" the entire distribution chain and its compulsory cooperation needs to be duly considered.
Objective 1: Focus on key public health priorities including availability of medicines and antimicrobial resistance 203 such as dementia. Also, the network's contribution to ensuring that the needs of special populations 204 including children and the elderly are met should be explored to ensure that these vulnerable groups 205 have timely access to appropriately developed medicines together with appropriate information to 206 support their use.	GIRP members (pharmaceutical full-line wholesalers) ensure that all medicines are available whenever and wherever needed so that even the most isolated patient can receive the most specialised medicine in a safe and timely manner. GIRP members guarantee the highest levels of supply chain quality, integrity and excellence. They are the trusted supply chain partners for manufacturers, pharmacists, healthcare professionals and, above all, patients. We would fully support public health priorities which focus on the issue of availability of medicines. We would encourage full and optimised recognition and use of the existing distribution network which is in place and operated by pharmaceutical full-line wholesalers. The contribution

	that the distribution network of pharmaceutical full-line wholesalers provide is often overseen in the discussion when it comes to ensuring medicines availability.
221 Over the next five years a priority will be to ensure that the network continues to be able to respond to 222 public health emergencies, whether novel infectious diseases or other threats, by facilitating the early 223 introduction of new treatments or preventative measures and learning from actions taken to address 224 public health crises such as the Ebola outbreak.	GIRP would like to inform that the pharmaceutical full-line wholesalers can play a key role in crisis preparedness and in times of public health threats and pandemics. In some countries where wholesale distributors are legally obliged to carry out a public service obligation they are typically required to have buffer stocks over a defined period of time. Involving wholesale distributors in crisis and emergency planning can be important for national competent authorities in terms of inventory management of medicines and for making such medicines available whenever and wherever needed. For this purpose GIRP has an emergency contact list in place.
225 The network is increasingly confronted with supply challenges and shortages/lack of availability of both 226 new and old medicines. These supply issues can be caused by falsified medicines, stolen medicines, 227 manufacturing/GMP non-compliance issues or many other factors including economic. Supply chains 228 for medicines have become more and more complicated with an increasing trend to manufacture 229 outside the EU. There is a continued need to ensure the quality of products wherever they are 230 manufactured. 231 The Falsified Medicines Directive (FMD) introduced a range of measures to strengthen the legal supply	Concerning the issue of shortages and lack of availability of medicines, GIRP would like to highlight that it stands ready to support initiatives which will help address these issues. While understanding the remit of the activities of the EMA, it is important to look at the issues from a holistic point of view. Shortages and the lack of availability of medicines are not only issues concerning manufacturing and GMP non-compliance. GIRP has published on its website (www.girp.eu) a reflection paper which sets out wholesaler distributors' perspectives on the root causes and possible solutions for mitigating the impact of shortages. It is therefore important to bring all stakeholders including pharmaceutical full-line wholesalers together to look at the root causes and to find common solutions which can help mitigate the problems arising from shortages and a lack of availability of medicines. The EMA can take a lead in

232 chains and protect them from falsified medicines. The network will continue to explore how it can best 233 address supply issues of whatever cause, including GMP issues, disruption of manufacturing processes 234 and reliance on a single or few manufacturers for essential medicines. It will work with other bodies 235 addressing the broader causes of supply problems. The network will also need to increase its cross 236 border collaboration in case of supply disruptions that affect multiple Member States.	facilitating the bringing together of all stakeholders in the pharmaceutical supply chain and public bodies to discuss these concerns and to find together measures which will address the issues mentioned here. GIRP therefore supports targeted initiatives that might look at these issues in a wider context.
Theme 2: Contributing to animal health and human health in relation to veterinary medicines *380 Objective 1: Increase availability of veterinary medicines and promote* *381 development of innovative medicines and new technologies*	GIRP certainly lends its support to a strategy which will contribute to animal health and human health in relation to the availability of veterinary medicinal products. The European institutions are currently working on revising the legislative framework for veterinary medicinal products. GIRP widely supports the new legislative developments in this field. However, as mentioned in our initial remarks on supporting for operators in the distribution chain a better regulatory environment, it is important that new obligations reflect the actual activities of the various operators. When wholesale distributors will be required to record certain information (e.g. batch number and expiry date) on the outer packaging of veterinary medicinal products, it will be important that such information be available in machine readable format. It is therefore crucial that the legislation ensures that upstream operators (marketing/manufacturing authorization holders and or importers) are obligated to place such information on the outer packaging in machine readable format.

412 Objective 2: Promote 'Better Regulation' 423 The network will seek to optimise 424 the operation and decision-making process of all authorisation procedures and cooperate to improve 425 Industry's regulatory excellence to ensure that resources for scientific scrutiny are prioritised to the 426 most important issues.	As already mentioned previously as part of the strategy to promote better regulation, it is important that regulation only sets obligations which are reflective of the actual activities and responsibilities of the various operators in the supply chain. Time and time again we see obligations being placed on wholesale distributors to record certain information from the outer packaging of products. Typically, the requirement involves wholesale distributors to record the batch number and expiry date of the products. However, in order for wholesale distributors to effectively comply with this requirement, it is important that the regulation obligates marketing/manufacturing authorization holders and importers to make this information available on the outer packaging in a suitable machine readable format. Furthermore, the machine readable codes should be standardized.
482 ***Theme 3: Optimising the operation of the network*** 499 Trust not only relies on the 500 quality of the scientific competence and the output of regulatory authorities, but also on their 501 commitment to seek active involvement of the stakeholders (in particular patients, human and animal 502 healthcare professionals, and the scientific community) in the work of the authorities. The network also 503 needs to work closely with those it regulates.	GIRP members stand willing and ready to take active involvement in the discussions with national regulatory agencies. It is often the case that representatives from the wholesale distribution community are not informed and not involved when important issues concerning Good Distribution Practices and Good Manufacturing Practices, which have a distribution perspective, are being discussed by national regulatory agencies in the presence of other stakeholders.

580 Objective 3: Ensure effective communication of and within the network 586 To generate understanding and trust, the network 587 must ensure that its approach to communication supports the overall objective of safeguarding human 588 and animal health. Only when trust can be fostered stakeholders will play their part in contributing to 589 such an overall objective.	As a stakeholder, GIRP supports this objective and believes that there is a need for effective communication between the network and stakeholder organisations such as ours. In order to achieve a better and smarter regulatory framework it is important to have a high level of understanding of the role of the different stakeholders and their organisations in contributing to achieve the current thoughts as outlined in the strategy.
598 One of the major challenges relates to the handling of emerging events with respect to authorised 599 medicines. Such events are mainly safety concerns or quality defects, putting into question the positive 600 benefit/risk balance of medicines. Important progress in this field has been made since 2010 by 601 putting in place a coordinated approach within the network towards communication on such emerging 602 events. This has allowed adopting whenever possible a proactive approach towards communication 603 within the network, fostering as much as possible a consistent message towards the stakeholders. 604 Nevertheless, the network will have to continue ensuring its outputs are usable, authoritative and 605 reliable. To make further improvement in this field, it will be imperative to even better understand the 606 expectations and needs of its stakeholders, in particular patients and healthcare professionals, so that 607 the necessary measures can be taken.	GIRP believes it has a role to play in helping address the major challenges related to the handling of emergency events with respect to authorised medicines. GIRP maintains an emergency contact list which can be used by central and national regulatory agencies in times of public emergencies. The emergency list is available on our website and the login details have been provided to the European Commission. GIRP members stand ready and are willing to take an active part in discussions which will lead to a better coordinated approach to the handling of public emergencies. GIRP members have been involved in dealing with public emergencies in the past such as during the H1N1 crisis and other pandemics.
613 Objective 4: Strengthen the links with other authorities and with stakeholders 621 A number of events in the past years in the field of medical devices have underlined the need to	With respect to objective 4 we would like to highlight, in the area of medical devices, it is important that the new legislation and other initiatives, such as the development of the unique device identifier

622 provide for a more robust regulatory framework and new legislation is now underway to address such 623 need. There will, however, remain areas, irrespective of the national situation, where collaboration 624 between medicines regulators and medical devices regulators will have to be strengthened, such as in 625 the field of combination products, companion diagnostics, borderline products, and ancillary medicinal 626 substances. The network will explore how such collaboration could be reinforced. In addition, 627 depending on the outcome of the discussions on the new legislation on medical devices, further areas 628 for collaboration with medical devices authorities may be identified, learning from areas of best 629 practice including NCAs who already have joint medicines and devices responsibilities.	system, will include obligations and requirements which are proportionate to the activities and responsibilities of distributors.