

## 《九价HPV疫苗扩龄至9-45岁》

“默沙东中国”近日发布消息称，其九价人乳头瘤病毒疫苗(九价HPV疫苗)的新适应证已获得中国国家药品监督管理局批准，此次获批标志着默沙东九价HPV疫苗在国内适用人群拓展至9-45岁适龄女性。



A woman is inoculated with a cervical cancer

vaccine in Jing'an county in Yichun, Jiangxi province on April 10, 2021.

[Photo/VCG]

China's top drug regulator has expanded the use of an imported vaccine against nine strains of the cancer-causing human papillomavirus to girls as young as nine and adults up to age 45.

中国国家药品监督管理局近日批准将九价人乳头瘤病毒疫苗(九价HPV疫苗)在国内适用人群拓展至9-45岁适龄女性。

The National Medical Products Administration first granted authorization to Gardasil 9, a 9-valent HPV vaccine created by global pharmaceutical giant Merck, for use in females aged 16 to 26 in 2018. On Tuesday, the administration said that its use is now broadened to females aged 9 through 45.

2018年，国家药品监督管理局首次批准全球制药巨头默克公司研发的9价HPV疫苗“加卫苗”上市，适用于16-26岁的女性。8月30日，国家药品监督管理局表示，该疫苗在国内适用人群拓展至9-45岁适龄女性。

In China, nearly 110,000 women were diagnosed with cervical cancer last year, and 59,000 had died of the disease, said Zhao Fanghui, a professor at the National Cancer Center and Chinese Academy of Medical Sciences' Cancer Hospital, citing data from the Global Cancer Observatory, a cancer data platform associated with the World Health Organization.

国家癌症中心、中国医学科学院肿瘤医院教授赵方辉援引全球癌症观察的数据说，中国去年有近11万名女性确诊宫颈癌，5.9万人因患宫颈癌去世。全球癌症观察是隶属于世界卫生组织的癌症数据平台。

Eliminating the disease would require consolidated efforts in boosting the vaccination rate, especially among those aged under 15, as well as promoting early screening and treatment. Due to limited supplies and low awareness, China is now lagging far behind some leading countries in terms of immunization coverage, according to Zhao.

赵方辉表示，消除宫颈癌需要大力提高疫苗接种率，特别是在15岁以下适龄人群中，并推进宫颈癌的早期筛查和治疗。由于疫苗供应有限以及人们的认识不足，中国目前在疫苗接种率方面远远落后于一些领先国家。

However, the rising number of highly effective domestic vaccines available on the market is expected to ramp up the efforts.

但是，随着市面上高效的国产疫苗数量的增加，疫苗接种率有望进一步提高。

A new study published in the journal The Lancet Infectious Disease on Friday shows that Cecolin, the first domestic vaccine that protects against two HPV strains, is 100 percent effective in protecting against genital lesions-a precancerous condition-and 97.3 percent effective against persistent infection.

8月26日发表在《柳叶刀-感染病学》期刊上的最新研究报告显示，首个国产二价HPV疫苗馨可宁对宫颈癌癌前病变的保护效果可达到100%，还可预防97.3%的HPV持续感染。

## 九价疫苗适合人群

我国批准上市的九价HPV疫苗，其接种适应年龄范围是9—45岁适龄女性女性。之所以定为该年龄段，具体依据来自三方面：

- 1.支持本疫苗上市的临床试验入组年龄为16岁~26岁女性。在此年龄段，该疫苗境外临床研究数据以及在东亚人群中表现出的针对持续感染的保护效力，均提示其获益大于风险。
- 2.我国9岁~15岁幼女性行为概率很低。9岁~15岁接种者仅进行了免疫桥接试验，且该试验东亚华裔人群的临床研究数据有限。
- 3.超过26岁女性有很大可能已经有病毒暴露感染史，而还没有证据证明本疫苗对这一年龄段的暴露后人群有保护作用。

来源：中国日报