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China Insight

Highlights on Adverse Event Following Immunization Compensation Under the New Vaccines Administration Law

Dear Sir or Madam,

Please find below our update on the Highlights on Adverse Event Following Immunization Compensation Under the New Vaccines Administration Law.

Kind regards,
CMS, China

On 29 June 2019, the Standing Committee of the National People's Congress promogulated *the Law of People's Republic of China (the "**PRC**") on Vaccines Administration* (the "**Vaccines Administration Law**") which will be implemented from 1 December 2019[1].

1. High-level recapitulation of adverse event following immunization compensation

1) Catalogue of adverse event following immunization compensation

Adverse event following immunization[2] ("**AEFI**") compensation scheme is one of the noticeable highlights in the *Vaccines Administration Law*. Pursuant to the *Vaccines Administration Law*, compensation should be given for damage such as death, severe disability or organ tissue injury, etc., which are abnormal in response to vaccination during the vaccination process or after vaccination. Although AEFI compensation scheme was already in place back in 2005 in the *Regulations on the Administration of Vaccine Circulation and Vaccination*, effective on 23 April, 2016 (the "**Regulation on Vaccines**")[3], the *Vaccines Administration Law* introduces the concept of "compensation catalogue"[4] as a new compensation management method, which provides that AEFI compensation shall be subject to such catalogue and dynamically adjusts it according to actual conditions on a case-by-case basis. This catalogue will be based on the collection, collation and analysis of a large number of abnormal response data in practice and form a dynamic unified standard for compensating adverse event to vaccination nationwide. This arrangement will make the investigation, diagnosis and identification of suspected serious abnormal reactions more scientific and standardized, making compensation fairer and more reasonable.

2) Source of fund

There is no substantial change to the source of fund for AEFI compensation under the *Vaccines Administration Law* compared to the stipulations under the *Regulation on Vaccines*. Both provide that compensation costs required for vaccination under immunization program vaccines (the "**Vaccines Under Program**", i.e. Class 1 Vaccines under the *Regulation on Vaccines*) shall be paid out of vaccination funds as arranged by competent

departments of finance under the relevant people's governments of provinces, autonomous regions or municipalities directly under the central government of the PRC; those required for vaccination not covered by immunization program vaccines (the "**Vaccines Beyond Program**", i.e. Class 2 Vaccines under the *Regulation on Vaccines*) shall be borne by the vaccine market authorization holders[5] (the "**Vaccines MAH**").

2. Civil liabilities of AEFI compensation

1) Civil liability of AEFI compensation

Vaccines are not without risks and it is commonly accepted that, regardless of proper development, manufacture and delivery, adverse events might occur following vaccination although serious adverse events are rare. Both the *Vaccines Administration Law* and the *Regulation on Vaccines* implement compensation scheme for AEFI[6]. In our view, this implies the civil liability of AEFI compensation, or we called the "nature" of AEFI compensation is still the equitable liability, which has not been changed under the *Vaccines Administration Law*. AEFI compensation is based on the premise that the adverse outcome is not attributable to a specific individual or industry but due to an unexpected risk link to vaccination. Such scheme is yielded due to social needs to compensate victim for the injuries suffered.

2) Burden of proof

AEFI compensation does not require injured parties to prove negligence or fault made by the inoculating medical institution, the health care system or the Vaccines MAH before compensation. AEFI compensation requires proof of a causal link between vaccination and injury, for which is supported by diagnostic or investigation conclusion issued by the Chinese Centre for Disease Control and Prevention ("**CDC**") or relevant medical association[7]. As we mentioned above, AEFI compensation only applies when no party has any fault. If the diagnostic or investigation conclusion proves that the abnormal reaction is caused by the negligence of the inoculating medical institution or by a defect of vaccines, AEFI compensation will not apply and the injury will be compensated pursuant to the applicable laws and regulations[8]. Vaccines MAH does not have to bear burden of proof if CDC or relevant medical association diagnoses as an AEFI, whilst if it is identified as a defect of the vaccine, then the burden of proof is shifted to the Vaccines MAH. Vaccines MAH has to prove the vaccine does not contain any defect through an identification process in accordance with the *Vaccination Abnormal Response Identification Measures*, effective on 1 December 2008 by submitting required documents related to such vaccine (including receipt, purchase, storage, transportation records, inspection report, if such vaccine is imported, the customs clearance documents of the wholesale enterprise shall also be provided.). Vaccines MAH is entitled to apply to the provincial medical association for reidentification if its vaccine is identified by the municipal medical association as defective. In case a victim files a case against Vaccines MAH for any damage caused by vaccine quality defect, Vaccines MAH shall assume the liability for such damage in accordance with the law unless it can prove that there is no defect in such vaccine. In addition, such Vaccines MAH may be confronted with administrative punishments pursuant to the *Vaccines Administration Law* if it fails to prove that its vaccine is free of defect.

3) Assessment of compensation obligation

Claimants have the right to seek for compensation either through compensation scheme (for Vaccines Under Program) or civil litigation (for Vaccines Beyond Program).

AEFI compensation for the Vaccines Under Program is an administrative system. Claimants are required to file with an administrative body (i.e. the competent health department and the drug administration of the local people's government) that decide on compensation eligibility and payment amounts. Once a final decision has been reached, claimants are compensated with a lump sum of money. As provided in the Vaccines Administration Law, "*Compensation scope, standards and procedures for AEFI shall be stipulated by the State Council, and specific implementing measures thereof shall be formulated by people's governments of provinces, autonomous regions and municipalities directly under the central government of the PRC.*" In the past years, quite a few provinces in China have promulgated their administrative regulations on AEFI compensation. By reviewing those, all and only specified provisions are the scope, standards and procedures for the Vaccines Under Program compensation.

Compared with Vaccines Under Program which has detailed scope, standards and operational procedures of AEFI compensation, the Vaccines Beyond Program still lack those provincial AEFI compensation regulations. The silver lining is those provisions which state the compensation amount of AEFI caused by the Vaccines Beyond Program could be calculated by referring to the standards of compensation for AEFI caused by the Vaccines Under Program. This somehow provides references for the negotiation and settlement of disputes between Vaccines MAH and claimants[9]. In practice, we also learnt from case judgements that certain courts ruled that manufacturers of vaccines shall compensate claimants in accordance with the local implementation

compensation standards[10].

3. Compulsory liability insurance and encouraging commercial insurance

1) Compulsory liability insurance

According to Article 68 of the *Vaccines Administration Law*, the State shall implement the rules for compulsory vaccines liability insurance. Vaccines MAH shall underwrite the compulsory vaccine liability insurance. As said by relevant financial insurance scholars in an interview: "Even though the *Vaccines Administration Law* has been officially launched, the vaccine compulsory insurance may take another 2-3 years to be implemented in practice.[11] " It is an integrated risk management system which would be much complicated than implementing just one single insurance product. For instance, the *Vaccines Administration Law* is still silent on who will be responsible for the development of the insurance product, what the average insurance premium will be, what exactly the insurance liabilities of the insurance company are, what should be excluded from the insurance coverage. So far, the *Vaccines Administration Law* has only provided that specific implementing measures for the compulsory vaccine liability insurance system shall be formulated by the medical products administration under the State Council in collaboration with the health administration and insurance regulatory authority under the State Council, etc.

Generally speaking, the term "compulsory" indicates "hard buy" for Vaccines MAHs and "hard sale" for insurance companies, which may result in additional insurance costs for foreign manufacturers of imported vaccines, since they may also have compulsory obligation to purchase vaccine liability insurance for the same vaccines in their own countries. Related to this, the questions have not yet been addressed in the *Vaccines Administration Law* (such as whether a foreign manufacturer of imported vaccines can be released from such compulsory insurance liability if it has already insured (which covers the PRC in its insured territory) in its country, whether the amount of insurance premium will be adjusted, and what is the order of insurance liabilities between offshore and onshore insurance companies). Unlike commercial insurance, there are certain conditions for underwriting, if there is red flag of the insured or risk is beyond the insurance company's control, the insurance company has the right to say no to the insured. In general, the insurance industry needs to further explore and research on a series of design and operation of vaccine-related insurance products.

2) Commercial insurance

The *Vaccines Administration Law* encourages the compensation of inoculated persons suffering from AEFI by multiple means including commercial insurance. The main obliged parties for AEFI not only create extra burden on finance of the government but also reduce the proactivity of the Vaccines MAH, which led to the passive situation of inoculated persons suffering from AEFI. To relieve such pressure, some of the provinces/cities (e.g. Guangxi Province, Guangdong Province and Guizhou Province) in the PRC implement the combined compensation scheme, which means the local government purchases basic insurance for each inoculated person of the Class 1 Vaccines. The basic insurance is basically the same as the original "financial compensation" but ease the financial burden of the local government and in the meanwhile improves and expands the scope of compensation and increases the amount of compensation. In addition to the basic insurance, the provinces of Guangxi and Guangdong also advocate inoculated persons to purchase supplementary commercial insurance voluntarily which further expands the scope of compensation, increases the insured amount, solves the problems which are not covered by the basic insurance, such as coincidental disease attack after vaccination of the inoculated person and immune failure, etc. In Guangdong, manufacturers of vaccines and importers of vaccines are encouraged to buy basic insurance for their vaccines. When any adverse response is identified as an AEFI, the insurance company will compensate the victim in accordance with the *Adverse Event Following Immunization Compensation Measures of Guangdong Province*.

[1] Please refer to our newsletter "Vaccines Administration Law in China": **click here**

[2] Article 52 of the Vaccines Administration Law states that "*Adverse event following immunization refers to an abnormal drug reaction where any tissue organ or function of an inoculated person is damaged during or after the standardized vaccination with a non-defective vaccine, for which no party concerned has any fault, excluding the following circumstances: (i) general post-vaccination reaction arising from characteristics of the vaccine per se; (ii) damage caused to the inoculated person due to defective vaccine quality; (iii) damage caused to the inoculated person due to the relevant vaccination unit's violation of vaccination work practices, immunization procedures, guidelines for the use of vaccines and vaccination schemes; (iv) coincidental disease attack after vaccination of the inoculated person is just in the latent period or prodromal period of certain diseases when being vaccinated; (v) acute relapse or aggravation of an original disease after vaccination where the inoculated person has a vaccination contraindication as prescribed in the vaccine instructions, but neither such inoculated person nor its guardian faithfully stated the inoculated person's health status, vaccination contraindication or other information concerned prior to vaccination; and (vi) psychogenic reaction of any individual or group due to psychological factors.*"

[3] Back in 2005, before the revision of the Regulation on Vaccines (2016 Revision), the concept of AEFI and the compensation scheme were addressed thereunder.

[4] As of today, this compensation catalogue is yet to be promulgated and implemented.

[5] Article 97 of the Vaccines Administration Law defines that "*Vaccine Market Authorization Holder refers to any enterprise that obtains a vaccine-related drug registration certificate and a drug manufacturing license in accordance with the law.*"

[6] Article 46 of the *Regulation on Vaccines* states that "*Where, due to any AEFI, an inoculated person dies or becomes heavily disabled, or any of his/her organs or tissues is injured, he/she shall be paid lump-sum compensation.*" Article 56 of the *Vaccines Administration Law* states that "*The State implements a vaccination-related abnormal reaction compensation system.*"

[7] According to the *Adverse Event Following Immunization Compensation Procedures of Shanghai*, effective on 12 January 2017, if CDC diagnoses that it is not an AEFI, the claimant is entitled to apply to the local medical association for identification.

[8] Compensation to the injury can be subject to the *Tort Law of the PRC*, the *Medical Malpractice Regulation*, the *Vaccines Administration Law*, the *Drug Administration Law* and other relevant laws and regulations on a case-by-case basis.

[9] For instance: According to the *Adverse Event Following Immunization Compensation Measures of Guangdong Province*, effective on 1 January 2012, "*A claimant shall provide his/her ID, the original version of the diagnostic proof or disability rating identification proof within 90 days to the competent health department and the drug administration after his/her receipt of such proof. The claimant will, under the coordination of the competent health department and the drug administration, conclude a compensation agreement with the vaccine manufacturer. The manufacturer shall pay the compensation in a lump sum to the claimant within 7 working days.*"

[10] Civil judgement by the Intermediate People's Court of Xuzhou City, Jiangsu Province (2016苏03民终5450号): **click here**

civil judgement by the First Intermediate People's Court of Beijing City (2017京01民终7268号): **click here**

[11] The director of Institute of Financial Insurance of Shanghai University of Finance and Economics said in an interview: **click here**

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