BEUC The European Consumer Organisation

The Consumer Voice in Europe

EU Medicines Agencies Network Strategy to 2020

Response to the public consultation

Contact: **Katrina Perehudoff – health@beuc.eu**

Ref.: BEUC-X-2015-066 - 29/06/2015

BUREAU EUROPÉEN DES UNIONS DE CONSOMMATEURS AISBL | DER EUROPÄISCHE VERBRAUCHERVERBAND
Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90 • Fax +32 (0)2 740 28 02 • consumers@beuc.eu • www.beuc.eu
www.twitter.com/beuc - EC register for interest representatives: identification number 9505781573-45

29 June 2015

EMA/201512/2015

EU Medicines Agencies Network Strategy to 2020 - Working together to improve health

1. Submission of comments

Comments from:

Name of organisation or individual
The European Consumer Organisation (BEUC)

BEUC The European Consumer Organisation

General comments

General comment (if any)	Outcome (if applicable) *<to be completed by the EMA/HMA>*
BEUC welcomes the opportunity to comment on the EU Medicines Agencies Network Strategy to 2020. To better address public health needs and optimise the safe use of medicines for human use in Europe, we encourage the EU Medicines Agencies to address the following: - The network's strategy should be more representative of the needs of all patients, rather than highly focusing on a narrow group of patients with unmet medical needs. - The trend to make new medicines available earlier must not be at the expense of the safety of medicines. All patients, including patients seeking early access to a medicine for unmet medical needs, deserve the same protection. - We welcome a discussion on knowledge generation and evidence requirements for medicines access. We strongly believe that 'early access' programmes should be limited to subset of medicines to treat genuine unmet medical needs or rare diseases. In this way, early access programmes should remain the exception and should not become the rule. - The term 'novel' suggests *newer* although it doesn't necessarily communicate that the products should be better than existing alternatives, which is what all patients deserve. Therefore, we suggest the term 'novel' be replaced with the term 'added therapeutic value' throughout the document.	

General comment (if any)	Outcome (if applicable) *<to be completed by the EMA/HMA>*
- European regulators can play a leadership role by stimulating sponsors to study and submit data on the comparative effectiveness of new medicines in the application for market authorisation. The earlier a medicine's comparative efficacy is known in the medicines lifecycle, the greater the benefits for pricing and reimbursement decisions, the faster access to medicines of added value, and the more informed decisions by healthcare providers and patients can be achieved. - The network strategy can acknowledge overconsumption and inappropriate prescribing as key challenges and integrate their reduction into the long term goals of the network. - In response to public health emergencies, we would like to see the rapid introduction of preventative and treatment measures that have been proven to be safe and effective. - Greater attention to drug shortages, particularly the economic factors that cause them, and the coordination and dissemination of information about them, would be beneficial to consumers. - Optimise the balanced involvement of stakeholders in the network's activity while appropriately handling potential conflicts of interest.	
As concerns medicines for veterinary use, BEUC would like to make the following recommendations: - If we welcome the work undertaken by EMA to update the SPCs of antimicrobials and integrate references to the prudent and responsible use of antimicrobials, we also believe that the strategy should mention the possibility to restrict, or even forbid, the veterinary use of certain antimicrobials deemed of critical importance for human health. This is particularly	

General comment (if any)	Outcome (if applicable) *<to be completed by the EMA/HMA>*
relevant as the EMA will help the European Commission identify which antimicrobials should be on the two lists mentioned in the new Veterinary Medicines Regulation – i.e. the list of antimicrobials restricted in veterinary medicine and the list of antimicrobials forbidden off-label. BEUC encourages EMA to prioritise the evaluation of modern cephalosporins and fluoroquinolones, which are used in livestock while being used as a last resort solution in patients with difficult-to-treat infections. For more information please access the BEUC position paper on antibiotic use in livestock and the BEUC position paper on the European Commission's proposals to tackle antibiotic resistance in the Veterinary Medicines and Medicated Feed legislations. - A record system for consumption data will greatly improve transparency and help determine where most efforts must be devoted. To do so it is important to collect relevant information and combine different kinds of data to get a full picture of antibiotic use in livestock. Consumption data should provide information on the duration of treatment, the dose administered, the number of animals treated, the therapeutic indication and the administration route. It is particularly important to monitor and record any metaphylactic use as this practice is not substantiated by any scientific studies but rather validated because of organisational matters. Ideally consumption data should be collected at farm level and at veterinarians' level to get a full picture of the true situation on the ground. In addition any off-label use should also be	

General comment (if any)	Outcome (if applicable) *<to be completed by the EMA/HMA>*
collected. For more information please access the BEUC position paper on antibiotic use in livestock and the BEUC position paper on the European Commission's proposals to tackle antibiotic resistance in the Veterinary Medicines and Medicated Feed legislations. - The new Veterinary Medicines Regulation might abolish the ranking system which helped determine what antimicrobials are most suitable when there is no drug available for the species and/or the indication. This means that antimicrobials only authorised in humans could be administered to food-producing animals. As such the EMA should update antimicrobials SPCs to reflect on the need to use antimicrobials only allowed in human medicine as a last resort solution after all veterinary medicines have been deemed unsuitable. For more information please access the BEUC position paper on antibiotic use in livestock and the BEUC position paper on the European Commission's proposals to tackle antibiotic resistance in the Veterinary Medicines and Medicated Feed legislations.	

Specific comments on text

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
163	Rationale: Polypharmacy, or the use of multiple medicines, is on the rise and it often goes hand-in-hand with inappropriate prescribing, or medicines for which the risks outweigh the benefits and for which there are effective, safer alternatives. Medicines are prescribed to treat symptoms or diseases that can also be addressed by lifestyle changes or non-drug therapies, which are often highly effective, lower cost and potentially safer options for patients and healthcare systems. We suggest that the challenge of polypharmacy and inappropriate prescribing also be acknowledged in the strategy for the network. Text: As the population ages, diseases such as dementia become more of a public health burden. **Polypharmacy and inappropriate prescribing can lead to serious and preventable adverse events, particularly in older people.**	
167 Also at 241, 246, 319…	Rationale: The term 'novel' suggests *newer* although it doesn't necessarily communicate that the products should be better that existing alternatives. Only products that are better than existing alternatives will give patients the added value they need. Therefore we suggest the term 'novel' be replaced with the term 'added therapeutic	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
	value' throughout the document. Text: It is important that the network keeps abreast of these advances in science to ensure that ~~novel~~ products **of added therapeutic value** can be developed optimally for the benefit of the health of the citizens of Europe.	
173	Rationale: Experiences in the US show that expedited regulatory evaluation programmes have resulted in safety implications for patients, including a higher risk of serious adverse drug reactions (ADRs) and higher rate of patient information leaflet (PIL) revisions for dose, safety and efficacy issues.[1] We suggest this challenge be more clearly acknowledged, substantiating the need for continuous monitoring. Text: Monitoring of products throughout their lifecycle has never been more critical, **as more information is needed on the benefit-risk balance of medicines, particularly those to which early access has been granted.**	
175	Rationale: In BEUC's view, the trend to make new medicines available earlier must not be at the expense of the safety of medicines. Consumers expect that all licensed medicines have been proven to be safe before reaching the market. All patients, including patients	

[1] Kesselheim et al. JAMA 2011;305:2320-6
Berlin. Am J Pub Hlth 2009;99:1693-8

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
	seeking early access to a medicine for unmet medical needs, deserve the same protection. Text: To enable promising new medicines to get to patients ~~**at the earliest opportunity**~~ **in a timely manner** requires us to **establish their safety profile before exploring** flexible licensing pathways and a life-span approach with clinical drug development, licensing, reimbursement, use in clinical practice and monitoring viewed as a continuum.	
187	Rationale: Forward looking regulatory initiatives are often best started by taking stock of what has already been accomplished in the field of regulatory incentives, particularly for orphan medicines and paediatric medicines. BEUC encourages the EU network of Medicines Agencies to host a public consultation and independent analysis of past regulatory incentives to bring products of added therapeutic value to the market, prior to embarking on future regulatory initiatives. Lessons learned from the past can inform best practice in the future. Text: It will also ~~review whether there are areas that could benefit from~~ **conduct an independent analysis of past** regulatory incentives to support the development of novel products **and, based on the results, determine whether there are areas that could benefit from future incentives.**	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
203	Rationale: Vulnerable groups such as older people and children are susceptible to overprescribing and inappropriate use of medicines. BEUC recommends that the network strategy acknowledges overconsumption as a key challenge and integrate its reduction into the long term goals of the network. Text: Also, the network's contribution to ensuring that the needs of special populations including children and the elderly are met should be explored to ensure that these vulnerable groups have timely access to appropriately developed medicines together with appropriate information to support their use **and reduce overconsumption**.	
221	Rationale: Patient safety is the centerpiece of any response to public health emergencies. BEUC would like to see the rapid introduction of preventative and treatment measures that have been proven to be safe and effective. The case of Tamiflu has illustrated that all balanced public health responses need to be based on established safety and efficacy of medicines, verifiable through access to clinical trials data, prior to medicines purchase and use. Text: Over the next five years a priority will be to ensure that the network continues to be able to respond to public health emergencies, whether novel infectious diseases or other threats, by facilitating the ~~**early**~~ **timely** introduction of new treatment or preventative measures	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
	proven to be safe and effective, and learning from actions taken to address public health crises such as the Ebola outbreak.	
226	Rationale: Economic factors have featured prominently in some cases of drug shortages in the EU, therefore, BEUC proposes to state this more clearly. Text: These supply issues can be caused by falsified medicines, stolen medicines, manufacturing/GMP non-compliance issues, ~~**or many other factors including**~~ economic **factors and many others**.	
235	Rationale: Greater attention should be paid to informing healthcare professionals and patients of impending or actual drug shortages, especially considering the cross border aspects of drug supply. Text: The network will also need to increase its cross-border collaboration in case of supply disruptions that affect multiple Member States, **in particular to rapidly coordinate and disseminate information about shortages or impeding shortages to healthcare professionals and patients**.	
243	Rationale: Access to medicines earlier in their lifecycle is sought by patients with unmet medical needs who want to expand their treatment options. Whereas patients whose medical needs are met do not have the same motivation to pursue so-called 'early access'. This nuance	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
	should be addressed in the text. Text: Patients **with unmet medical needs** increasingly demand access to new and innovative medicines at an earlier stage. Regulators need to balance the need for more information on the quality, safety and efficacy against the need for access, particularly in areas of unmet need.	
245	Rationale: In general, regulators are the 'guardians' of medicines safety and efficacy and it is their responsibility to balance the highest safety & efficacy standards with access. As this is a statement of their general responsibility, we suggest to remove the reference to unmet need. Text: Regulators need to balance the need for more information on the quality, safety and efficacy against the need for access~~, particularly in areas of unmet need~~.	
246	Rationale: The original statement should clearly be linked to medicines of added therapeutic value. Although new medicines with only marginal benefits compared to competitors can create some price competition between patented medicines, it doesn't tend to lead to price reductions in practice[i] and can detract from investments from other, much needed areas of research. Text: There is clear consensus amongst industry, regulators and HTA/pricing and reimbursement bodies	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
	that timely access to ~~appropriate novel~~ medicines **of added therapeutic value** is a priority.	
260	Rationale: Consumers expect that all marketed medicines are proven safe and this same approach must be taken to all 'timely access' measures for medicines. Text: In the next five years the network will have to progress the adaptive pathways pilot, review the outcome and promote ways to ensure timely access to new medicines for patients**, while still ensuring that expedited access is not at the expense of medicines safety**.	
265	Rationale: When considering HTA/pricing and reimbursement mechanisms, BEUC finds it important to consider the policy context of each country and respect the autonomy of each health system to choose which technologies and medicines it wishes to use. Studying the comparative efficacy of medicines can help enable access to the most optimal and safest treatments for patients. The earlier an assessment of comparative efficacy can take place in the medicines lifecycle, the quicker decisions about pricing and reimbursement can be made down the line, the faster medicines of added value can reach patients, and the more informed decisions can be made by healthcare providers and	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
	patients about the best available therapy. Moreover, European regulators can play a leadership role by stimulating sponsors to study and submit data on comparative effectiveness at the application for market authorisation. The EMA has already embraced the comparative efficacy criterion in situations where there are concerns about the safety or inferiority of a new drug.[2] Text: Furthermore, collaboration with other key bodies such as HTA/ pricing and reimbursement bodies and patient and healthcare groups will need to be strengthened to enable appropriate decision making **that respects national competencies** and sharing of information to allow optimal access. **To this end, the network will consider how to stimulate the collection and submission of data on the comparative efficacy as part of the application for market authorisation of a new product for all conditions for which alternative treatments exist. This will facilitate future** HTA/ pricing and reimbursement **decisions ~~of medicines~~ that** are essential in getting innovative medicines to patients earlier.	

[2] European Medicines Agency. Reflection paper on the need for active control in therapeutic areas where use of placebo is deemed ethical and one or more are available. EMA/759784/2010. November 2010.

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
267	Rationale: By including stakeholders in the various working groups, the network proves to be inclusive and responsive to societal needs and expectations. In this respect, it is vital to achieve a balance of stakeholders represented and to take into account possible conflicts of interest. Text: Further efforts should be made to incorporate patients' values and preferences into the scientific review process which could influence benefit risk decision making across the network. **Due attention should be given to achieving a balance of stakeholders participating in consultations, and a transparent declaration of any conflicts of interest they may have.**	
271	Rationale: Medicines that change classification from prescription to over-the-counter (OTC) products can obtain one year of data exclusivity, which can prevent competing products from gaining market authorisation on the basis of the same data. Blocked competition keeps prices high for consumers. BEUC suggests to remove the reference to 'improving patient access' because affordability following a switch to OTC can be an issue for some consumers. Text: A further area for focus of the network in the coming years will be to ensure the most appropriate legal classification is applied to products and the mechanisms for allowing those that can be safely reclassified as non-prescription medicines are in place, effective and being	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
	used~~**, thereby improving patient access**~~**.**	
280	Rationale: A reliable and efficient regulatory environment is needed to protect and uphold consumers' right to access safe and effective medicines. In most EU member states, the financial crisis bears some responsibility for the cuts in public R&D expenditure, not an unfavorable regulatory environment. Text: Clinical trial activity has slowed in recent years as a consequence of increased competition globally **and strain on public budgets following the financial crisis**. ~~**and an unfavourable regulatory environment.**~~	
307	Rationale: An unaffordable medicine is just at inaccessible for patients as a medicine that doesn't exist. BEUC would like to see references to HTA, pricing and reimbursement take a balanced approach to innovation to ensure that the results of medicines R&D are affordable for consumers and healthcare systems. Text: Although outside of the remit of the network, HTA and pricing and reimbursement also play an important role in fostering ~~**innovation**~~ **innovative and affordable products** in Europe.	
309	Rationale: The results of added therapeutic value assessments should serve to minimise the use of drugs with marginal benefits and ensure the most optimal	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
	treatments are affordable for patients and healthcare systems. The latter objective should be communicated more clearly when describing the network's objectives. Text: The network will strengthen the collaboration with HTA/ pricing and reimbursement bodies taking into account the discrete roles regulators and HTA/ pricing and reimbursement bodies have in bringing medicines to patients **in order to increase access to the best available therapies**.	
330	Rationale: BEUC supports the EMA to optimise its interaction with stakeholders while taking into account possible conflicts of interest. For example, the systematic involvement of the EMA at an early stage of the drug development process could influence the final assessment of the product and open the door to possible conflicts of interest. Text: Regulatory science, as an approach to how products are developed and regulated will become more prominent and regulators will need to work more closely with the academic community, industry and others to ensure appropriate support is given to the developments in this area, **while also addressing potential conflicts of interest to maintain public trust in regulators' (perceived and actual) independence**.	
331	Rationale: Considering the EMA has regular and systematic exchanges with patients, consumers and	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
	healthcare professionals, we suggest these groups also be named in the text. Text: Regulatory science, as an approach to how products are developed and regulated will become more prominent and regulators will need to work more closely with the academic community, industry, **patients, consumers, healthcare professionals**, and others to ensure appropriate support is given to the developments in this area.	
346	Rationale: While BEUC welcomes the potential for large healthcare datasets to contribute to medical advance, it reminds the network that patient data belongs to individual patients. Therefore, patients' individual informed consent should be sought before their information is collected, transmitted and shared. Text: The network will explore the use of 'big data' which has huge potential to enhance capability and reduce cost whilst **ensuring individual informed consent for data use** and respecting individual patient privacy.	
355	Rationale: The new European Medicines Agency policy on publication of clinical data represents a major step towards transparency. However, we are concerned that the regulation and the EMA policy only applies to new medicines - which effectively leaves out most of the medicines prescribed to or purchased over the counter by consumers. We consider it essential that the results of all	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
	past clinical trials are reported. The EMA should ensure that all data related to the efficacy and safety of medicines, submitted to regulatory authorities (at national and supranational levels) is publicly available, including all pre-market clinical data and post-authorisation studies. Text: With the EMA's policy on publication of clinical data and the Clinical Trials Regulation, the EU has set a global example for increased transparency but the network will need to consider extending this level of transparency to all of its work whilst keeping personal data and **only** truly commercially confidential information out of the public domain. **In particular, the network will consider how greater transparency can be given to clinical trials data held by regulators supporting medicines licensed before 2015.**	
461-462	Rationale: See general remarks on veterinary medicines. Text: **The network will also liaise with other food safety bodies to develop an international strategy to combat antimicrobial resistance**.	
461-462	Rationale: See general remarks on veterinary medicines. Text: **The network will collect data on the use of antimicrobials in veterinary medicine to determine which policy options should be recommended.**	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
466	Rationale: See general remarks on veterinary medicines. Text: **The network will also provide recommendations to the European Commission on the antimicrobials that should be restricted or prohibited in veterinary medicine, and in particular when they are used outside the terms of the license, because they are deemed of critical importance in human medicine.**	
470	Rationale: See general remarks on veterinary medicines. Text: **The framework will be regularly evaluated to make sure any important information that would help better monitor and map antimicrobials use in veterinary medicine is collected.**	
473	Rationale: See general remarks on veterinary medicines. Text**: In particular, EMA should continue to cooperate with EFSA and ECDC to identify high resistance to antimicrobials in animals and humans and how they can be interlinked.**	
481	Rationale: See general remarks on veterinary medicines. Text: **The network will also provide guidance as to the use of any new antimicrobials to ensure they are used responsibly and any resistance**	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
	phenomenon is minimised.	
532	Rationale: In recent years, the EMA has introduced progressively more rigorous policies to handle conflicts of interest between its agency and its stakeholders. Although there is still room for improvement, the EMA's policy on handling conflicts of interest can encourage national competent authorities with weaker or without such policies to adopt similar measures. Ultimately, the network should work towards an upwards harmonisation of handling conflicts of interest throughout Europe. Text: In addition, the network will continue efforts in order to strike the most optimal balance between ensuring the impartiality and independence of experts and securing the best possible scientific expertise within the network. **To this end, the network will pursue a high standard of handling conflicts of interest, particularly by introducing new or reinforcing existing policies at all national competent authorities.**	
571	Rationale: Regulatory efficiencies can result in benefits for the pharmaceutical industry and consumers, such as faster access to medicines proven safe. BEUC reminds the network that any legislative changes to reduce regulatory burdens must uphold the highest standards of safety, efficacy and quality to ensure consumer protection. Text: Therefore, the network will consider further	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
	optimisation of the regulatory framework within the current legislative provisions **and in a manner that upholds the highest standards of safety, efficacy and quality to ensure patient safety**.	
596	Rationale: BEUC encourages the network to seize the opportunity to learn from the EMA's structures for stakeholder consultation (i.e. Patients & Consumers Working Party, Healthcare Professionals Working Party, public written consultations, public meetings, etc.) and integrate these mechanisms in the work of national authorities, particularly concerning product information. Text: The network will explore – together with patients and healthcare professionals – how to achieve product information more aligned with stakeholders' expectations and needs. **This can be achieved through the EMA's own consultation fora and also through greater consultation of patients, consumers and healthcare professionals, by the national competent authorities.**	
634	Rationale: BEUC suggests that the key stakeholders should be made explicit and the network should actively strive for a balance of stakeholders. Text: The network will put in place more streamlined mechanisms to obtain regular feedback from **a balanced group of** key stakeholders**, such as patients, consumers, healthcare professionals, and**	

Line No. of the first line(s) affected	Comment and rationale; proposed changes	Outcome (if applicable) *<to be completed by the EMA/HMA>*
	pharmaceutical companies on the operation of its activities and the quality of its output, which may result, as also explained in objective 2 in the current theme, in a revision of the scientific and operational procedures to optimise their functioning.	
699	Rationale: Regulators are the 'guardians' of medicines safety and efficacy and it is their responsibility to balance the highest safety & efficacy standards with access. This core objective should be emphasised when referring to the network's leadership role in a global context. Text: The network will take a lead role in convergence of global standards assuring appropriate representation in international fora and will put in place mechanisms to **uphold patient safety and** strengthen cooperation with non-EU regulators in a consistent and integrated manner.	

[i] Hollis, A. (2004). Me-too drugs: is there a problem. *WHO report.*