



UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION



PERSONAL PROTECTIVE EQUIPMENT (PPE): BRIDGING THE STANDARDISATION GAP

VIRTUAL SEMINAR | AN INSIGHT

PERSONAL PROTECTIVE EQUIPMENT (PPE) IN THE FIGHT AGAINST COVID-19



The Covid-19 pandemic has spread to most parts of the world and over the last months, the world has witnessed the demand for Personal Protective Equipment (PPE) reaching unprecedented levels. Personal protective equipment is a term that encompasses many of the products that have been designed to protect the wearer from hazardous infections. These include - but are not limited to - protective clothing, gloves, facemasks and goggles, essential to protect the safety and health of frontline medical workers, but also citizens. The World Health Organization (WHO) estimates that the monthly demand of PPE in response to Covid-19 is more than 89 million medical masks, over 76 million examination gloves, and 1.6 million goggles. To meet the rising demand for PPE, manufacturers worldwide have increased or shifted their production to ensure the supply of such goods worldwide.

One of the main challenges in the global trade of PPE products relates to quality, rather than quantity. Given the rising demand, PPEs are stopped at borders due to non-compliance with local standards, technical regulations, or conformity assessment requirements.

The quality of PPE products is defined by relevant standards, and technical regulations at the national, regional and international level, and requires corresponding conformity assessment procedures to attest compliance. These standards and conformity assessment requirements, however, are diverse and differ from country to country. The diversity of these quality requirements hinders trade and results in a limited ability of national health authorities to mobilize adequate supply of fit-for-purpose PPEs in response to the exceptional circumstances in the context of the COVID-19 pandemic. Now more than ever, international cooperation is required to ensure compliance with PPE regulatory regimes, standards and conformity assessment to facilitate the global supply of PPEs.





BRIDGING THE STANDARDISATION GAP

On May 15, the United Nations Industrial Development Organization (UNIDO), in collaboration with the World Health Organization (WHO), the European Commission, the United Nations Economic Commission for Europe (UNECE), the Beijing Municipal Institute of Labour Protection, and the West African Accreditation System (SOAC), convened a virtual seminar to discuss the global quality and compliance challenges related to Personal Protective Equipment.

The seminar focused on the initiatives developed and actions taken by national, regional, and international quality infrastructure institutions. Renowned speakers discussed the need to bridge the gaps in the global landscape of PPE standards and conformity assessment systems, to meet the increased demand for fit-for-purpose PPE products that are vital to protect the safety and health of our frontline medical workers and citizens in the pandemic.

The virtual event elaborated on the relevance of standards in achieving the UN Sustainable Development Goals, especially SDG3 on good health and well-being. The discussion furthermore highlighted the significant need for information on guidelines and access to relevant standards to ramp up PPE production and meet the increased demand.

The virtual seminar is part of UNIDO's Special Webinar Series on Quality and Standards in the Fight Against COVID-19, which aims to share knowledge and experience on how quality infrastructure can support the global efforts in mitigating the negative effects of the COVID-19 pandemic.



Mr. Bernardo Calzadilla-Sarmiento

Director, Department of Trade, Investment and Innovation, UNIDO



Ms. Adriana Velazquez Berumen

Group Lead Medical Devices and In-Vitro Diagnostics, WHO



Ms. Ying Ling Lin

Clinical Engineer Consultant, Operations Support and Logistics, WHO



Ms. Silvia Vaccaro

Policy Officer Standardisation, European Commission



Ms. Lorenza Jachia

Secretary, Working Party on Regulatory Cooperation and Standardization Policies, UNECE



Mr. Ji Liu

Associate Professor, Beijing Municipal Institute of Labor Protection



Mr. Marcel Gbaguidi

Director General, West African Accreditation System, SOAC



The event was a complete success with attendees from 44 countries around the world actively participating

Angola, Armenia, Austria, Bangladesh, Botswana, Burkina Faso, Burundi, Cabo Verde, Cameroon, China, Colombia, Côte d'Ivoire, Egypt, Finland, France, Ghana, India, Indonesia, Israel, Italy, Kenya, Kyrgyzstan, Lao People's Democratic Republic, Madagascar, Mali, Nigeria, Peru, Philippines, Russian Federation, Saudi Arabia, Senegal, Sierra Leone, South Africa, South Sudan, Spain, Switzerland, Togo, Trinidad and Tobago, Ukraine, United Arab Emirates, United Kingdom, United States of America, Viet Nam, Zimbabwe

INSIGHTS FROM THE SPEAKERS



Mr. Bernardo Calzadilla-Sarmiento

Director, Department of Trade, Investment and Innovation, UNIDO

- » **“We currently have a mismatch of demand and supply for PPE products and the glue to bringing them together is quality.”**
- » “Certainly we are experiencing an increase demand for PPE, but we need to look at the quality, not only the quantity.”
- » “PEE needs to have certain characteristics in order to be fit-for purpose, it needs to be fluid resistant, it needs to provide leak protection, have a certain filtering capacity and resistance to tears and snags. All these characteristics are defined in standards.”

Ms. Adriana Velazquez Berumen

Group Lead Medical Devices and In-Vitro Diagnostics, WHO

- » The WHO has an important interest in fostering standards harmonization, facilitate acceptance of equivalence and address regulatory gaps.
- » **“The main issue is that personal protective equipment was used in the chemical industry, construction industry, and only a little niche was health industry. We have to change from being industrial to having our main concerns on the quality, safety, effectiveness, appropriateness, affordability, and acceptability by the users of PPE in the health sector.”**
- » “The main thing that is really worrisome is that most of these standards were made, considering the industrial part, and not the biochemical, chemistry or pharmaceutical part.”
- » “Mostly high-income countries and the industry are making standards. So how can we really encourage other voices to be able to provide information about how standards should be made.”

Ms. Ying Ling Lin

Clinical Engineer Consultant, Operations Support and Logistics, WHO

- » There are differences in PPE standard and they are linked to the regions
- » **“There is no single global regulatory body for these items and as a repercussion of this is that there is no post market surveillance.”**
- » “There are also some low-cost PPE items such as disposable aprons, and disposable face shields that are not quite meeting any specific standards just because they are disposable.”

Ms. Silvia Vaccaro

Policy Officer Standardisation, European Commission

- » **“Covid was a shock to the global supply chains. Exceptional circumstances call for exceptional responses.”**
- » “Quality infrastructure in the EU is based on trust, responsibility of the manufacturers, and market surveillance.”
- » “For QI at large, a series of actions were undertaken by the European Commission in order to ensure smooth free movement of goods in the single market.”
- » “The main conclusions from this crisis is that no one was adequately prepared, that the world is now even more interconnected and interdependent than before, and that we may need to consider to move some competences in the health sector from the Member States to the European Union.”

Ms. Lorenza Jachia

Secretary, Working Party on Regulatory Cooperation and Standardization Policies, UNECE

- » PPE standards often lack a gender dimension across all sectors that UNECE Gender Responsive Standards Initiative are promoting.
- » “It is important to give firms information on guidelines and access to identify the right standards to ramp up PPE production and meet the demand. This is a good example of why standards matter for all SDGs, especially for SDG3 on health.”
- » “We witness how important it is to give firms and administrations access to information on the relevant guidelines for them to adapt their production facilities and for them to ramp up production to meet the demand.”
- » “We need to continue to work together and take example from the standards world that have been so generous and cooperative which we should also see in other areas of the world.”
- » **“One-size-fits all PPE is not suitable for women. It has severely affected the safety of frontline women healthcare workers exposed to COVID19.”**

Mr. Ji Liu

Associate Professor, Beijing Municipal Institute of Labor Protection

- » China has experience in guiding fit-for-purpose mask production through developing related guidelines.
- » It is important to promote acceptance of PPE products based on their performance in spite of the different standards used and conformity assessment procedures applied.
- » **“If we want to ensure the quantity and availability of PPE products in response to Covid-19, we firstly have to promote the acceptance of PPE’s standards in different countries through analyzing and comparing them.”**

Mr. Marcel Gbaguidi

Director General, West African Accreditation System, SOAC

- » It is important to deploy a rapid conformity assessment system and provide trainings to local industries and enterprises in developing countries for testing and verifying compliance of PPE products and supporting to local supplies.
- » “We have a new need of local handcraft tailors, especially in West Africa and to find new ways to train local industries and enterprises. Because of Covid-19, it’s important to relay training & understand the need to support”
- » **“In developing countries, the youth of the existing conformity assessment mechanism has resulted to a lack of robustness and which consequently can allow non-conforming products to pass.”**



KEY TAKEAWAYS

- » **While the Covid-19 crisis has caused an astronomic increase in the procurement and demand for PPE products, besides focusing on the quantity of goods produce, it is equally important, if not more, to focus on ensuring quality.**
- » PPE standards have been primarily designed for the industrial sector by high-income countries with the health sector being a niche in the past. The current crisis has demonstrated the importance of focusing not only on the quality, safety, effectiveness, appropriateness, affordability, and acceptability by the users in the health sector, but also that PPE standards should allow more voices to contribute to formulation taking more than merely the industrial sector into account.
- » Covid-19 did not only demonstrate that countries were not adequately prepared to combat such a crisis, but also showed the interconnectivity between nations and the importance of Quality Infrastructure to be built on trust.
- » **Standards are highly relevant in achieving the UN Sustainable Development Goals, especially SDG3 on good health and well-being.**
- » There is a significant need for information on guidelines and access to relevant standards to ramp up PPE production and meet the increased demand.
- » There are still improvements to be made including gender inequalities present in PPE equipment which are severely affecting the safety of female healthcare workers, as well as training and supporting conformity assessment mechanisms in developing countries.





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