식품의약품안전처 보도참고자료

보도시점 배포 즉시 배포 2025. 7. 3.(목)

WHO, 베트남 정부의 보건역량 견인한 한국 식약처의 노력에 대해 조명

- WHO 대표누리집 기사에서 한국 식약처의 지원을 통해 기여한 공로를 자세하게 소개
- 지난 10년간 연간 9억원 투자, 코로나19 진단기술 확보와 글로벌 기준 반영한 의약품법 제정 등에 기여

식품의약품안전처(처장 오유경)는 **베트남**의 **의약품·의료기기 규제 수준 향상**을 위한 대한민국 식약처의 **지원과 협력**에 대한 **그 간의 성과**를 **소개**하는 **기사**가 WHO 대표 누리집에 **게재***되었다고 밝혔다.

* (홈페이지) https://www.who.int/westernpacific/newsroom/feature-stories/item/safe-and-effective-medical-products-in-viet-nam--who-highlights-10-years-of-progress-with-support-from-the-government-of-korea

식약처는 '15년부터 서태평양 지역 국가(라오스, 몽골, 베트남, 캄보디아, 필리핀)를 대상으로 **의약품 등 규제기관**의 **역량 강화**를 위한 **교육**, **의약품 평가기술 지원** 등 연간 9억원을 지원하고 있다.

WHO 기사의 주요내용은 ▲코로나19 대유행 시 **신속**하고 **정확**한 **코로나19 진단기술 확보** ▲글로벌 기준이 반영된 **의약품법 제정**('24.9월)을 통한 **허가체계 간소화** ▲**규제기관 담당자**의 **역량 강화** 등 **베트남**의 **규제 수준 제고**와 **보건위기 예방** 및 **대응 역량 강화**에 **식약처**가 **기여**했다고 다뤘다.

식약처는 이번 사례를 계기로 한국의 **의약품 규제 역량**과 **국제 기여**를 **적극**적으로 **알리고** 국내 의약품의 신속한 허가를 위한 참조국(reference country) 지정을 요청하는 등 실질적인 규제협력을 통해 **한국 규제체계 확산**과 국내 의약품의 **국제 경쟁력 강화**를 **적극 지원**할 계획이다.

<붙임> 1. WHO 홈페이지 게재 사진
2. 홈페이지 게제 번역본

담당 부서	의료제품연구부 바이오의약품연구과	책임자	과 장	이철현 (043-719-4701)
		담당자	연구관	오호경 (043-719-4704)
담당 부서	글로벌수출전략담당관	책임자	과 장	오영진 (043-719-1351)
		담당자	사무관	강은빈 (043-719-1353)
담당 부서	기획조정관 국제협력담당관	책임자	과 장	김 솔 (043-719-1551)
		담당자	연구관	김성철 (043-719-1598)

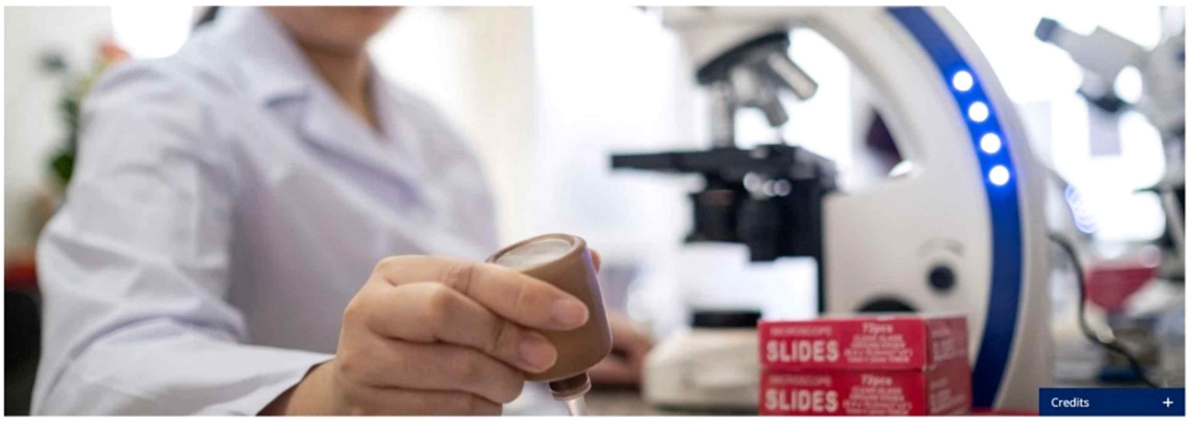
붙임 1 **WHO 홈페이지 게재 사진**

Global Regions Countries Select language

World Health Organization Western Pacific Viet Nam Donate

Health topics Our work News Emergencies About us

Home / News / Feature stories / Item / Safe and effective medical products in Viet Nam: WHO highlights 10 years of progress with support from the Government of Korea



Safe and effective medicines, vaccines and medical devices of assured quality are critical for any health system.

Patients and health professionals must rely on regulatory authorities to legally authorize that these biomedical products meet national or relevant international standards.

Since 2015, Viet Nam has strengthened the systems that regulate medicines, vaccines and devices, with support from the Government of the Republic of Korea's Ministry of Food and Drug Safety, through the World Health Organization (WHO).

Collaboration with the Republic of Korea was particularly important in supporting Viet Nam's successful response to the COVID-19 pandemic. Around the world, national regulatory authorities faced immense pressure to make rapid decisions on vaccine approvals, despite limited scientific data. Support from the Republic of Korea and WHO's Viet Nam Country office and Western Pacific Region helped decision makers in Viet Nam navigate the challenges and contributed to the country's ability to authorize vaccines in a timely and informed manner. Similarly, this support enabled Viet Nam to buy rapid antigen and PCR tests to ensure fast and accurate diagnoses.

In September 2024, Viet Nam adopted the Pharmaceutical Law, whose development was supported by the Republic of Korea and WHO. The Law incorporates lessons from the pandemic, international best practice and streamlines regulatory approvals. These changes reinforce the legal authority of the Viet Nam National Regulatory Authority, enabling it to more effectively ensure the quality, safety and efficacy of medicines and vaccines.

WHO supported the law's development with technical advice, policy briefs, and sponsoring and participating in key consultations, including a major consultation with nearly 1000 participants including representatives from all relevant stakeholders, provincial health facilities, drug quality centres, institutes and the pharmaceutical industry.

"WHO is enormously grateful for the generous support from the Government and people of the Republic of Korea over the past decade, including in times of crisis, to help ensure people have access to safe and high-quality medicines, vaccines and medical devices," WHO Representative in Viet Nam Dr Angela Pratt said.

"With this support, Viet Nam has been able to build its capacity to prevent and respond to health emergencies, regulate more effectively, improve its manufacturing and procurement to avoid stock-outs, develop the Pharmaceutical Law and much more."

"Viet Nam can be proud of the progress it has made in the past decade toward building a strong and trustworthy regulatory system based on legislation, policy and good practice that aims to ensure people's safety and well-being. WHO is very pleased to have been able to contribute to these efforts."

Republic of Korea Minister of Food and Drug Safety Oh Yu-Kyoung said, "The Republic of Korea is delighted to mark 10 years of progress in health regulation with Viet Nam. We are proud to play an active role in collaborating with WHO to improve the health of people in Viet Nam through regulatory capacity strengthening, as we work together for a safer and healthier world."

Among the highlights of two countries' collaboration are enhancing staff capacity to implement and enforce regulatory policies, boosting good laboratory practices so that more labs are equipped with updated methodologies and accredited, and other work to align processes with WHO standards and international best practices.

Related

- Viet Nam and Republic of Korea: working towards universal health coverage while fighting COVID-19
- Viet Nam's vaccine regulatory system reaches WHO's second-highest level
- National Regulatory Authority of Viet Nam Meets International Standards for Vaccine Regulation
- Moving forward on goal to boost local pharmaceutical production, WHO establishes global biomanufacturing training hub in Republic of Korea
- The Republic of Korea, Ministry of Food and Drug Safety - multi-bilateral aid to support Member States
- Substandard and falsified medical products

The Republic of Korea's support has helped strengthen Viet Nam's National Regulatory Authority, which is composed of the Drug Administration of Viet Nam, the Viet Nam Administration of Disease Prevention, the National Institute for Quality Control of Vaccine and Biologicals, the Administration of Science, Technology and Training, the National Institute of Drug Quality Control and the National Information and Adverse Drug Reaction Center.

These agencies play varied roles, including protecting against substandard and falsified medical products, which are a significant global problem. They can be found in all countries, impacting all types of medical products, including life-saving treatments like vaccines, antibiotics and cancer therapies. In 2017, WHO estimated that 1 in 10 medicines in low- and middle-income countries failed quality control tests, suggesting the product was substandard or falsified. This can lead to serious health risks, treatment failures and even death.

The economic burden is also substantial, with billions of dollars lost annually due to ineffective treatments, increased health-care costs and loss of productivity. For patients, the consequences are dire: relying on ineffective or harmful products can exacerbate illnesses, lead to prolonged suffering and contribute to drug resistance, making diseases harder to treat.

To tackle sub-standard, fake and counterfeit medical products, WHO supports global cooperation, robust regulations, legal frameworks and public awareness.

The Partnership between WHO and the Republic of Korea's Ministry of Food and Drug Safety is also contributing to regulatory system strengthening in Cambodia, the Lao People's Democratic Republic and Mongolia.

A 6-month-old baby girl held by a man receives a measles vaccine shot as part of the government's immunization campaign addressing outbreaks across Viet Nam. Credit: Loan Tran / WHO

붙임 2 WHO 홈페이지 게재 영문본/번역본

Safe and effective medical products in Viet Nam : WHO highlights 10 years of progress with support from the Government of Korea

Safe and effective medicines, vaccines and medical devices of assured quality are critical for any health system.

Patients and health professionals must rely on regulatory authorities to legally authorize that these biomedical products meet national or relevant international standards.

Since 2015, Viet Nam has strengthened the systems that regulate medicines, vaccines and devices, with support from the Government of the Republic of Korea's Ministry of Food and Drug Safety, through the World Health Organization (WHO).

Collaboration with the Republic of Korea was particularly important in supporting Viet Nam's successful response to the COVID-19 pandemic. Around the world, national regulatory authorities faced immense pressure to make rapid decisions on vaccine approvals, despite limited scientific data. Support from the Republic of Korea and WHO's Viet Nam Country office and Western Pacific Region helped decision makers in Viet Nam navigate the challenges and contributed to the country's ability to authorize vaccines in a timely and informed manner. Similarly, this support enabled Viet Nam to buy rapid antigen and PCR tests to ensure fast and accurate diagnoses.

In September 2024, Viet Nam adopted the Pharmaceutical Law, whose development was supported by the Republic of Korea and WHO. The Law incorporates lessons from the pandemic, international best practice and streamlines regulatory approvals. These changes reinforce the legal authority of the Viet Nam National Regulatory Authority, enabling it to more effectively ensure the quality, safety and efficacy of medicines and vaccines.

WHO supported the law's development with technical advice, policy briefs, and sponsoring and participating in key consultations, including a major consultation with nearly 1000 participants including representatives from all relevant stakeholders, provincial health facilities, drug quality centres, institutes and the pharmaceutical industry.

"WHO is enormously grateful for the generous support from the Government and people of the Republic of Korea over the past decade, including in times of crisis, to help ensure people have access to safe and high-quality medicines, vaccines and medical devices," WHO Representative in Viet Nam Dr Angela Pratt said.

"With this support, Viet Nam has been able to build its capacity to prevent

and respond to health emergencies, regulate more effectively, improve its manufacturing and procurement to avoid stock-outs, develop the Pharmaceutical Law and much more."

"Viet Nam can be proud of the progress it has made in the past decade toward building a strong and trustworthy regulatory system based on legislation, policy and good practice that aims to ensure people's safety and well-being. WHO is very pleased to have been able to contribute to these efforts."

Republic of Korea Minister of Food and Drug Safety Oh Yu-Kyoung said, "The Republic of Korea is delighted to mark 10 years of progress in health regulation with Viet Nam. We are proud to play an active role in collaborating with WHO to improve the health of people in Viet Nam through regulatory capacity strengthening, as we work together for a safer and healthier world."

Among the highlights of two countries' collaboration are enhancing staff capacity to implement and enforce regulatory policies, boosting good laboratory practices so that more labs are equipped with updated methodologies and accredited, and other work to align processes with WHO standards and international best practices.

The Republic of Korea's support has helped strengthen Viet Nam's National Regulatory Authority, which is composed of the Drug Administration of Viet Nam, the Viet Nam Administration of Disease Prevention, the National Institute for Quality Control of Vaccine and Biologicals, the Administration of Science, Technology and Training, the National Institute of Drug Quality Control and the National Information and Adverse Drug Reaction Center.

These agencies play varied roles, including protecting against substandard and falsified medical products, which are a significant global problem. They can be found in all countries, impacting all types of medical products, including life-saving treatments like vaccines, antibiotics and cancer therapies. In 2017, WHO estimated that 1 in 10 medicines in low- and middle-income countries failed quality control tests, suggesting the product was substandard or falsified. This can lead to serious health risks, treatment failures and even death.

The economic burden is also substantial, with billions of dollars lost annually due to ineffective treatments, increased health-care costs and loss of productivity. For patients, the consequences are dire: relying on ineffective or harmful products can exacerbate illnesses, lead to prolonged suffering and contribute to drug resistance, making diseases harder to treat.

To tackle sub-standard, fake and counterfeit medical products, WHO supports global cooperation, robust regulations, legal frameworks and public awareness.

The Partnership between WHO and the Republic of Korea's Ministry of Food and Drug Safety is also contributing to regulatory system strengthening in Cambodia, the Lao People's Democratic Republic and Mongolia.

베트남의 의료제품 안전성 및 효과 증진 – 한국 정부의 지원에 힘입어 이룩한 10년간의 진전 상황을 WHO에서 조명하다

의약품, 백신, 의료기기의 안전성과 효과, 품질을 제고하는 일은 어느 보건 체계에서건 필수 요소이다.

환자들과 보건 분야 종사자로서는, 이러한 바이오 의료제품 가운데 국내 및 유관 국제 기준에 부합하는 제품을 법적 허가하는 규제기관이 꼭 필요하다.

2015년부터 베트남은 대한민국 식품의약품안전처의 세계보건기구(WHO)를 통한 지원에 힘입어 의약품, 백신, 의료기기 규제 체계를 강화하였다.

코로나19 대유행 대응 시 특히 대한민국의 이러한 협업이 베트남에 요긴하게 작용하였다. 당시 전 세계 국가규제기관은 백신 허가 여부를, 과학적 입증 자료가 아직 부족함에도 조속히 결정하여야 한다는 막대한 부담감을 겪은 바 있었다. 베트남에서 이러한 상황을 분석하고, 관련 지식을 갖추어 백신을 적시기에 허가할 수 있게 된 것에는 베트남 국가사무소와 서태평양 지역을 통한 대한민국, WHO의 지원이 한몫하였다. 또한 이러한 지원 덕에 신속 항원 검사 및 PCR 검사 기구를 조달하여 신속하고 정확하게 코로나19를 진단할 수 있었다.

한편 베트남은 대한민국과 WHO의 지원을 받아, 코로나19 대유행이 시사하는 바와 글로벌 현행 우수 기준을 반영하고 규제상의 허가 체계를 간소화하는 의약품법을 2024년 9월 마련하였다. 베트남 국가규제기관의 법률상 권한을 강화해 의약품과 백신의 품질, 안전성, 유효성을 효과적으로 제고할 수 있도록 하는 변화였다.

WHO에서 기술자문과 정책 요약 보고를 통해 해당 법 제정을 지원하였다. 지원의 하나로 또한, 유관 이해관계자, 지방 보건시설, 의약품 품질 센터, 연구기관, 의약품 업계 일체에서 1000명에 육박하는 인원이 참여한 자문회의 등 여러 자문회의에 참여하거나 이를 후원하였다.

베트남에서 근무 중인 WHO 측의 Angela Pratt 박사는 “위기의 시기를 비롯한 지난 10년간 의약품, 백신, 의료기기의 안전성과 품질을 제고하여 사람들이 널리 사용할 수 있도록 도움을 주신 대한민국 정부와 국민 여러분께 깊이 감사드린다. 이러한 지원이 있었기에 베트남에서 보건위기 예방 및 대응 역량을 강화하고, 의약품 규제의 효과를 높이며, 의약품 생산과 조달 체계를 향상시켜 의약품 고갈을 막고, 의약품법을 제정하는 등 수많은 성과를 거둘 수 있었다”고 전하였다.

또한 그는 “법률, 정책, 기준을 중심으로 규제 체계의 역량과 신뢰도를 높여 국민의 안전과 안녕을 도모하기 위해 힘쓴 지난 10년 동안의 발전에 대해 베트남은 자부심을 가져도 좋다. 이와 같은 노력에 이바지할 수 있었음에 WHO는 매우 기뻐하고 있다”고 하였다.

대한민국 식품의약품안전처의 오유경 처장은 “보건 분야 규제 체계 발전을 지난 10년간 베트남과 함께 견인할 수 있었음을 대한민국은 기쁘게 생각한다. 더욱 안전하고 건강하게 사는 세상을 함께 일구는 과정에서 규제 역량 강화에 WHO와 협력하여, 베트남 국민의 보건 증진에 적극적으로 우리의 역할을 수행할 수 있었음에 뿌듯함을 느낀다”고 전하였다.

두 국가의 협력 분야 가운데 두드러지는 영역이 바로 직원 역량 강화 및 규제 정책 집행으로, 실험실 우수 기준에 따라 시험 방식을 새로이 도입하고 인증을 취득하는 실험실 수를 늘리는 등, WHO의 기준과 글로벌 현행 우수 기준에 발맞추는 작업이었다.

규제 역량 향상 지원을 대한민국으로부터 받은 베트남 국가규제기관으로는 의약품청, 질병예방청, 국립 백신 및 바이오의약품 품질관리원, 과학기술교육청, 국립 의약품 품질관리원, 국립 의약품 정보 및 이상반응 센터가 있다.

해당 기관들이 수행한 역할은 여러 가지로, 이 중 현재 전 세계에서 문제가 되는 부정불량의약품의 유통 방지도 있었다. 부정불량의약품은 백신이나 항생제, 암 치료제 등 환자의 생명을 살리는 의약품 가운데서도 국가를 막론하고 존재한다. 중저소득국가의 의약품 10분의 1이 품질 시험 기준에 미달하는 부정불량의약품일 것으로 WHO에서 2017년 추정한 바 있다. 복용 시 인체에 심각한 위해를 끼칠 수 있고, 치료가 실패하거나 심하면 환자가 사망하는 결과까지도 초래할 수 있다.

치료 효과 저해, 보건의료 비용 상승, 생산성 저하로 매년 수십억 달러의 손실이 발생하는 등 부정불량의약품의 경제적 악영향도 크다. 효과도 없고 유해한 제품을 복용함으로 인해 질병이 외려 악화하고, 투병 기간이 길어지며, 의약품 저항성이 높아져 질병 치료가 더욱 어려워지는 등 환자에게도 중대한 악영향을 미친다.

이러한 기준 미달, 위조, 변조 의약품 문제를 타개하고자 WHO는 국제 협력, 규제 및 법률 체계 강화, 대중 인식 환기 활동을 지원하고 있다.

한편, 캄보디아, 라오스, 몽골의 규제 체계 강화 또한 WHO와 대한민국 식품의약품안전처의 협력 체계를 통해 지원하고 있다.