



Convention

entre

Glaxo Group Limited
Glaxo Wellcome House
Berkley Avenue
Greenford
UB6 0NN
Royaume Uni

("GGL")

GlaxoSmithKline Biologicals SA
Rue de l'Institut 89
B-1330 Rixensart
Belgique

("GSK Bio")

GlaxoSmithKline SA
Rue du Tilleul 13
B-1332 Genval
Belgique

("GSK SA")

(collectivement "GSK")

et

L'Etat Belge, représenté par son Ministre de la Santé Publique

("MSP")

SPF Santé publique, Sécurité de la Chaîne alimentaire et Environnement
Place Victor Horta 40 boîte 10
1060 Bruxelles
Belgique

concernant

La fourniture de vaccins pandémiques contre la grippe

2.4 Conditions suspensives

Les obligations relatives aux délais de Livraison des Vaccins Pandémiques en vertu de la présente Convention sont soumises à la condition suspensive de :

- (a) la réception par GSK ou une Société Affiliée des réactifs calibrés pour le Germe de l'Antigène Pandémique du laboratoire de référence désigné de l'OMS ; et
- (b) l'octroi par l'Autorité Réglementaire Compétente d'une Autorisation Réglementaire concernant le Vaccin Pandémique, permettant de mettre sur le marché le Vaccin Pandémique ou, à défaut, l'octroi d'une Autorisation Temporaire par l'Autorité Réglementaire Compétente. A défaut d'Autorisation Réglementaire ou d'Autorisation Temporaire, GSK aura le droit de suspendre la Livraison au MSP des Doses déjà fabriquées pour le compte de celui-ci et de les vendre à tout tiers de son choix. En ce cas, les délais fixés dans le Planning Final seront suspendus jusqu'à la date de l'octroi, par l'Autorité Réglementaire Compétente, de l'Autorisation Réglementaire ou d'une Autorisation Temporaire, étant entendu que les dates de début et de fin de Livraison seront postposées d'autant de jours que la durée de la suspension.

8 Autorisation Règlementaire

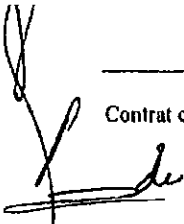
8.1 Obtention et maintien de l'Autorisation Règlementaire

GSK mettra en œuvre des Efforts Commerciaux Raisonables pour obtenir, conserver et, le cas échéant, renouveler toute Autorisation Règlementaire ou toute Variation requises pour le Vaccin Pandémique (en ce compris pour ce qui concerne l'usage pédiatrique et la prolongation de la Durée Avant Péréemption) et/ou pour les Nouveaux Composés et leur usage pédiatrique, et ce dans l'Union Européenne et/ou en Belgique.

Dans la mesure du possible, et à la requête raisonnable de GSK, le MSP fournira son assistance en vue de l'obtention de l'Autorisation Règlementaire concernant le Vaccin Pandémique.

8.2 Livraison sans Autorisation Règlementaire

Avant que soit octroyée l'Autorisation Règlementaire ou avant l'approbation par l'Autorité Règlementaire Compétente de toute Variation nécessaire, la Livraison du Vaccin Pandémique ou des Nouveaux Composés pourra avoir lieu, pour autant qu'une Autorisation Temporaire ait été octroyée.



2 AUTRES

2.1 Conditionnement Primaire

Les Composés du Vaccin Pandémique (Composé Antigène et Composé Adjuvant) seront fournis dans des flacons en verre contenant 10 doses avec un bouchon en caoutchouc. L'information détaillée sur le conditionnement primaire sera exprimée en anglais conformément à l'Annexe aux présentes spécifications.

2.2 Stabilité

Le Vaccin restera stable jusqu'à sa date de péremption, sauf si:

- il n'est pas stocké à une température de 2-8 °C,
- il est exposé à la lumière, ou
- il est congelé.

2.3 Péremption

La durée de péremption minimale du Vaccin Pandémique, estimée par GSK à la Date d'Entrée en Vigueur, est de 18 mois à dater de la fabrication.

2.4 Conditionnement final

Le Vaccin Pandémique sera emballé dans une boîte de carton contenant le Composé Antigène Pandémique emballé dans une boîte en carton comprenant 50 flacons et le Composé Adjuvant emballé dans 2 boîtes en carton de 25 flacons chacune.

D'autres conditionnements pourront être utilisés en consultation avec les Autorités Réglementaires Compétentes.

Tout conditionnement devra être suffisamment solide pour protéger les flacons en verre.

2.5 Etiquetage et Information sur le Produit

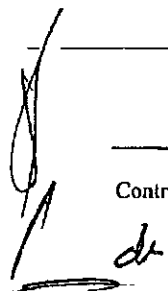
Toute étiquette et information produit sera exprimé en anglais conformément à l'Annexe aux présentes Spécifications.

2.6 Stockage et Transport

Le lieu de stockage devra être certifiée au regard des BPF pour un stockage en chaîne du froid. Le Vaccin Pandémique doit être stocké et transporté entre 2 et 8 °C. La température du transport doit être contrôlée et enregistrée.

2.7 Administration du Vaccin Pandémique

Le Vaccin Pandémique doit être administré par voie intramusculaire.



Annexe à l'Annexe A

ETIQUETTES GENERIQUES

Note – L'étiquette standard du Vaccin Pandémique sera similaire aux étiquettes ci-après, à l'exception du nom de la souche virale du Vaccin Pandémique qui sera mise à jour au plus tard au moment de la Livraison.

Flacon Antigène



Flacon Adjuvant



Boîte Antigène



Boîte Adjuvant



Etiquette boîte de groupage extérieure (information minimale requise, complétée à destination)



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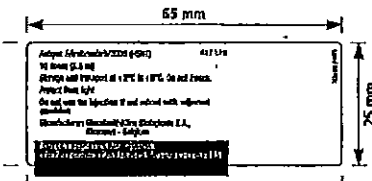
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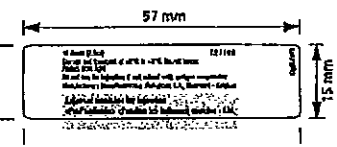
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Market or Pack Owner: *Biologicals-IVR-GEXP	Technical Reference No(s): BIO_DAW3 <small>(Do NOT include the technical reference doc id version no's)</small>	BSC /AV/ Version: 1		
Market Trade Name: Adjuvant for Flu vaccine	Point of Sale Code No.: No			

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Manufacturing Site: GSK-BEL-Wavre-BEWAV				
Market or Pack Owner: *Biologics-IVR-GEXP	Technical Reference No(s): BIO_DRW15 <small>(do NOT include the technical reference code varnish code)</small>			
Market Trade Name: Pre-pandemic Influenza	Point of Sale Code No.: No			
				GSK AMW Version: 1

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Biologics Additional Information Panel
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Perforation: N/A

60 mm

55 mm

Antigen suspension for injection
«Pre-pandemic» «Pandemic» Influenza vaccine
(split virus, inactivated, adjuvanted) IM.


Split influenza virus, inactivated, containing antigen* suspended in:
1.2% aluminium hydroxydichloride
Medium: Hydroxyethylcellulose (HCEC)

Excipients: Polyethylene glycol, sodium chloride, disodium hydrogen phosphate, potassium dihydrogen phosphate, potassium chloride, magnesium chloride, water for injection


50 x 10⁶ Virus particles
20 x 10⁶ HCEC (2.5 mg)

* Suspensions to be exclusively mixed with sodium chloride intravenous solution

Preparation for use:
Read the package insert before use.
Open all of the vials and stop at 45°C.
Reconstitute product, subject to medical prescription.
Storage and transport at +2°C to +8°C. Do not freeze. Protect from light.
Store in the original package. Do not reuse.
GSK Biologics, Marnixlaan - Belgium



Lot:
MPC:



Antigen suspension for injection
«Pre-pandemic» «Pandemic» Influenza vaccine
(split virus, inactivated, adjuvanted) IM. 427277

PHARMA CODE N° 92

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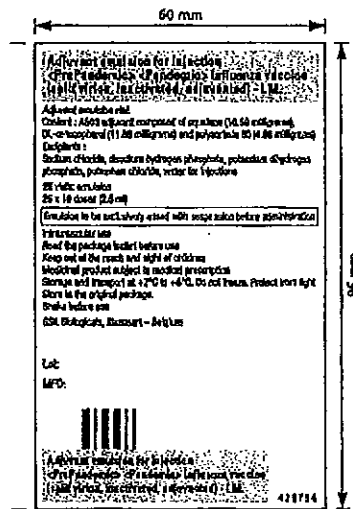
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Market or Pack Owner: *Biologicals-IVR-GEXP	Technical Reference No(s): BIO_DRW15 <small>(Do NOT include the technical reference doc) (version 0011)</small>				RSC A/W Version: 1
Market Trade Name: Adjuvant for Flu vaccine	Point of Sale Code No.: NO				

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Market or Pack Owner: *Biologicals-IVR-GEXP		Technical Reference No(s): BIO_DRW16 <small>(do NOT include the technical reference code version code)</small>			RSC A/W Version: 1
Market Trade Name: Pre-pandemic Influenza		Point of Sale Code No.: NO			

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Material weight: N/A
Folded dimensions: N/A
Perforation: N/A

100 mm

**<PrePandemic> <Pandemic> Influenza vaccine
(split virion, inactivated, adjuvanted) 1.M.**

Active ingredients are:
 Split influenza virus, inactivated, containing antigen equivalent to:
 A/Indonesia/05/99 (H5N1) 2.5 micrograms* per 0.5 ml dose (see mixing with excipients and preparation in text)
 = haemagglutinin


Polysorbate 80, ethylene glycol (10), potassium acetate, sodium chloride, disodium hydrogen phosphate, potassium dihydrogen phosphate, potassium citrate, mannitol, thiomersal, water for injection

Adjuvant contains:
 AS01 adjuvant composed of squalene (10.00 mg/ml),
 DL- α -tocopherol (1.00 mg/ml) and polysorbate 80 (1.00 mg/ml)
 Sodium chloride, disodium hydrogen phosphate, potassium dihydrogen phosphate, potassium acetate, water for injection


25 ml x 5 x 10 mm vial
 50 ml x 10 mm vial

The volume after mixing 1 vial of suspension (2.5 ml) with
 1 ml of squalene (2.5 ml) corresponds to 10 doses of vaccine (0.2 ml
 1 dose = 0.2 ml)

Information for use
 Read the package leaflet before use
 Keep out of the reach and sight of children
 Medicinal product subject to medical prescription
 Storage and transport at +2°C to +8°C. Do not freeze. Protect from light
 Store in the original package
 Shake before use
 GSK Italy/UK, Belgium - Belgium



Lot's n°/Spec:
 Lot's n°/Batch:
 MFD:



**<PrePandemic> <Pandemic>
 Influenza vaccine (split virion,
 inactivated, adjuvanted) 1.M.**

428795

120 mm

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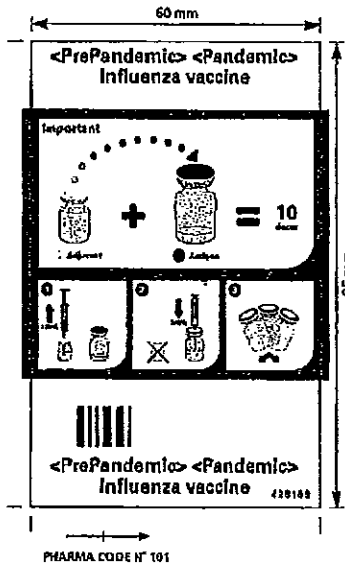
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Item Number: 428109	List Colours: <small>(Provide colour to file providing e.g. spot / PANTONE / CMYK equivalent)</small>	P PrBLK	P 2955	P 228	P 477
Manufacturing Site: GSK-BEL-Wavre-BEWAIV		P 306			
Market or Pack Owner: *Biologicals-IVR-GENP	Technical Reference No(s): BIO_DRW38 <small>(do NOT include the technical reference code/revision code)</small>				RSC Art/ Version: 2
Market Trade Name: Pre-pandemic influenza	Point of Sale Code No.: No				

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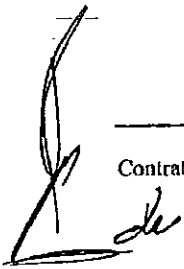
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Annexe B

CONDITIONS SPÉCIFIQUES

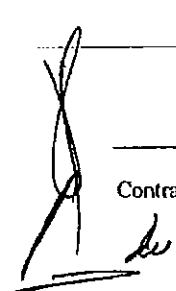
1. Volume Pandémique Total

12.600.000 Doses de Vaccin Pandémique



10. Durée

La Durée sera de 5 ans à dater de la Date d'Entrée en Vigueur.

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Annexe D

LIGNES DIRECTRICES RELATIVES À LA COMMUNICATION

1. Information Confidentielle

a. LISTE ROUGE

Les informations suivantes concernant les transactions envisagées dans la présente Convention sont considérées comme des Informations Confidentielles:

- a) Le texte intégral de la présente Convention ou des extraits de la présente Convention à l'exception des éléments repris dans la Liste Verte
- b) Prix par Dose
- c) Prix par Composé
- d) Droit de Mise à Disposition
- e) Détails des Spécifications du Vaccin Pandémique (par opposition à la description générique de "nouveau vaccin adjuvanté H1N1 (ou souche pandémique)")
- f) Tout détail ou toute référence aux arrangements ou aux problèmes que GSK pourrait avoir avec des tiers
- g) Tout détail du plan de développement, en ce compris les résultats intérimaires ou finaux des tests cliniques avant publication par GSK.
- h) Toute information relative à la sécurité (étant entendu que cela ne limitera pas les droits et obligations de l'Autorité Réglementaire Compétente dans sa conduite de ses obligations en vertu du droit belge
- i) Principes de production du Vaccin Pandémique

b. Liste Verte

Toute information non reprise au point 1.1 ci-dessus et, notamment les informations suivantes, ne seront pas considérées comme des Informations Confidentielles:

- j) Le vaccin pandémique est un vaccin à deux composés
 - k) Le fait que le Composé Antigène Pandémique est moins cher que le Composé Adjuvant
 - l) La réservation de Doses et la quantité de Doses du Vaccin Pandémique
 - m) La Livraison après Autorisation Réglementaire
 - n) Livraison sans Autorisation Réglementaire en cas de menace pandémique
 - o) Lieu de production:
- le Vaccin Pandémique sera produit en Allemagne et en Belgique
 - p) L'approbation du Vaccin Pandémique par l'Autorité Réglementaire Compétente
 - q) Durée de la Convention
 - r) Considérations générales sur le plan de développement: "*GSK travaille de manière rapprochée avec des experts de l'OMS pendant la période contractuelle*"
-
- s) Le conditionnement du Vaccin Pandémique.